Witness Name: Dr Rosie Benneyworth

Statement No.:

Exhibits: 33

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UK COVID-19 INQUIRY

WITNESS STATEMENT OF DR ROSIE BENNEYWORTH, CHIEF INVESTIGATOR, HEALTHCARE SAFETY INVESTIGATION BRANCH / ACTING CHIEF EXECUTIVE HEALTH SERVICES SAFETY INVESTIGATIONS BODY

I, Dr Rosie Benneyworth, will say as follows in response to the request by UK COVID-19 Inquiry in a Rule 9 letter dated 24 July 2023 to provide a statement setting out:

1.1 The Healthcare Safety Investigation Branch (HSIB) was established in April 2017 to undertake independent patient safety investigations into NHS-funded care across England. HSIB operated with functional independence and shared oversight. It was funded by the Department of Health and Social Care (DHSC) and reported on its performance to both the DHSC and to NHS England (NHSE). From 1 October 2023, HSIB ceased to exist and was replaced by its successor organisation the Health Services Safety Investigations Body (HSSIB) under the Health and Care Act 2022.

1.2 HSIB's formation was initiated by a recommendation from the Public Administration Select Committee **(RB/1) (INQ000320212)** for the Secretary of State for Health and Social Care to:

"…bring forward proposals, and eventually legislation, to establish a national independent patient safety investigation body…Experience in other safety critical industries demonstrates how resources devoted to investigating and learning to improve clinical safety will save unnecessary expense by reducing avoidable harm to patients…The new body must be primarily a centre of expertise and promoter of good investigatory practice

and expertise. It must have its own substantial investigative capacity, so that it can lead by example, oversee local investigations, and conduct its own investigations when necessary."

1.3 In 2015, the DHSC established an Expert Advisory Group (EAG) to consider and make proposals for establishing HSIB. In their report to DHSC **(RB/2) (INQ000320219)**, the EAG emphasised that the HSIB should be independent in structure and operation, and this must be established in primary legislation.

National Investigations

1.4 In May 2016, the government laid in Parliament directions to establish HSIB ('the 2016 Directions') **(RB/3) (INQ000320220)**. The 2016 Directions governed HSIB's national investigations. They set out the HSIB's composition and required investigatory function to:

- investigate incidents or accidents which evidence, or are likely to evidence, risks affecting patient safety.
- ascertain the facts relevant to such risks and analyse those facts.
- identify improvements or areas for improvement to patient safety.
- publish reports about its investigations; and the development of skills used to investigate local safety incidents in the health service and to learn from them, including suggesting standards which may be adopted in the conduct of local patient safety investigations.

1.5 The 2016 Directions also stipulated that, in fulfilling its investigation function, the HSIB must:

- take care to ensure it operates independently.
- obtain prior patient or family permission to access medical records before it can commence an investigation.
- as best feasible, involve the affected patients, families, and healthcare staff in the investigation; and
- apply the 'safe space' principle as explained in the Directions 2016, whereby the identity of investigation witnesses and materials is protected from external disclosure unless required by statutory order, or where the HSIB determines there's evidence of an immediate and ongoing risk to patient safety.

1.6 The 'safe space' principle is based on similar provisions for investigations undertaken internationally in aviation, and in the UK in the transport sectors. This protection is designed to ensure that investigation witnesses can participate with full confidence that the information is being gathered for the sole purpose of learning to improve safety, rather than to apportion blame or liability for adverse outcomes. The safe space principle does not impede other regulatory and investigatory bodies, the police, or the courts from exercising their statutory responsibilities to ascertain the circumstances of an incident including to require information from witnesses.

1.7 HSIB's national investigation remit extended to, and not beyond, any healthcare service funded by the NHS in England. This included healthcare delivery within private and independent healthcare settings that has been commissioned or funded by the NHS.

1.8 HSIB was a small organisation. It was initially funded to complete up to 30 national investigations a year and had approximately 30-40 members of staff. An HSIB national investigation took between 6-18 months to complete and usually involved extensive fieldwork undertaken in healthcare settings. Recommendations were made at 'system-level' to national healthcare agencies, and other organisations with responsibilities relevant to the healthcare services being investigated. As of 30 September 2023, HSIB had produced:

- 93 national investigation and national learning reports.
- Over 240 safety recommendations for the NHS and national healthcare organisations.

1.9 HSIB's national investigations were conducted by individuals with diverse experience working in safety investigation in healthcare and other safety critical industries such as aviation, rail, and defence. In addition, HSIB investigations were informed by input from specialised clinical and safety science advisors appropriate to the topic of investigation.

HSIB's maternity investigations

1.10 On 28 November 2017, the HSIB maternity investigations programme was announced as part of progress against ambitions set in the national maternity safety strategy **(RB/4) (INQ000320221)**:

HSIB will apply its independent, professionalised investigative approach to the investigations of early neonatal deaths, term stillbirths and cases of severe brain injury in

babies ('Each Baby Counts' cases), as well as all cases of maternal death. Like HSIB's national-level investigations, these maternity investigations will be about understanding the facts of what went wrong, rather than assigning blame or liability and will focus on the human and system factors that may be contributory causes. However, this group of maternity investigations will differ from HSIB's national investigations in important ways. They will have a dual purpose. To provide the family of the baby or mother who was harmed with a full account of what happened in the individual case; and, by finding out what went wrong, to extract the maximum learning for the individual Trust in question and for the wider healthcare system. This should mean that HSIB maternity investigations will be shorter allowing families to know what happened more quickly and ensure that all relevant information is passed to the family. Each HSIB maternity investigation will take a clinically appropriate approach, working with families, clinicians with neonatal, paediatric, and obstetric expertise and with local teams to establish what happened. (p.24)

1.11 Directions were established to enable the maternity investigations function from 1 April 2017 onwards, to be undertaken in all NHS maternity services in England **(RB/5) (INQ000320223)**. In response, the size of HSIB as an organisation grew to approximately 200-240 staff in this period, with most additional staff forming part of the distinct maternity investigations programme.

1.12 As of 30 September 2023, the HSIB maternity investigations programme completed over 3000 maternity investigations across all trusts providing maternity services across the NHS in England. The investigation reports were not published; they were produced for the family and the trust. Table 1 provides a summary overview of the differences between the two programmes:

National investigations programme	Maternity investigations programme
2016 Directions – core purpose of HSIB	**2018** Directions – additional specific programme
Diverse range of healthcare services and safety risks	Explicit focus on NHS maternity services in England
Criteria: we decide • scale of risk and harm • potential for learning to prevent future harm • impact on individuals and public confidence in the healthcare system	**Criteria: set for us** • RCOG Each Baby Counts programme • Direct maternal deaths • Indirect maternal deaths while pregnant or within 42 days of giving birth
Up to **30** investigations a year	Circa **1000** investigations a year
Do not replace local investigations	Replaces the local investigation
Recommendations made to healthcare and beyond	Recommendations made only to the trust
Reports published on HSIB website	Reports belong to the family and the trust

Table 1: Summary of HSIB investigation programmes

Legal standing: HSIB and the Health and Care Act 2022

1.13 The abolition of the NHS Trust Development Authority in the Health and Care Act 2022 saw a transfer of the hosting function for HSIB to NHSE **(RB/6) (INQ000320224)**; the actual terms of the HSIB's investigative role and remit remained unchanged. Similarly, the legislative basis for the maternity investigations programme's function was updated in April 2022 **(RB/7) (INQ000320225)** with no changes made to the function of the programme.

1.14 The Health Services Safety Investigations Body (HSSIB) was subsequently enacted by Part 4 of the Health and Care Act 2022 **(RB/8) (INQ000320222)** and establishes HSSIB's independence in statute as a non-departmental public body (NDPB) of the DHSC. After a period of operating in shadow form, HSIB transitioned to operating as the HSSIB on 1 October 2023 in accordance with the legislation.

1.15 As an NDPB, the HSSIB is accountable to the Secretary of State for Health and Social Care. It has a board led by a chair (Professor Ted Baker) appointed by the Secretary of State, and non-executives appointed by the chair. The chief executive of HSSIB will be appointed by the non-executives and I currently fulfil this role on an interim basis.

1.16 The HSSIB operates with enhanced powers which encompass:

- Prohibition of disclosure, which means that HSSIB's investigation materials must not be disclosed outside the organisation unless permission is granted by the High Court or the chief executive of HSSIB determines it to be appropriate for patient safety (see Schedule 14 of **RB/8 - INQ000320222**)
- Powers of entry, seizure and inspection which enable HSSIB investigators to quickly access healthcare premises to commence an investigation, without the prior permission of the organisation, patient, or family to access relevant medical records; and
- Powers to require information from investigation witnesses and other relevant persons.

1.17 It is HSSIB's intention that these powers will be a safeguard used only in the most exceptional circumstances. It is our experience that healthcare staff and organisations, and patients and families, share a common purpose in seeking to understand the systemic causes of patient safety harm and, to that end, have mainly been willing and voluntary participants in HSIB investigations.

1.18 A key difference will be that HSIB's maternity investigations programme will not become part of the HSSIB. Instead, on 9 April 2023 the DHSC announced that HSIB maternity investigation functions would be taken over by the Care Quality Commission (CQC) from 1 October 2023. The Maternity and Newborn Safety Investigations (MNSI) programme is now hosted by the CQC.

The HSIB National Investigation process

1.19 HSIB received intelligence about risks to patient safety from a variety of sources. During the period in question, this commonly included:

- Incident reporting data from NHSE.
- Referrals received via the HSIB website from members of the public and healthcare staff.
- Internal referrals generated when HSIB staff had concerns shared with them by members of the public or healthcare staff whilst on HSIB business.
- Horizon scanning of relevant media coverage and publications by other healthcare organisations.
- Aggregation of data and findings being generated from HSIB reports.

1.20 On receiving this information HSIB had a team of intelligence analysts who considered the available evidence and data surrounding a patient safety concern. Investigation topics were selected based on criteria that determine whether a patient safety risk entails:

- evidence of systemic risk – prevalence across the national health system, rather than only isolated incidents in limited healthcare providers or services.
- significant adverse impact on patients, families, and healthcare staff; and
- learning potential – HSIB's investigation would bring new insight into how the system can address the matter.

1.21 Potential topics for investigation (or for a national learning report) were presented approximately each calendar month at an internal meeting chaired by the Medical Director. At this meeting, intelligence reports outlining the proposed topics for investigation were discussed, with topics selected for investigation going forward to a scoping Investigation.

1.22 A scoping investigation typically considered a relevant reference event. This is where a real patient safety incident is identified as the starting point of a HSIB investigation. HSIB would then investigate that incident from a systems level perspective to determine what

factors that impacted on that incident occurring may also impact on other incidents of harm happening across the NHS.

