HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

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# FAILURES IN COMMUNICATION OR FOLLOW-UP OF UNEXPECTED SIGNIFICANT RADIOLOGICAL FINDINGS

I2018/015

Independent report by the
**Healthcare Safety Investigation Branch**

July 2019 Edition


HSIB
HEALTHCARE SAFETY
INVESTIGATION BRANCH

# PROVIDING FEEDBACK AND COMMENT ON HSIB REPORTS

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# ABOUT HSIB

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England.

Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or have the potential to cause harm to patients. The recommendations we make aim to improve healthcare systems and processes in order to reduce risk and improve safety.

Our organisation values independence, transparency, objectivity, expertise and learning for improvement.

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

# OUR INDEPENDENCE

We are funded by the Department of Health and Social Care and sponsored by NHS England and NHS Improvement, but we operate independently.

Following recommendations from a parliamentary select committee in August 2018, we expect that a Bill for establishing the Health Service Safety Investigations Body (HSSIB) will be introduced to Parliament soon. The Bill will establish our full statutory independence and enshrine our right to conduct national investigations under protected disclosure. This provision, commonly known as *'safe space'*, enables staff to share their experience of a patient safety incident without fear of reprisal. It does not prevent us from sharing important details with families, regulators or organisations about an incident or to address immediate risks to patient safety.

The Health Service Safety Investigations Bill will also establish our responsibility for NHS maternity investigations that meet specific criteria. Full information about the draft Bill is available on the **Department of Health and Social Care website**.

# A NOTE OF ACKNOWLEDGEMENT

The patient whose experience is central to this investigation is referred to as *'the patient'* throughout this report in accordance with her husband's wishes. HSIB would like to thank the patient's husband, whose information has helped inform the investigation and provided invaluable insight into the impact of such incidents.

We also thank the NHS staff, specialists and subject matter advisors[1] who have given their time to provide us with information and expertise which has contributed towards this report; and the stakeholder organisations, royal colleges, professional bodies who have supported the investigation.

[1] The subject matter advisors included five practising consultant radiologists, including:

- the Patient Safety Advisor to the Royal College of Radiologists
- the National Clinical Director for Diagnostics for NHS England
- the Medical Director for Professionsal Practice for Clinical Radiology at the Royal college of Radiologists
- the National Advisor for Imaging for NHS Improvement
- a consultant with experience of designing and implementing a results acknowledgement system, who was formerly an assessor for the Imaging Services Accreditation Scheme.

Subject matter advice on emergency department practice was provided by the Chair of the Royal College of Emergency Medicine's Safer Care Committee.

Subject matter expertise on lung cancer was provided by a practising respiratory consultant who is also the Clinical Director for Audit and Accreditation at the Royal College of Physicians and Chair of the British Thoracic Society Specialist Advisory Group.

# OUR INVESTIGATIONS

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

We undertake patient safety investigations through two programmes.

## NATIONAL INVESTIGATIONS

Our national investigations can encompass any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. We consider the requirement to investigate potential incidents or issues based on wide sources of information including that provided by healthcare organisations and our own research and analysis of NHS patient safety systems.

We decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, as well as the potential for learning to prevent future harm. We welcome information about patient safety concerns from the public, but we do not replace local investigations and cannot investigate on behalf of families, staff, organisations or regulators.

Our investigation reports identify opportunities for relevant organisations with power to make appropriate improvements though:

- *'Safety recommendations'* made with the specific intention of preventing future, similar events.
- *'Safety observations'* with suggested actions for wider learning and improvement.

Our reports also identify actions required during an investigation to immediately improve patient safety. Organisations subject to our safety recommendations are requested to respond to us within 90 days. These responses are published on our **investigation pages**.

Find out more in the **investigations** section.

## MATERNITY INVESTIGATIONS

From 1 April 2018, we became responsible for all patient safety investigations