1.23 A scoping investigation involved speaking with the patient or family involved in the incident, visiting the healthcare organisation in question to collect evidence, and speaking with relevant staff. Once completed, the outcome of the scoping investigation (or any initial work-up of national learning reports) was presented at an executive scoping meeting chaired by the Director of Investigations with a proposal to either proceed or not proceed to a national investigation. At this point, terms of reference for the national investigation were set and notification of the investigation was communicated via the HSIB website.

1.24 Reference events were not used in every HSIB investigation and where this is the case this is made clear in the investigation report. For example, 'COVID-19 transmission in hospitals: management of the risk – a prospective safety investigation' **(RB/17)** **INQ000130588** did not utilise a reference event model and instead used a proactive approach to understand the risk of nosocomial transmission of COVID-19. In this case, the initial phase of the investigation focused on understanding whether and how a HSIB investigation could contribute to knowledge in this area before a decision was made to proceed to a national investigation.

1.25 HSIB also produced non-investigation outputs in national learning reports. These include aggregated learning from existing HSIB investigation work to provide more depth and insight into a patient safety concern.

1.26 If an investigation (or national learning report) was launched following the executive scoping meeting, this would proceed to a national phase where additional evidence would be collected to understand the patient safety concern. This could include a range of interactions, including visits to other healthcare organisations, literature reviews, interviews with national organisations, focus groups and interviews with patient and family groups, and engagement of subject matter advisors. This would also involve identifying relevant national organisations who may be subject to safety recommendations and discussions with these organisations to confirm safety recommendation wording.

1.27 The HSIB governance process provided a framework for a review at the mid-point of an investigation, when recommendations were being developed and agreed, and a final review of the investigation report. Following a review, each report entered a consultation period of at least four weeks (where recommendations were being made) or two weeks (if no recommendations were made) to allow relevant stakeholders to comment on the factual

accuracy of the HSIB report. Once consultation was finalised and any appropriate amends were made to the report, HSIB reports were made publicly available on the HSIB website.

1.28 During the COVID-19 pandemic several HSIB staff were redeployed back to frontline NHS services and HSIB agreed to pause some existing investigations, or planned non-COVID-19 related investigation work, to ensure it could focus on supporting the healthcare system to respond to the pandemic **(RB/26) (INQ000255847) and (RB/27) (INQ000252915)**. The impact of the pandemic on our work is noted in the preamble to relevant investigation reports, as this limited the evidence available to complete our investigations in some circumstances. For example, where we could not carry out observations in clinical practice due to COVID-19 restrictions or meet with patients and families in their homes.

1.29 Additional work taken on during this period via the DHSC and NHSE led to reports concerning the planning and assurance of Nightingale hospital sites **(RB/30) (INQ000339825)**, the assurance of COVID-19 testing facilities **(RB/31) (INQ000339826) and (RB/32) (INQ000339827)**, and the response to a critical oxygen incident at Watford General Hospital **(RB/33) (INQ000339828)**. These reports are summarised below at 1.129 to 1.137. This work was initiated following direct contact from these organisations with HSIB to request assistance (**RB/26) (INQ000255847) and (RB/27) (INQ000252915)**. These reports were not published and were provided directly to DHSC and NHSE for information and action.

The HSIB maternity investigation process

1.30 The maternity investigations were undertaken within a defined criteria set out initially in the 2018 Directions and continued in the 2022 Directions. These were:

a) a case which involves a baby which falls within one of the categories of "eligible babies" as described in the Each Baby Counts Report; or
b) a case of direct or indirect maternal death as defined in the MBRRACE report, "Saving Lives, Improving Mothers' Care", 2016.

1.31 This meant that the HSIB maternity programme undertook investigations into care provided to eligible babies, includes all term babies (at least 37 completed weeks of gestation) born following labour who had one of the following outcomes:

- **Intrapartum stillbirth:** when the baby was thought to be alive at the start of labour but was born with no signs of life.

- **Early neonatal death:** when the baby died within the first week of life (i.e., days 0–6) of any cause.

- **Severe brain injury:** diagnosed in the first 7 days of life, when the baby—
    - was diagnosed with grade III hypoxic ischaemic encephalopathy (HIE),
    - was therapeutically cooled (active cooling only), or
    - had decreased central tone, was comatose and had seizures of any kind.
    - For the purpose of this paragraph "labour" includes—
        - any labour diagnosed by a health professional; this includes the latent phase of labour (less than 4cm dilatation).
        - where there has been a report to the unit of any concerns of being in labour, for example (but not limited to) abdominal pains, contractions, or suspected ruptured membranes.
        - induction of labour.
        - where the baby was thought to be alive following suspected or confirmed premature rupture of membranes.

- **Maternal deaths:** a case of a maternal death means the direct or indirect death of a woman while pregnant or within 42 days of the end of the pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.

1.32 The HSIB maternity programme was required to complete the investigations within a reasonable period under its directions. This included, as far as reasonably practicable, producing an investigation report in a period not exceeding six months from the date on which the qualifying maternity case in question was referred to it. The 'safe space' principle applicable to HSIB national investigations did not apply to the maternity programme.

1.33 Referrals to the HSIB maternity programme were made directly from trusts using a website-based portal. Each trust had designated individuals who made the referrals and uploaded all the associated information. The requirement for referrals to the HSIB maternity programme were not mandated. However, a trust's requirement to comply with the NHS Resolution (NHSR) Maternity Incentive Scheme (MIS): Safety Action 10 and demonstration to the CQC as part of their regulatory functions compels trusts to refer all

eligible cases. The HSIB maternity programme received referrals from 122 hospital and 11 ambulance trusts in England.

1.34 From April 2020 up until April 2022, HSIB acted on behalf of NHSR in relation to referrals to reduce the burden for trusts. This meant HSIB would receive the referrals and share the data with NHSR from cases which met their criteria, on completion of an investigation HSIB would share the completed report with NHSR. This process was enabled by a notice issued by the Secretary of State for Health and Social Care during the Pandemic under Regulation 3(4) of the Health Service (Control of Patient Information) Regulations 2002 (COPI) to require organisations to process confidential patient information.

1.35 Once a referral was received HSIB was required to respond within two working days to the referring trust to confirm the investigation criteria has been met and the information provided was accurate. There was no requirement for a trust to refer an eligible case within a defined time frame. Whilst most referrals were received within a week of the incident happening, there were occasions when the incident may have happened an extended period prior to referral. Where referrals were received, and a police investigation was in progress the HSIB maternity investigation would be placed on hold until it could be established there was further criminal consideration.

1.36 HSIB maternity investigations could only be undertaken when consent had been obtained from the family. It required trusts to have completed their responsibilities in relation to Duty of Candour and shared information about HSIB and its investigations to support the initial sharing of family contact information. Once HSIB had received the initial information it would contact the family within five working days to complete the full consenting process to access their medical notes.

1.37 On occasions HSIB received referrals without family contact information included, this made it aware of the potential referral whilst the trust completes their processes to support consent to access their medical records. Where a family did not consent for an investigation to be undertaken by HSIB, the responsibility of an investigation being undertaken was deferred back to the trust. Families were provided an opportunity to request a referral back to HSIB through the trust in the event they changed their mind and there was no time limit for them to do this. Where the event happened a significant time ago families were made aware this may impact on the evidence provided and depth of investigation that can occur.

1.38 Once initial consent had been confirmed the investigation team contacted the family to complete the consenting process, agree terms of reference and confirm a communication plan. The maternity programme had a dedicated family engagement team to support any communication needs a family may need.

1.39 Once the team reviewed the medical notes, they completed an initial review panel which was supported by the clinical advice team. The clinical advice team supported the investigation team to consider which staff members need to be interviewed, areas to focus questions and any specialist advice that may need to be requested.

1.40 A second review panel was undertaken approximately eight weeks later, this provided an opportunity for the investigator to present the facts of the case, findings and analysis and propose where safety recommendations maybe required.

1.41 The final review of the investigation was undertaken at report panel where the draft report was shared. The review ensured the findings and analysis reflected the outcome of the investigation, agreement of proposed safety recommendations and confirmation the style guide had been adhered to.

1.42 The final part of the investigation was completion of the factual accuracy check, initially by the trust then by the family prior to sharing of the completed investigation.

1.43 During the pandemic the maternity investigation programme was required to continue to receive referrals. There was a recognition that it needed to reduce the burden of work for trusts. In agreement with DHSC in April 2020 the decision was made to amend the eligibility criteria in relation to babies with severe brain injury. Historically the criteria were met by receiving treatment for presumed brain injury through cooling therapy. The changes made required HSIB to only investigate the babies who had a confirmed severe brain injury through confirmation on Magnetic Resonance Imaging (MRI) or the requirement to receive ongoing clinical care. HSIB made the discretionary decision to undertake the remaining cases only if there was a trust or family concern.

1.44 During the pandemic the investigation team were required to adapt their approach using virtual technology to undertake interviews and observation of clinical areas. This required considerable skills from across the team when undertaking difficult and emotional conversations with family and staff.

National Investigation findings and recommendations

1.45 HSIB investigations made findings about healthcare safety which were generated via the collection and analysis of evidence during a HSIB investigation. Under the Directions, HSIB could also make safety recommendations. In addition to this, HSIB also chose to make safety observations (not targeted as specific organisations and not requiring a response), record safety actions (where an organisation has responded to a risk during a HSIB investigation) and set out elements of local learning to try and assist NHS organisations in responding to safety risks.

1.46 Findings, recommendations, and other safety learning were provided within published HSIB investigation reports. Findings are presented in the executive summary, with relevant recommendations, observations and safety actions also highlighted within the body of the investigation report.

1.47 The Directions set out that organisations must respond to HSIB to set out how they will act on our recommendations within an agreed timescale; typically, three months from publication of our report. HSIB also chose to publish responses to recommendations on its website for transparency to allow the public to see how organisations have responded to our recommendations.

1.48 However, the Directions (and the subsequent Act) provided no legal powers for HSIB, and no subsequent legal powers for HSSIB, to enforce or monitor the implementation of recommendations. HSIB did internally 'grade' recommendation responses to determine if further engagement was possible with stakeholders to generate improved responses to HSIB recommendations before responses were published. A similar process continues as HSSIB.

1.49 In addition, during the period in question, HSIB had the ability to escalate safety recommendations to the National Patient Safety Committee where it had concerns that safety recommendations had not been responded to or where a response was seen to be significantly lacking. This was hosted by NHSE; however, the committee may only have met on a very few occasions and was subject to cancellations which impacted on the ability for HSIB to escalate safety recommendation responses. HSIB was not able to escalate any responses to safety recommendations from the relevant investigations to this committee. NHSE would be able to provide more information about the make-up, frequency, and role of the committee during the period in question.

Maternity Investigation findings and recommendations

1.50 The maternity programme undertook investigations into individual cases that include findings and safety recommendations that are directed to the trust who provided the care. Safety recommendations are not designed to propose a solution that identify where a system or process has directly impacted on the outcome for the mother or baby.

1.51 Trusts were encouraged to review both the findings and safety recommendations to identify areas of learning and actions that need to be undertaken. Some maternity reports did not make any safety recommendations.

1.52 The HSIB maternity programme could not compel a trust to implement any safety recommendations made. Once a report had been shared with the trust and family the responsibility for following up safety recommendations sat with the Integrated Care Boards (ICBs) and CQC as part of their commissioning and regulatory roles.

1.53 During an investigation there were occasions when an issue is identified that requires immediate escalation or a theme arises across several investigations. When this occurred, the trust was made aware as soon as is possible with an expectation that they respond within a defined period and provide assurance actions have been taken to mitigate future events reoccurring.

National Investigation reports relevant to the COVID-19 Inquiry

1.54 The relevant HSIB national investigation reports are available via links on the HSSIB website at legacy HSIB content. Each report includes a summary report where the key focus, findings, recommendations, or other safety learning are clearly set out. For confirmation these include the following investigations:

Oxygen issues during the COVID-19 pandemic **(RB/9)** **INQ000270026**

1.55 The investigation explored a reference event where an acute hospital trust declared a major incident when demands on its oxygen supply led to patients being diverted to different hospitals and a need to transfer patients between clinical environments.

1.56 The national investigation explored the increased demand for oxygen gas in hospital wards during the COVID-19 pandemic and challenges posed in meeting this demand by hospital medical gas pipeline systems (MGPS). The investigation produced two interim bulletins to highlight specific urgent risks to healthcare system in relation to challenges

posed by different types of MGPS **(RB/10) (INQ000320201)** and the role and make-up of medical gas committees **(RB/11) (INQ000320202)**.

1.57 Key findings from the national investigation were:

- There was a lack of shared ownership and knowledge of MGPS among hospital based multidisciplinary teams; this limits trusts' ability to effectively respond to MGPS patient safety concerns.
- Organisations that utilised a multidisciplinary approach to understanding and planning the MGPS involvement in the COVID-19 response were better able to respond to demands on the MGPS system.
- Guidance on the design and management of MGPS contained within the relevant health technical memorandum was outdated and did not reflect developments in oxygen therapy and challenges in managing MGPS.
- Assurance mechanisms for MGPS were not effective in ensuring that MGPS-related patient safety concerns are proactively identified and resolved.
- A lack of financial investment in updating MGPS infrastructure created challenges for NHS trusts in responding to the COVID-19 pandemic.

Treating COVID-19 patients using continuous positive airway pressure (CPAP) outside of a critical care unit **(RB/12) (INQ000320203)**

1.58 The investigation explored a reference event where a patient with COVID-19 requiring continuous positive airway pressure (CPAP) in hospital, was found on the floor of a side room having called for assistance. The CPAP tubing had become disconnected from the mask meaning the patient's breathing was not supported. Sadly, the patient died.

1.59 The national investigation explored the safety risk of treating patients with COVID-19 with CPAP outside of critical care units. Key findings from the national investigation were:

- Caring for patients with COVID-19 on CPAP in side rooms on general wards poses a safety risk as unless there is central monitoring as 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. Public Health England guidance which removed the need for fully vaccinated people to self-isolate after contact with a person with COVID-19 could mitigate against the staffing challenges seen during the reference event.
- Staff caring for patients with COVID-19 requiring CPAP on general wards need training and competency assessment to feel confident in delivering care.
- The levels of care for unwell patients requiring CPAP therapy for treatment of COVID-19 is at least similar to patients receiving acute non-invasive ventilation and such patients may require a 1:2 nursing ratio.

NHS 111's response to callers with COVID-19-related symptoms during the pandemic **(RB/13) (INQ000320204)**

1.60 The investigation explored four patient stories about contact with NHS 111 services during the COVID-19 pandemic, described by participants at focus groups. Each story was tracked from each patient's first call to NHS 111 with COVID-19-related symptoms until their last contact.

1.61 The national investigation explored how learning from these experiences, and others, could support improvements in the delivery of NHS 111 and other telephone triage services during a national healthcare emergency. Key findings from the national investigation were:

- Demand on the NHS 111 system exceeded the system's capacity in March 2020.
- Evidence from families indicated that aspects of NHS 111 telephone triage, such as routing all COVID-19-related calls to the COVID-19 response service (CRS), did not function as intended.
- Strong national messaging advised people with suspected COVID-19 to stay at home. This may have impacted on patients' willingness to seek medical advice from elsewhere, even if their condition deteriorated.
- The CRS algorithm did not allow for an assessment of caller's comorbidities to establish whether a clinical assessment would be beneficial. Callers would only be transferred to a clinician/receive a clinical call back if they were "so ill that … [they've] stopped doing all of …[their] usual daily activities".

- The healthcare system specified that patients with COVID-19 related symptoms and underlying conditions (including diabetes) who went through to core NHS 111 (instead of CRS) should be escalated to a clinician for assessment. However, some patients did not receive a clinical assessment.
- The intent was that COVID-19-related calls would be diverted to the CRS, which was operationally independent from NHS 111. Many COVID-19-related calls continued to go through the core NHS 111 service. Once callers had reached the core NHS 111 service, there was no way to route them to the CRS.
- The decision to redirect the public to call NHS 111 rather than access healthcare advice in other ways (for example, through their GP) shifted the immediate burden of managing patients with COVID-19 in the community. This increased capacity, in the wider healthcare system, but risked disrupting continuity of care for patients with complex health needs.
- Learning and developments throughout the pandemic led to improvements in how callers to NHS 111 are assessed and managed. These included recognising the importance of pulse oximetry (that is, measuring blood oxygen levels) to identify silent hypoxia (when a patient has low oxygen saturation levels without becoming breathless) in patients with COVID-19.
- Text messages that told a patient they had a positive polymerase chain reaction (PCR) test result included information about isolating and the legal requirements. It did not include sufficient safety-netting advice regarding symptoms to watch for and when and from where to seek medical advice. While this is not related to NHS 111 services, the investigation considered it important to highlight for the future.

National Learning Report: Early warning scores to detect deterioration in COVID-19 inpatients **(RB/14) (INQ000320205)**

1.62 The national learning report explored a reliance on existing early warning score tools (NEWS2) to help identify signs of deterioration in patients with COVID-19. Key findings from the national learning report were:

- In response to COVID-19, general wards were typically not staffed by respiratory specialists and consequently early warning scores were being relied upon for escalation decision making. This was problematic given that early warning scores should be used alongside appropriate clinical judgement.

- Staff who were less familiar with managing acute medical patients were sometimes falsely reassured by no change or additional change in early warning score.
- If a patient's oxygen requirements increase over a short period of time, because of a reduction in oxygen saturation, this might not change the NEWS2 score if other parameters remain unchanged.
- Rapidly increasing oxygen requirements is a condition specific trigger for COVID-19 that should inform clinical judgement regarding the need for escalation.

National Learning Report: Maternal death - learning from maternal death investigations during the first wave of the COVID-19 pandemic **(RB/15)** **INQ000216631**

1.63 The national learning report explored themes arising from 20 maternal death investigations completed by HSIB maternity involving patient deaths between 1 March and 31 May 2020. The key themes identified by the national learning report were:

- Unprecedented demand for telephone health advice caused delays in accessing health care: Several women, or their family members, attempted to contact NHS services by telephone. These included NHS 111, GPs, and maternity helplines. Families described experiencing significant delays, making repeated attempts, and abandoning calls after waiting to connect with an operator.
- Public messaging and 'safety netting' advice caused delays in seeking healthcare: The message from the UK government during March to May 2020 was to 'Stay Home. Protect the NHS. Save Lives'. HSIB investigations found that women and their families were concerned about their health or the risk of exposing their unborn baby to COVID-19, and about the requirement to attend hospital without the support of their families. Because of these concerns they put off going to hospital for longer than they otherwise may have done
- Guidance changed rapidly: The effort to produce guidance to inform clinicians and the public about COVID-19 was unprecedented and the resultant wave of information being directed at staff on the frontline was considerable. It is evident from HSIB investigations that it was difficult for hospital trusts to keep staff apprised of updates to guidance.
- Use of early warning scores did not always detect deterioration: HSIB investigations identified that early warning systems (clinical observations and tests used to check the state of a patient's health) were not always used as intended. The issue of compliance in monitoring and recording clinical observations requires an understanding of working

practices, and there are complexities in how scoring systems are embedded in practice. There is no nationally agreed maternity-specific early warning score in England, and investigations found examples where the NEWS 2 score, not designed for use in pregnant women, was used.

- Personal protective equipment requirements changed due to COVID-19: The design of work processes and the environment did not adapt to account for the increase in time to don (put on) personal protective equipment (PPE). Environments were described as "noisy" with staff having to repeat requests and seek clarity of instructions. Clinicians' voices were "muffled", and staff reported "heightened stress levels" because of communication difficulties associated with wearing PPE.
- Staff described feelings of stress and distress which can affect performance: Stress was aggravated for example by communication difficulties caused by PPE, redeployment to unfamiliar work areas, and reduced staffing levels. The report highlights areas where organisational resilience may be increased.
- Difficulties in making a diagnosis and choosing treatment strategies: Several investigations highlighted diagnostic challenges which may have resulted in missed or delayed diagnosis. Diagnosis was impeded by lack of communication and face-to-face assessment, access to tests and concerns about infection prevention and control, as well as complexity caused by rapidly acquired knowledge of a new disease and the physiology of pregnancy.

National Learning Report: Intrapartum stillbirth - learning from maternity safety investigations that occurred during the COVID-19 pandemic, 1 April to 30 June 2020 **(RB/16) INQ000176655**

1.64 The national learning report explored a rise in the number of referrals seen by HSIB maternity during the COVID-19 pandemic. Between April and June 2019, 24 stillbirth referrals were made to HSIB that met maternity investigation programme criteria between 1 April and the end of June. Between April and June 2020 there were 46; a 92% increase. Of the women and pregnant people referred to in the report, eight received a COVID-19 test; none tested positive. Twenty-three were not tested, in line with changes in national testing policy during the period covered by this report. Key themes identified by the national learning report were:

- Guidance: In response to the changing situation and developing understanding of risks during the first wave of the COVID-19 pandemic, a large volume of rapidly changing guidance was produced. Despite best efforts to make this accessible to staff, investigations found variation in local implementation, difficulty in assimilating the

changes and in one instance an important discrepancy between two sets of current national guidance on the management of reduced foetal movements.

- Management of risk: Although the NHS identified continued provision of maternity services as a priority, operational changes were made to reflect the need to reduce the risk of transmission of infection. In all the cases reviewed, the women and pregnant people received the recommended number of appointments and scans, and appropriate bereavement care was provided. Some face-to-face antenatal (pre-birth) visits were replaced with remote consultations, resulting in fewer opportunities to perform physical examinations such as symphysis-fundal height measurement (measurement of the size of the uterus which is used to assess a baby's growth during pregnancy), and carbon monoxide testing (a simple non– invasive breath test which gives women an immediate indication of the carbon monoxide level in their body) was paused. Some hospital ultrasound scans were stopped or delayed during this period.
- Telephone triage: Difficulties in communication were identified, relating to the availability and presentation of clinical records, documentation, and communication of information from triage calls, and availability of interpreters particularly in urgent circumstances. The usual reliance on family members to provide translation support, which is not in line with national guidance, was emphasised when policies were introduced requiring women and pregnant people to attend antenatal appointments alone.
- Interpretation services: The review identified that family members do provide translation support when interpretation services cannot be provided by the local maternity service, even though this is not in line with national guidance. However, during the first wave of the pandemic, when women and pregnant people were required to attend antenatal appointments alone, the provision of interpretation services was even more critical.
- Work demands and capacity to respond: Changes were identified in work processes, staffing levels and physical layout of the space in which staff were working, resulting from the pandemic. Membrane sweeps (a midwife or doctor uses a single finger to sweep around the cervix), designed to reduce the need for formal induction of labour, were stopped in some centres, to reduce the infection risk associated with more prolonged contact between patients and staff. Some of the necessary changes made to the physical space, for example to enable staff to don and doff (put on and take off) personal protective equipment, had unintended and unforeseen consequences in terms of the usability of equipment in its new position.

- Neonatal resuscitation: The review highlighted gaps between how neonatal resuscitation (delivery of inflation breaths with or without chest compressions) is expected or imagined to work and how it actually happens. This issue has been highlighted in other types of national reports. The review identified that existing systems, equipment, and environments to support neonatal resuscitation do not appear to consistently enable all staff to act and respond as required by the guidance.

COVID-19 transmission in hospitals: management of the risk – a prospective safety investigation **(RB/17)** **INQ000130588**

1.65 The national investigation explored the transmission of COVID-19 in hospitals, due to concerns raised which suggested that people were being admitted to hospital without signs of COVID-19 and by the time they were discharged, or soon after, they had contracted COVID-19. Key findings from the national investigation were:

- There was a lack of clarity regarding national responsibilities, ownership, and process for the development of national infection prevention and control (IPC) guidance.
- Key national guidance did not fully reflect the range of mitigation measures suggested within the principles of the hierarchy of controls (an approach that sets out measures to mitigate risk ranked by their effectiveness).
- It was challenging for the NHS to develop, interpret and implement guidance due to the volume of guidance disseminated and the speed at which guidance updates have been required. At local level, the need to interpret the volume of guidance required the use of additional organisational resources.
- Access to sufficient patient and staff testing (Pillar 1 testing) and rapid testing played a key role in how effectively NHS trusts could manage operational capacity.
- There was no regular surveillance testing of staff in the reference trusts outside of the Public Health England SIREN (Sarscov2 Immunity and Reinfection Evaluation) study.
- There was little evidence of a national strategic approach to address how trusts might overcome the obstacles faced when attempting to implement national guidance on patient testing.
- A lack of clarity and changing guidance on PPE use created anxiety for staff, patients, and families.
- Clinical activities in hospitals could be restricted because of the provision of different types of FFP3 (filtering facepiece class 3) respirator masks, which required repeated fit testing for staff.

- The availability of IPC expertise was variable with a national lack of IPC staff and shared understanding of their role and national IPC requirements.
- The design of the hospital estate impacted on the ability to comply with IPC guidance and take mitigation efforts to reflect the higher levels of the hierarchy of control.
- The flow and layout of staff work activities and equipment create additional transmission risks.
- Considerations about the design and use of hospital ventilation systems were an emerging factor in mitigating the risk of COVID-19 transmission.
- Staff who engaged with the investigation reported significant fatigue and emotional distress associated with COVID-19 activity.
- The organisational response to COVID-19 has required significant adaptability in NHS systems and leadership.

National Intelligence Report: Personal protective equipment (PPE) - care workers delivering homecare during the COVID-19 response **(RB/18) (INQ000320210)**

1.66 The national intelligence report considered a safety risk related to PPE requirements for care workers delivering homecare during the COVID-19 response. The report highlights how these concerns were shared with Public Health England and how it updated relevant guidance.

Emergency response to heart attack **(RB/19) (INQ000320211)**

1.67 The investigation explored a reference event where there was a delay in an ambulance attending a patient suffering a heart attack. The national investigation explored systems that enabled effective response to suspected heart attack. The reference event occurred before the COVID-19 pandemic; given this, factors associated with COVID-19 were not directly considered in the investigation report.

1.68 Key findings from the national investigation were:

- There were increasing delays in ambulance responses to chest pain calls.
- PPCI is the preferred treatment option for ST-elevation myocardial infarction (STEMI) where patients can present to hospital within 12 hours of the onset of their symptoms, and where primary percutaneous coronary intervention (PPCI) can be given within 120 minutes of the time when a STEMI is diagnosed.
- Where patients may have suffered a STEMI, ambulance delays can impact on the ability to provide PPCI within target timescales.
- Delays in receiving PPCI can increase the risk of in-hospital and 30-day patient mortality.

- There is a lack of evidence to show the impact on death rates in the longer term beyond 30 days, the effect on patients' health in the longer term, and the impact on NHS resources stemming from delays in patients receiving PPCI.
- National and professional guidance recommends thrombolysis as an alternative treatment for STEMI where PPCI cannot be provided within target timescales.
- There is a lack of evidence to support which treatment option is best in treating STEMI where patients encounter delays: PPCI delayed beyond the target timescale of 120 minutes from a STEMI diagnosis, or thrombolysis provided after 120 minutes of a STEMI diagnosis.
- Thrombolysis is now rarely used within the NHS for pre-hospital STEMI treatment.
- Thrombolysis medication is no longer carried by 6 of the 10 English ambulance services.
- In four ambulance services, thrombolysis medication is only retained in more rural areas where patients may routinely be unable to access PPCI within target timescales or where it is administered by specialist paramedics.
- Paramedic staff may not be competent to administer thrombolysis medication due to the limited circumstances in which this is now required.
- The withdrawal of thrombolysis as an alternative treatment, and lack of competence of paramedics to administer thrombolysis, places greater emphasis on the need to ensure STEMI patients present to hospital as soon as possible for PPCI.

Surgical care of NHS patients in independent hospitals **(RB/20) (INQ000320213)**

1.69 The investigation explored a reference event where a patient with bowel cancer underwent NHS surgery in an independent hospital because of COVID-19. He deteriorated post operatively and later died because of sepsis.

1.70 The national investigation explored the safe provision of surgical care, with reference to a specific incident, and how decisions are made around which patients are cared for in independent hospitals. Key findings from the national investigation were:

- National and local NHS organisations had limited understanding of independent hospitals' capabilities. This resulted in variation in how independent hospitals were used during COVID-19.
- Some independent hospitals saw patients with increasingly complex conditions and undertook more complex operations during COVID-19. The increasing complexity was

well managed where capability of the independent hospitals had been evaluated and addressed prior to implementation of new services.

- Other factors that created risks in NHS-funded surgical pathways between NHS and independent hospitals included: unclear roles and responsibilities; limited integration of information and communication systems; and variation in what surgery was deemed suitable for an independent hospital.
- There was variation in how preoperative assessments were undertaken across NHS and independent hospitals. This included what tests were ordered and risk assessments undertaken.
- Remote preoperative assessment became the norm during COVID-19, but created risks when staff were not able to see the patient. Lack of video call facilities and staff preference meant assessments were commonly done by telephone.

Management of sickle cell crisis **(RB/21) (INQ000320214)**

1.71 The investigation explored a reference event where a patient who attended hospital in sickle cell crisis. The patient later died due to cardiorespiratory failure caused by acute sickle cell crisis and morphine toxicity.

1.72 The national investigation explored how sickle cell crises are managed within hospital settings. Key findings from the national investigation were:

- Trusts faced competing priorities during the COVID-19 pandemic and many trusts may have needed to alter the normal pathway of care for patients with sickle cell disease.
- Where reconfiguration of services required patients in sickle cell crisis to be cared for in alternative wards/departments within the hospital or by new staff, there may not be the necessary equipment, knowledge or staff training required for care to be delivered safely.
- Staf workload, particularly during the COVID-19 pandemic and in emergency departments, impacted on the ability of staff to conduct increased monitoring requirements, such as the monitoring of patients on high-strength opiates.

Access to critical patient information at the bedside **(RB/22) (INQ000320215)**

1.73 The investigation explored a reference event where a patient was misidentified as having a do not attempt resuscitation order in place during an emergency. This meant the patient did not receive immediate support when he was found to have stopped breathing.

1.74 The national investigation explored the factors that affect the ability of staff to access critical patient information at the bedside. A single factor noted as impacting on the reference event was relevant to COVID-19. The investigation found that wards at the Trust had been repurposed and staff redeployed because of the COVID-19 pandemic, to meet the demand created by increasing numbers of patients with medical problems. The situation was described as "all very new and reacting". In the months prior to the reference event, the ward had been an elective (planned) day-case surgery ward for patients without COVID-19. Shortly before the reference event the ward had been repurposed. This meant that it was changed from caring for patients following day-case surgery, to caring for patients with other types of medical problems, often with frailty and dementia.

1.75 No findings or recommendations were made in the wider report in relation to this single issue or specifically in relation to COVID-19 response. Findings made by the national investigation were:

- Clinical staff are not always able to access accurate, critical patient information at bedsides to support decision making in emergencies.
- Patient identity wristbands are not consistently checked by staff during the undertaking of clinical tasks.
- The expectations of how staff should identify patients in an emergency and access critical information in relation to their care cannot always be met in practice because of limitations of technology and the work environment.
- Concerns around confidentiality can prevent the display of critical patient information at bedsides that may be needed to support safe care, particularly in emergencies.
- What and how critical patient information is displayed at the bedside varies across hospitals, with differences in positioning, visibility, readability, and legibility.
- There is no national guidance to support consistency and visibility of critical patient information on low-technology displays (whiteboards/posters) or high-technology displays (via digital systems).
- Lighting on hospital wards can make it difficult for staff to see critical patient information, either through too little light, or too much light causing glare.
- Clinical staff consistently report difficulties accessing digital systems because of limited or poorly functioning hardware. This can result in the use of less reliable, paper-based systems for accessing critical patient information.
- Limited interoperability of multiple digital systems means critical patient information may not be accessible or consistent across all systems used in the care of a patient. Staff need to know which systems contain the information they need.

- Limited ability at a national level to influence the functionality of digital systems and their procurement means healthcare organisations are implementing systems with varying design and functionality.
- At the hospital level, the configuration of electronic patient record systems can introduce further safety risks where the infrastructure and staff training needs necessary for successful implementation have not been fully considered, and the needs of the clinical users have not been fully established.
- There is variation in the words and symbols used to indicate cardiopulmonary resuscitation (CPR) recommendations, and in the level of understanding of CPR recommendations across hospitals, which may influence responses to cardiac arrests.
- Nursing handovers (where information about patients is passed between nursing staff at shift changes) may not provide the information staff need to care for their patients because of where and how they are undertaken. There is no national guidance on how best to undertake handovers of care.
- The implementation of electronic handover systems in clinical workplaces is limited by digital infrastructure, and systems that do not meet the needs of their users.

National Learning Report: Support for staff following patient safety incidents **(RB/23) (INQ000320216)**

1.76 The national learning report explored HSIB's insights into how NHS staff are supported by organisations following patient safety incidents, with a focus on good practice. The national learning report noted that COVID-19 pandemic had a significant impact on healthcare staff and that staff were being redeployed to unfamiliar work environments. They also faced difficult working conditions, escalating death rates, and challenges to delivering the expected quality of care. Staff also reported having their own domestic pressures, resulting in a combination of work and home stressors with associated burnout and psychological harm. The ability of organisations to undertake the full range of patient safety investigations in a timely manner was noted and the importance of staff support capabilities was identified.

Interim Bulletin: Harm caused by delays in transferring patients to the right place of care **(RB/24) (INQ000320217)**

1.77 The interim bulletin for this investigation explored the systems that are in place to manage the flow of patients through and out of hospitals and considers the interactions between the health and social care systems. The Bulletin included comment on COVID-19 'rules' posing significant challenges for NHS organisations when trying to discharge patients into social care settings.

1.78 No specific report has focused solely on reorganisation of NHS services, but many of the above reports do include findings and evidence related to the impact of reorganisation because of COVID-19. In addition, we have produced a blog post highlighting the wider impact of reorganisation of NHS services and the impact this may have on patient care **(RB25) (INQ000320218)**. The blog summarised learning from HSIB investigations to share the challenges seen about the design of ward areas, including where ward areas were repurposed during COVID-19 in reference to 'Oxygen issues during the COVID-19 pandemic – Interim bulletin 2' **(RB/11) (INQ000320202)**, **'**Management of sickle cell crisis' **(RB/21) (INQ000320214)**, and 'Access to critical patient information at the bedside' **(RB/22) (INQ000320215)**. The blog asked NHS staff to try and create capacity to proactively plan for these challenges by considering the following steps:

- Create capacity to proactively plan for repurposing and redeployment decisions.
- Ensure a full range of professions and specialisms are included (clinical and non-clinical) that can consider the different impacts repurposing or deployment may have on patient care.
- Consider what specific environmental adaptations may be needed to support specialist patient care in a new environment.
- Consider what additional equipment and technology may be needed to provide care in repurposed environments.
- Consider what additional training, competencies or support staff may need to provide care to groups of patients they may not routinely care for.

1.79 Specific maternity investigation reports are not publicly available and are provided to the family and organisation involved in a safety event. Relevant investigations are included in the aggregated data provided within the national learning reports, to allow for thematic issues across investigations to be understood and responded to.

1.80 HSIB also completed discrete, unpublished pieces of work to support the NHSE and Department of Health and Social Care response to the COVID-19 pandemic. These are summarised below at 1.129 to 1.137.

Healthcare Inequalities considered in HSIB investigations.

1.81 HSIB investigation reports include reference to any relevant factors identified with respect to healthcare inequalities and protected characteristics. However, for further context, there were specific investigations where this has been considered in more depth.

1.82 'NHS 111's response to callers with Covid-19-related symptoms during the pandemic' **(RB/13) (INQ000320204)**: HSIB first became aware of the concerns about NHS 111s response to callers with COVID-19 related symptoms, via the HSIB Citizens Partnership. The Citizens' Partnership ran between 2021 and 2023. Its purpose was to ensure the public perspective is integral to our strategy, patient safety investigations and plans. There was initially some suggestion by members that there were concerns about how people with protected characteristics (primarily ethnicity) were having a poorer experience with NHS 111.

1.83 At the outset, HSIB held two focus groups with families who wanted to share their experience of calling NHS 111 for COVID-19 related symptoms. Most of the families felt that either the inability to get through to NHS 111 or the advice provided to callers with COVID-19 related symptoms contributed to a delay in their family member receiving treatment. The investigation explored with participants whether they felt that the ethnicity of the caller impacted on the advice provided or the experience of the caller. Additionally, during interviews as part of the subsequent reference events, the investigation explored with the families whether they felt ethnicity impacted on the care or advice provided.

1.84 While three of the four callers in the reference events were from an ethnic minority background, none of the families felt as though ethnicity directly impacted on their experience of NHS 111. The investigation therefore did not have evidence to explore this as a standalone term of reference, but nonetheless kept ethnicity in mind as a consideration when examining the four reference events. The investigation did this through a variety of means, one way was by using a conversational linguistics expert to ascertain whether the way in which questions were asked impacted on the ability of callers to respond, particularly when English was not the caller's first language. The investigation also explored the risks associated with remote assessment and this included the language used in eliciting information from callers.

1.85 In one of the reference events, the investigation identified two potential problems with the remote assessment where English was not the caller's first language and may have impacted on their experience/advice provided:

- Ali may not have understood the question. Ali's family questioned whether health advisors are trained to manage the differences in language used by ethnic minorities.

- Ali was too unwell to answer the question.

1.86 'National Learning Report Maternal death: learning from maternal death investigations during the first wave of the COVID-19 pandemic' **(RB/15)** **INQ000216631** The national learning report noted that the UK Obstetric Surveillance System released a pre-print publication describing outcomes for 427 pregnant women and their babies admitted to hospital with COVID-19, which found that 55% of pregnant women admitted to hospital with COVID-19 were from a Black, Asian, or other ethnic minority background. This resulted in updated guidance being issued by the Royal College of Obstetricians and Gynaecologists.

1.87 Eight of the 19 cases used to generate the national learning report involved the death of a woman from Black, Asian, or other ethnic minority backgrounds. However, the disparity in maternal deaths according to ethnicity had been observed prior to COVID-19. MBRRACE UK found that Black women are five times more likely to die in pregnancy, childbirth or in the period after giving birth, compared to white women, and Asian women are twice as likely to die, compared to white women.

1.88 'National Learning Report: Intrapartum stillbirth - learning from maternity safety investigations that occurred during the COVID-19 pandemic, 1 April to 30 June 2020' **(RB/16)** **INQ000176655** English was not the first language for 16 (43%) of the 37 women and pregnant people whose care formed the basis of the report. Eleven women and pregnant people (30%) were from an Asian British, Asian Indian, or Asian Pakistani background. Five (14%) were from a Black British, Black Caribbean, or Black African ethnic background.

1.89 The inability to identify timely or appropriate interpretation services presented the greatest risk to the safety of women and pregnant people and babies during unplanned admissions. This national learning review identified variable adherence to guidance on the use of interpretation services. In the 37 investigations reviewed, 8 (22%) of those concerning families whose first language was not English highlighted a lack of access to interpretation services. In four of these eight cases it was possible to identify that this affected the care received. These cases highlighted that typically relatives act as interpreters where unplanned maternal care is provided or when a timely or appropriate interpretation service cannot be provided.

1.90 Families were not available to provide interpretation where COVID-19 guidance prohibited (or was interpreted to prohibit) partners from accompanying women and pregnant people either to antenatal appointments or into a maternity unit until confirmed labour was established. This risk was not managed during the COVID-19 pandemic and the adjustment to guidance created the unexpected consequence of women and pregnant people being without any form of translation or support in the early stages of labour or when they found out that their baby had died.

National investigation recommendations that may assist in future pandemic management.

1.91 HSIB sets out all relevant learning in its finding, recommendations, and other safety actions contained within its investigation reports. All the reports listed in the Exhibits contain relevant safety learning that may improve patient safety in the event of a future pandemic. There were investigations where specific recommendations or learning were shared with the express intent to help the NHS respond to future, similar pandemic illness:

1.92 'Oxygen issues during the COVID-19 pandemic' **(RB/9)** **INQ000270026**: A recommendation was made to NHSE to update advice on the type and design of MGPS infrastructure recommended for NHS trusts.

1.93 NHSE responded to this recommendation to state that the update of the Health Technical Memorandum (HTM) 02-01 NHS estates guidance for medical gas pipeline systems had started and would include consideration of all the recommendations raised by the HSIB report.

1.94 'Treating COVID-19 patients using Continuous Positive Airway Pressure (CPAP) outside of a critical care unit' **(RB/12) (INQ000320203)**: Safety questions were included to help NHS trusts consider how they would care for patients requiring CPAP outside of a critical care unit.

1.95 'NHS 111's response to callers with Covid-19-related symptoms during the pandemic' **(RB/13) (INQ000320204)**: A recommendation was made to NHSE to review the risks posed by utilising telephone triage in future national healthcare emergencies. A safety observation was also made to address the potential benefits of face-to-face assessment and to consider the language used when communicating with unwell patients, to avoid them not seeking care.

1.96 NHSE responded to this recommendation to state that it would work with partners to review risks following national healthcare emergency response as part of the lessons identified process. These lessons would then be reviewed and applied where relevant to current services as part of an established process.

1.97 'National Learning Report Maternal death: learning from maternal death investigations during the first wave of the COVID-19 pandemic' **(RB/15)** **INQ000216631** Safety observations were made to suggest further work was required to understand the higher maternal death rate of women from Black, Asian or minority ethnic backgrounds and to implement a toolkit to improve communication with women from Black, Asian or minority ethnic backgrounds.

1.98 'COVID-19 transmission in hospitals: management of the risk – a prospective safety investigation' **(RB/17)** **INQ000130588** All recommendations made to NHSE, NHSX and DHSC were intended to address risks posed by COVID-19 or future pandemic illnesses that could be spread in hospital settings.

1.99 DHSC received two recommendations in relation to IPC guidance and mechanisms to learn from the pandemic. It responded to state that there would be improvements in how IPC guidance was developed and disseminated. DHSC told HSIB that this process would benefit from enhanced, proactive professional stakeholder engagement to support both content and ensure the avoidance of concerns raised following publication. Where there is an absence of evidence of a structured engagement process, DHSC said it would support consensus and allow guidance development or implementation challenges to be raised proactively.

1.100 DHSC also told HSIB that opportunities to look back, analyse and reflect on all aspects of COVID-19 would be available, but for now the Government was focused entirely on responding to the pandemic and saving lives. The response identified mechanisms that would help inform lessons learned, such as the proposed inquiry, National Audit Office's studies into how well prepared the government was for the COVID-19 pandemic, and ongoing changes to the structure of the health and care system, most notably the establishment of the National Institute for Health Protection (NIHP).

1.101 NHSE received five recommendations and responded to state:

- In relation to COVID-19 testing, that there was increased provision for symptomatic and asymptomatic testing of NHS staff, including lateral flow antigen testing kits being

made available to all NHS trusts and with a plan to roll out to primary care. For patients, NHSE told HSIB that provision was in place to test patients on admission, at regular intervals during a hospital stay, 48 hours before discharge, and that support was also now available to advise on testing for people accompanying maternity patients.

- In relation to developing and supporting a national IPC programme, the national IPC team had established an assurance system through regional teams on delivery of these key actions by NHS provider organisations. This included daily data collection in infection information and the establishment of a regionally led intensive support programme for IPC in October 2020. NHSE also told HSIB that proposals were being developed for a programme of work to further improve IPC capacity and capability to support delivery of strategic objectives in the NHS Long Term Plan.
- In relation to the design of the built hospital environment, the principles set out in the hierarchy of controls had been applied in the development of ventilation guidance and answers to frequently asked questions shared with NHS Trusts.
- In relation to the role of hospital ventilation systems, learning from UK and international experience had informed development of ventilation guidance, and specifically a review of the relevant health technical memorandum (HTM 03-01). This had included academics and devolved nations NHS staff with expertise in building ventilation and healthcare ventilation.
- In relation to staff fatigue and distress, targeted support has been made available to critical care staff via a range of health and wellbeing resources. This included sessions for critical care leaders on support resources available and training at least one nurse per critical care team in restorative clinical supervision by April 2021 to enable wider support. NHSE told HSIB there was also a wider wellbeing support offer for all staff, which featured a confidential staff support helpline, offering staff access to trained advisers by phone or text, further bereavement and counselling services and a range of wellness resources and professional line manager support. In addition, an enhanced health and wellbeing offer was being piloted across 14 systems and integrated staff mental health support was available through 40 system-wide mental health and wellbeing hubs.

1.102 NHSX told HSIB that it had worked with its partner organisations to support staff and organisations to make changes during the pandemic - including the rapid, national roll out of Microsoft Teams and video consultation platforms. NHSX had also established a procurement framework to make it easier for organisations to purchase the communication tools they need for clinical staff. NHSX said that it would conduct further work to consider the role of communication tools in reducing transmission of infections in hospitals -

including tools to support staff deployment, bed management and corporate communications.

1.103 'Emergency response to heart attack' **(RB/19) (INQ000320211)**: Two safety recommendations were made to NHSE. The first asked NHSE to revise the Ambulance Clinical Quality Indicator for Clinical Outcomes for ST-elevation myocardial infarction to reflect each element of the call to balloon response and review this indicator alongside the critical time standards workstream.

1.104 NHSE responded to the safety recommendation to state that it would explore the feasibility, the associated burdens and benefits of additional data collection, and potential unintended consequences of reporting the component parts of the call to balloon time to reflect the times for call to scene, on scene, scene to door and door to balloon. A standing item of "emerging risks and research highlighting factors impacting on effective ambulance response" has been added to the agenda of the Joint Ambulance Improvement Programme Board, where matters of concern can be raised and actioned as appropriate.

1.105 Discussions had taken place regarding revising the Ambulance Clinical Quality Indicator: Clinical Outcomes for ST-elevation myocardial infarction. It proposed to report the component parts of the call to balloon time to reflect the times for call to scene, on scene, scene to door and door to balloon and to analyse where improvements can be made to reduce the call to balloon time. NHSE said it would explore the feasibility, the associated burdens and benefits of this additional data collection, and potential unintended consequences before finalising any new national data collection. Subject to these findings, improvements would be realised through supporting those trusts and local systems with the greatest challenges to improve. This work will run alongside the critical time standards work.

1.106 NHSE said that any revisions to the Clinical Quality Indicator would be explored during Summer 2021, with any revisions taken to the Autumn 2021 Ambulance Transformation Forum meeting for approval.

1.107 The second safety recommendation to NHSE asked it to support the Joint Ambulance Improvement Programme to respond to emerging risks and research highlighting factors impacting on effective ambulance response. NHSE responded to state that a standing item of "emerging risks and research highlighting factors impacting on effective ambulance response" had been added to the agenda of the Joint Ambulance Improvement

Programme (JAIP) Board, where matters of concern can be raised and actioned if appropriate.

1.108 A safety recommendation was made to the Association of Ambulance Chief Executives (AACE) to working with the College of Paramedics and cardiology specialists, produces a position statement on the use of pre-hospital thrombolysis by paramedics. AACE responded to state that an ambulance service Medical Director brought together representatives from four organisations: the Association of Ambulance Chief Executives, the College of Paramedics, the British Cardiothoracic Society, and the Joint Royal Colleges Ambulance Liaison Committee who agreed a consensus for a UK wide position statement on the use of pre-hospital thrombolysis that was issued on 20 July 2021.

1.109 'Surgical care of NHS patients in independent hospitals' **(RB/20) (INQ000320213)**: Safety recommendations were made to NHSE to ensure integrated care systems understand capability and capacity of local independent hospitals. NHSX was asked to consider how information transfer between NHS and independent hospitals could be better achieved.

1.110 NHSE did not respond to this recommendation. HSIB understand that elements of this recommendation may have now been taken forward in the elective recovery plan. Given the lack of response, HSIB has closed this recommendation and confirmed the closure to DHSC. This area may be explored further on the establishment of the Healthcare Services Safety Investigations Body (HSSIB).

1.111 NHSX responded to this recommendation to state that programmes of work were underway to improve the flow of data between secondary care trusts and community-based services within Integrated Care Systems (ICSs), with a view to expanding to interoperability between ICSs over time. In this work, NHSX agreed that the independent sector must not be regarded in isolation, but rather as a key component of the ICS in which they sit. This was of particular importance, given their evolving role in supporting the NHS to provide timely care to NHS patients (including urgent NHS elective surgical care, and the delivery of cancer pathways). To underpin this, NHS would continue to support providers across the health and care sector in the adoption of Fast Healthcare Interoperability Resources standards, to optimise the sharing of information between IT systems used in health and care. NHSX recognised that these endeavours pose questions of cybersecurity, information governance, and clinical safety, which must be addressed if true system-wide interoperability is to be achieved.

1.112 'Access to critical patient information at the bedside' **(RB/22) (INQ000320215)**: The national investigation made a total of eight safety recommendations to NHSE, the Office of the National Data Guardian, the Resuscitation Council UK, the British Standards Institute, and the Royal College of Nursing.

1.113 NHSE received five safety recommendations and responded to state:

- In relation to developing guidance to providers to help ensure critical patient information is available to clinical staff when accessing electronic patient record systems, that the Frontline Digitisation programme would ensure that the next iteration of the Digital Maturity Assessment incorporates guidance to give clarity to NHS Trusts on the priority of ensuring critical patient information is available to staff accessing electronic patient record systems.
- In relation to providing guidance to healthcare organisations to support local design and configuration of electronic patient records to enable end users to access critical patient information, that the Frontline Digitisation programme provides guidance to NHS trusts in a variety of ways, and the key channels will be used to highlight the outcome of this investigation, and its recommendations for access to critical patient information. This was to include provider support teams, the online electronic patient records support hub, and that the investigation report would be shared with suppliers via the TechUK forum.
- In relation to reviewing the relevant HBN and Health Technical Memoranda (HTM) to include a consideration that bedside patient information should be consistently visible, that the recommendation would be implemented in the upcoming HBN 04-01: Adult Inpatient update by 31 December 2023. In addition, the recommendation would also be incorporated in the following documents when they were due to be updated: HBN 04-02: Critical Care Units, HBN 23: Designing hospital accommodation for children, and HTM 08-03: Bedhead services.
- In relation to assessing the priority, feasibility, and impact of future research into what and how critical information pertaining to the emergency care of patients in the acute hospital setting can be readily and reliably accessed at a patient's bedside, the recommendation would be considered through NHSE's established research commissioning routes with the aim of developing practical and deliverable research that will provide decision makers with the needed evidence to improve patient safety. This would include and initial topic assessment and developing research questions during March-May 2023, submitting a request for policy

research to NHSE's research needs panel by July 2023, and any research request being considered by the DHSC committee. If prioritised, the research request would then be progressed from October 2023 onwards.

1.114 A recommendation was made to the Office of the National Data Guardian to support local interpretation of the Caldicott Principles to give organisations and staff the confidence to display full patient names at the bedside to support correct patient identification for safer care. It responded to state that hospitals displaying a patient's full name above their bed or on the door of their room so that they may be correctly identified in an emergency is supported by both Caldicott Principle 7 and the Health and Social Care (Safety and Quality) Act (2015). The Office of the National Data Guardian highlighting the report and re-affirmed Principle 7 in their newsletter.

1.115 A recommendation was made to the Resuscitation Council UK to clarify and promote expectations around the sharing, presentation, and language of cardiopulmonary resuscitation recommendations in hospital ward environments in line with the findings of this investigation. It responded to state Resuscitation Council UK strongly supports the adoption and implementation of the Recommended Summary Plan for Emergency Care Treatment (ReSPECT) process, which enables the fulfilment of the findings in the report. It said that it was constantly working with stakeholders to improve the process and communication and learns from the experiences of everyone using it. It was aware of the paper and digital challenges with different systems across the UK, and the challenges between the different health and care sectors. Working with its stakeholders, it would highlight and promote the benefits ReSPECT brings when done well and would be developing further educational tools for use by areas using the process to encourage best practice.

1.116 A recommendation was made to the British Standards Institute to, with support from relevant stakeholders, provided symbology to standardise how information relating to a patient's resuscitation status can be displayed in digital systems. It responded to state BSI would work with NHSE and the Resuscitation Council UK to assess the current availability of resuscitation information on digital displays and gather user feedback and input into the best solutions for displaying the necessary information. This feedback will be shared with the appropriate medical device standardisation committees to ensure an appropriate and acceptable solution is delivered by quarter four of 2023. It would also consider authoring an industry paper

on challenges around communicating critical patient information at the bedside by quarter one of 2024, identify which international standardisation committee(s) are responsible for this type of symbology, and work to influence development of an international symbol, and work with NHSE, Resuscitation Council of UK, and the Royal College of Nursing to educate healthcare staff on the use and meaning of symbols use to convey patient information through standards awareness and knowledge, by quarter four of 2024.

1.117 A recommendation was made to the Royal College of Nursing to develop guidance for ward-based nursing handovers with consideration of how handovers are organised, their content, the environment in which they take place, and the technology needed to support them. It responded to state that it was in the process of developing wider guidance regarding nursing handovers that will be applicable in all settings and will incorporate this recommendation. It expected this guidance to be available by the end of 2023.

HSIB interactions with DHSC, NHSE and other stakeholders during the COVID-19 pandemic

1.118 During the pandemic I understand that the HSIB senior leadership team were involved in routine meetings and engagement with NHSE and DHSC in response to COVID-19. However, the senior leadership team in place at HSIB during the period the inquiry covers is no longer in post at HSSIB. This has severely limited our ability to provide information on the representations and ongoing contact between the senior team and these organisations during this period.

1.119 We have searched our internal database and have identified two documents that may be of assistance to the enquiry. A 'COVID-19 correspondence log' **(RB/26) (INQ000255847)** was kept between March and June 2020. The log includes internal HSIB actions and discussions, but also includes several references to meetings and interactions with NHSE and DHSC as part of the initial COVID-19 response. The log is made available to the Inquiry in full to ensure any relevant interactions are noted. A 'Timeline of Events, Decisions and Actions' **(RB/27) (INQ000252915)** also includes reference to a range of internal HSIB actions during this period, but again includes reference to external meetings and engagement with NHSE and DHSC. This is made available to the Inquiry in full to ensure any relevant interactions are noted.

1.120 In addition, between March and June 2020 it appears that HSIB was invited to attend two meetings hosted by NHSE. A weekly 'virtual response meeting' appears to have taken place on 16 April, 30 April, 7 May, 14 May, 21 May, 28 May, 4 June, 11 June, 18 June, 25 June where general patient safety risks were discussed. A 'National Patient Safety Response Advisory Panel' meeting also seems to have taken place on 11 March and 10 June, with meetings on 8 April and 13 May being cancelled and possible reference to a further meeting planned for 8 July. In both instances, NHSE chaired the meeting and may have further records of discussions.

1.121 I asked the former Chief Investigator of HSIB, Keith Conradi (KC), to provide his comments on this period and received the following responses from him to confirm:

- KC attended twice-weekly meetings with the wider NHS leadership network where there were opportunities to discuss and listen to the work being done in all areas and therefore co-ordinate. KC later delegated this task but commented that it provided an excellent sounding board for where HSIB might want to concentrate its efforts. I also attended these meetings as part of my previous role in the CQC and believe that the meetings KC is referring may have been the DHSC safety cell meetings.
- HSIB offered specialist advice to the design of the Nightingale Hospitals from a safety perspective. KC felt this was generally well received by NHSE and HSIB were readily invited to attend each new 'hospital' and give our observations before it was fully commissioned.
- HSIB offered, at an early stage of lockdown, the capability and desire to investigate specific NHS staff deaths that appeared to have occurred because of their working closely with COVID-19 infected patients. KC recalled several meetings he participated in with DHSC, likely in early Summer 2020, to work through the practicalities of this, but ultimately DHSC considered an investigation was more appropriately placed with the Health and Safety Executive and the National Medical Examiner. KC considered this a lost opportunity due to the wider perspective HSIB could have brought but the offer was not taken up.
- KC recalls that 'COVID-19 transmission in hospitals: management of the risk – a prospective safety investigation' **(RB/17)** **INQ000130588** was not well received by NHSE. KC has said that the lack of data from NHSE seriously hampered the ability of the investigation to draw accurate conclusions from some of the findings. KC personally wrote to the Chief Executive of NHSE to request the data after multiple escalations, but ultimately it was never provided.

1.122 We would suggest that if further specific information is required about any of these interactions, or additional engagement during the period in question, individuals forming the HSIB senior leadership team at that time would need to be contacted by the inquiry to take evidence. The senior leadership team in post during that time was:

- Chief Investigator: Keith Conradi
- Medical Director: Dr Kevin Stewart
- Deputy Medical Directors: Dr Lesley Kay and Dr Sean Weaver
- Director of Corporate Services: Lynne Spencer
- Director of Investigations: Dr Stephen Drage (May 2019 to August 2021); Tracy Hampson (September 2021 to December 2021); Sue Pritchard (January 2022 to March 2022).

National Investigation interactions

1.123 HSIB investigations included routine contact with DHSC, NHSE and other healthcare organisations as part of evidence collection and stakeholder engagement. Any engagement with national organisations is referenced within HSIB investigation reports when evidence is presented from organisations, and they are named. In addition, HSIB has previously provided the inquiry with a list of NHS organisations that assisted with our relevant investigations but, as in our standard process, are not named in our investigation reports.

1.124 Where recommendations are made to organisations within HSIB reports there was also additional engagement to ensure those organisations are aware of our intention to make a recommendation and confirm the wording that will be used in our report.

1.125 All HSIB investigation reports were also provided to a range of stakeholders on consultation for the factual accuracy checking process before any final report was confirmed. This would always include any reference event organisation, NHSE, DHSC, and then specific organisations referred to within the investigation report.

1.126 Two investigations, 'NHS 111's response to callers with Covid-19-related symptoms during the pandemic' **(RB/13) (INQ000320204)** and 'COVID-19 transmission in hospitals: management of the risk – a prospective safety investigation' **(RB/17)** **INQ000130588** required some additional engagement with NHSE to try and access data that HSIB

requested. In relation to **RB/13 (INQ000320204)** this involved requests for data concerning NHS 111. Between October 2020 and March 2022, several requests were made for this data and no data was received. In relation to **RB/17** **INQ000130588** this involved requests for data relating to nosocomial COVID-19 infection rates from NHSE and Public Health England. Between July and October 2020, several requests were made for this data and no data was received. This was noted in the investigation report.

1.127 In May 2022, the chair of the HSIB advisory panel raised concerns about NHSE engagement with these specific investigations with DHSC. In addition, they also raised wider concerns about NHSE interaction with HSIB **(RB/28) (INQ000256360)**. A response to these concerns was received from DHSC in September 2022 **(RB/29) (INQ000256361)**.

1.128 In addition, HSIB completed specific work outside of its usual investigation programme to support the COVID-19 response from DHSC and NHSE. This work is detailed below.

Nightingale hospital sites **(RB/30) (INQ000339825)**

1.129 HSIB was asked by the NHSE's Central Strategic Incident Team to support mobilisation visits to the Nightingale hospitals as part of a multi-agency team. The purpose of the report was to provide a summary of HSIB observations relating to these visits to help support the safe establishment of Nightingale facilities.

1.130 Common themes identified across the facilities were challenges posed by the different physical environments at each facility, differences in staffing models and the impact on local organisations, variability in the availability of diagnostic support services, commonality in medication support services, variability in PPE requirements, challenges in family engagement, common incident reporting procedures, and availability of electronic record systems.

1.131 There were some common areas that HSIB identified as requiring further consideration prior to the Nightingales being used at full capacity:

- Review of staffing rotas and ratios to ensure sufficient cover, skill mix and clinical leadership, learning from a graduated opening of the units.
- Review of potential bottle necks in the donning and doffing of PPE processes.
- Review models for resuscitation to ensure that there are clear processes for commencement of resuscitation for staff with appropriate PPE. In some units' resuscitation teams could be a considerable distance from some patients.

The assurance of COVID-19 testing facilities: Local testing site review **(RB/31) (INQ000339826)**

1.132 HSIB was asked by DHSC to provide a review of the systems and processes in place at a sample of local testing sites (LTS) for Covid-19. This review allowed HSIB to gather evidence from observations across attended five local testing sites. All the sites visited were run by contracted firms. The review aimed to:

- ensure that the local testing sites are being run efficiently and safely.
- gather data that could provide guidance and direction on areas that could be improved.
- gather data that could inform revisions to the current Standard Operating Procedure.

1.133 The review provided a series of observations aimed at helping to improve practice and safety at these sites. The observations made were:

- It may be beneficial to review the messages given to the public on the coronavirus test booking site to manage expectations. This would ensure that it is obvious to members of the public that they will be required to conduct the test themselves.
- Consideration should be given to developing a set of tools for staff to use to support the communication of instructions. These tools should support communication for the widest range of individuals possible. This should include sensory impairment, cognitive impairment, people for whom their first language is not English, low levels of literacy.
- The standard operating procedure should include that where a family group are sharing a cubicle, they are instructed to have one testing kit only in use at a time to avoid cross contamination or mixed samples.
- The storage temperature of kits and completed tests should be monitored regularly and recorded throughout the day. Consideration should be given to continuous temperature monitoring with alarming when temperatures become sub-optimal.
- Consideration should be given as to how to manage samples (and staff welfare) in the tents in hot or cold weather if air conditioning cannot be used.
- It would be beneficial for sites to receive feedback on their testing results to inform them on whether their procedures are working or if improvements need to be made in certain areas.
- Clear signage to sites should be placed on main roads. This should be professional signage and include a number of signs in each possible direction.

- If attendees are attending via bicycle, guidance should be given that this should preferably be their own bicycle or to take further precautions e.g., enhanced PPE.
- It may be beneficial to separate doffing and donning areas to maximise staff flow and minimise cross-contamination.
- It may be beneficial for all sites to liaise with their local authority to get artwork made by local schools and community groups.
- Consideration should be given to relocating the Newcastle site to a better location with easier access for those who wish to walk or cycle to the site.
- It may be beneficial for a review of the inventory list for sites with clear identification of which party is supplying which elements of the list. Guidance should be given on the number of items required and as much time as possible should be given to procurement of items to allow for an appropriate quality of items to be purchased in a cost-effective manner.
- It may be beneficial for a review of ambient temperature storage of samples throughout the pathway from manufacture to delivery to the laboratory, to maximise the success of reliable samples.
- It may be beneficial for all sites to liaise with their local fire and rescue service (FRS) so that FRS can familiarise themselves with the site and provide fire safety advice.

The assurance of COVID-19 testing facilities: mobile and regional (fixed) testing site **(RB/32) (INQ000339827)**

1.134 HSIB was asked by DHSC to provide a review of the systems and processes in place at a sample of fixed and mobile testing facilities for COVID-19. This review allowed HSIB to gather evidence from observations across seven regional (fixed) and six mobile testing sites. All the mobile testing sites observed by HSIB were run by members of the British Army or Royal Navy (Royal Marines). The review aimed to:

- ensure that the regional (fixed) / mobile testing sites were being run efficiently and safely.
- gather data that could provide guidance and direction on areas that could be improved.
- gather data that could inform revisions to the current Standard Operating Procedure (SOP).

1.135 The review provided a series of observations aimed at helping to improve practice and safety at these sites. The observations made were:

- It may be beneficial to review the messages given to the public on coronavirus test booking site to manage expectations and ensure that it is obvious to members of the public that they will be required to conduct the test themselves. It may be beneficial to apply user centred design principles which is promoted by the government for the development of materials.
- Consideration should be given to developing a set of communication tools for staff to use to support the communication of instructions. These tools should support communication for the widest range of individuals possible. This should include sensory impairment, cognitive impairment, non-English speakers, and poor levels of literacy.
- It would be beneficial to review how appointment times are allocated to create a steady flow of attendees throughout the day.
- The instruction leaflets should reflect the procedure that is being used, learning the lessons that have been identified.
- It may be beneficial to create a more detailed video resource than currently available to explain the process expected at a self-test, through arriving on site, swabbing procedure to drop off of test kit. This could include what a site may look like and that there may be military personnel in uniform and full PPE.
- It may be beneficial to amend the standard operating procedure to incorporate the visual checking of completed tests prior to the sealing of bags, to ensure that all components have been completed and labelled correctly.
- The DHSC may like to consider removing the amber zone within the site model. All areas other than the green rest area would then be designated red areas with appropriate PPE. Using PPE, combined with social distancing, could enable staff to speak to attendees through a window rolled down by one to two inches (at all stages of 11 the process) allowing easier communication than via mobile phone, speeding up the process and leading to less assistance required during the self-sampling procedure.
- If mobile phones are kept as the main form of communication, it may be beneficial for staff at test sites who are in direct contact with attendees to have hands free equipment to allow them to perform all tasks required of them while maintaining efficient communications with attendees.
- The suitability of and requirement to wear PPE (eye protection, masks, and aprons) be reviewed with consideration to the environment and the tasks staff are required to perform.

- It would be beneficial to provide more suitable storage containers at each collection point, considering potential environmental conditions (such as heat and wind).
- The storage temperature of kits and completed tests should be monitored continuously throughout the day.
- It may be beneficial to have one type of testing kit, designed to ensure it was intuitive for the user.
- It would be beneficial for sites to receive feedback on their testing results to inform them on whether their procedures are working or if improvements need to be made in certain areas.
- Clear signage to mobile sites should be placed on main roads. This should be professional signage and include several signs in each possible direction.
- Local authorities should consider how traffic congestion might be avoided at mobile testing sites.
- Exit and entrance to mobile testing sites should be clearly marked and not rely on the normal carpark signs.
- The DHSC may like to consider removing the amber zone within the site model. All areas other than the green rest area would then be designated red areas with use of appropriate PPE.
- It would be beneficial for there to be a military leader who has experienced running an MTS to support all new incoming teams (on site) who are new to the process, ensuring continuity of process and lesson learned are transferred locally.
- It would be beneficial to have a 'check list' of key information points available to prompt staff at each stage of the process. This would be of benefit to inexperienced staff who are less familiar and experienced staff who may adopt their own individual style.
- There should be a daily team briefing led by the nominated organisation responsible for the site to include (but not limited to) site induction, site operation, PPE, fire safety, escalation of concerns and traffic management.
- Any new /modifications to testing operational models should be simulated and opportunities to identify hazards and use errors identified to inform process.
- It may be beneficial for a review of storage of samples throughout the pathway from manufacture to delivery to the laboratory, to maximise the success of positive samples.

Response to a critical oxygen incident at Watford General Hospital **(RB/33) (INQ000339828)**

1.136 HSIB was invited to contribute to an NHSE review into the circumstances that occurred at Watford General Hospital over the period of 1 April to 4 April 2020. A low oxygen pressure alarm alerted on the hospitals critical care unit. On review, this was found to be due to a technical issue with the oxygen gas supply system, whereby the supply pipe was experiencing significant icing-up due to the demands being placed on the system.

1.137 This led to a critical incident being declared that ran for 11 hours and 40 minutes. During this period some patients had to be transferred to other hospitals in the area and approximately 60 ambulances were diverted. The HSIB report included safety observations to help improve the future safety of oxygen systems during the COVID-19 pandemic. The observations were:

- the technical details shared initially with the Trust, in respect to the oxygen supply system, allowed them to develop an undeliverable COVID-19 enhancement plan.
- It would be beneficial for all oxygen delivery systems to have a mechanism to measure/monitor flow and consumption in real time. This would support efficient management of system loading across the Trust.
- The increase in icing invoked a significant increased loading on the engineering team resources which had not been anticipated. Additionally, this increased frequency in de-icing has not been articulated in the latest information form the manufacturers.
- Although the newer vaporisers are available, NHSE/DHSC are aware of many Trusts that are experiencing limitations to their ideal oxygen delivery systems and need to prioritise their installation.
- A System Safety Case would have defined system configuration, detailed system maximum capacities (per component) which could have informed a rapid assessment of options to increase capacity at an earlier point.

1.138 If there are specific investigation reports or further interactions that the Inquiry would like to learn about in more detail, we would be happy to assist in providing further information. Given the volume of routine interactions with healthcare organisations as part of our investigation work, it would be impractical for us to provide evidence of all these interactions at this point. However, we are happy to assist with any further specific questions the Inquiry may have about any interactions in this period, and it would be helpful to understand in more detail what may be required.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Interim Chief Executive Officer, HSSIB

Dated: 20/11/2023

Exhibits

RB/1 - **INQ000320212 -** House of Commons Public Administration Select Committee. (2014). Investigating clinical incidents in the NHS. Available online: https://publications.parliament.uk/pa/cm201415/cmselect/cmpubadm/886/886.pdf

RB/2 - **INQ000320219 -** Report of the Expert Advisory Group. (2016). Healthcare Safety Investigation Branch. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/522785/hsibreport.pdf

RB/3 - **INQ000320220 -** The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 [Withdrawn]. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1088077/Withdrawn_HSIB_directions.pdf

RB/4 - INQ000320221 - Department of Health. (2017). Safer maternity care. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662969/Safer_maternity_care_-_progress_and_next_steps.pdf

RB/5 - **INQ000320223 -** The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662969/Safer_maternity_care_-_progress_and_next_steps.pdf

RB/6 - **INQ000320224 -** The NHS England (Healthcare Safety Investigation Branch) Directions 2022. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1087677/30.6.22_National_directions_.pdf

RB/7 - INQ000320225 - The NHS England (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2022. Available online: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1087676/30.6.22_Maternity_directions_final.pdf

RB/8 - **INQ000320222** - Health and Care Act 2022. Available online: https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted

RB/9 - INQ000270026 - Healthcare Safety Investigation Branch. (2021). Oxygen issues during the COVID-19 pandemic. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Oxygen_issues_during_the_COVID-19_pandemic_Report_V11.pdf

RB/10 - INQ000320201 - Healthcare Safety Investigation Branch. (2021). Oxygen issues during the COVID-19 pandemic – Interim bulletin 1. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/hsib-first-interim-bulletin-oxygen-issues-during-the-COVID-19-pandemic.pdf

RB/11 - INQ000320202 - Healthcare Safety Investigation Branch. (2021). Oxygen issues during the COVID-19 pandemic – Interim bulletin 2. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/hsib-second-interim-bulletin-oxygen-issues-during-the-COVID-19-pandemic.pdf

RB/12 - INQ000320203 - Healthcare Safety Investigation Branch. (2021). Treating COVID-19 patients using Continuous Positive Airway Pressure (CPAP) outside of a critical care unit. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/Treating_COVID-19_patients_using_CPAP_outside_of_a_critical_care_unit_Report_V07.pdf

RB/13 - INQ000320204 - Healthcare Safety Investigation Branch. (2022). NHS 111's response to callers with Covid-19-related symptoms during the pandemic. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_NHS_111s_response_to_callers_with_COVID-19-related_symptoms_during_the_pa_7hyXbu4.pdf

RB/14 - INQ000320205 - Healthcare Safety Investigation Branch. (2020). National Learning Report - Early warning scores to detect deterioration in Covid-19 inpatients. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/hsib-national-intelligence-report-early-warning-scores.pdf

RB/15 - INQ000216631 - Healthcare Safety Investigation Branch. (2021). National Learning Report Maternal death: learning from maternal death investigations during the first wave of the COVID-19 pandemic. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Maternal_Death_Report_V13.pdf

RB/16 - INQ000176655 - Healthcare Safety Investigation Branch. (2021). National Learning Report: Intrapartum stillbirth - learning from maternity safety investigations that occurred during the COVID-19 pandemic, 1 April to 30 June 2020. Available online: https://hsib-

kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Intrapartum_Stillbirth_Report_web.pdf

RB/17 - **INQ000130588** Healthcare Safety Investigation Branch. (2020). COVID-19 transmission in hospitals: management of the risk – a prospective safety investigation. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/hsib-report-covid-19-transmission-hospitals.pdf

RB/18 - INQ000320210 - Healthcare Safety Investigation Branch. (2020). National Intelligence Report: Personal protective equipment (PPE) - care workers delivering homecare during the Covid-19. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/PPE_care_workers_delivering_homecare_during_the_Covid-19_response.pdf

RB/19 - INQ000320211 - Healthcare Safety Investigation Branch. (2021). Emergency response to heart attack. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Emergency_response_to_heart_attack_Report_V05.pdf

RB/20 - INQ000320213 - Healthcare Safety Investigation Branch. (2021). Surgical care of NHS patients in independent hospitals. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Surgical_care_of_NHS_patients_in_independent_hospitals_Report.pdf

RB/21 - INQ000320214 - Healthcare Safety Investigation Branch. (2023). Management of sickle cell crisis. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/hsib-report-management-of-sickle-cell-crisis.pdf

RB/22 - (INQ000320215) - Healthcare Safety Investigation Branch. (2023). Access to critical patient information at the bedside. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/hsib-report-access-to-critical-patient-information-at-the-bedside.pdf

RB/23 - INQ000320216 - Healthcare Safety Investigation Branch. (2021). National Learning Report Support for staff following patient safety incidents. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Support_for_staff_following_patient_safety_incidents_Report_V03_003.pdf

RB/24 - (INQ000320217) - Healthcare Safety Investigation Branch. (2021). Interim Bulletin: Harm caused by delays in transferring patients to the right place of care. Available online: https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/hsib-interim-report-harm-caused-by-delays-in-transferring-patients-to-the-righ_EPeMfuS.pdf

RB/25 - INQ000320218 - Healthcare Safety Investigation Branch. (2022). Blog: The impact of reorganising NHS services on patient safety. Available online: https://www.hsib.org.uk/news-and-events/the-impact-of-reorganising-nhs-services-on-patient-safety/

RB/26 - INQ000255847 - Healthcare Safety Investigation Branch – Internal: COVID-19 correspondence log.

RB/27- INQ000252915 - Healthcare Safety Investigation Branch – Internal: COVID-19 timeline of decisions, actions, and events.

RB/28 - INQ000256360 - Healthcare Safety Investigation Branch – Internal: E-mail from Murray Anderson-Wallace to Keith Conradi, 25 May 2022.

RB/29 - INQ000256361 - Healthcare Safety Investigation Branch – Internal: E-mail from Murray Anderson-Wallace to Dr Lesley Key and Deinniol Owens, 12 September 2022.

RB/30 - INQ000339825 - Healthcare Safety Investigation Branch. (2020). Summary of Nightingale hospital mobilisation visits. Internal report made available to NHS England.

RB/31 - INQ000339826 - Healthcare Safety Investigation Branch. (2020). Local testing site review. Internal report made available to the Department of Health and Social Care.

RB/32 - INQ000339827 - Healthcare Safety Investigation Branch. (2020). Mobile and regional (fixed) testing site review. Internal report made available to the Department of Health and Social Care.

RB/33 - INQ000339828 - Healthcare Safety Investigation Branch. (2020). Oxygen supply concerns at Watford General Hospital. Internal report made available to NHS England.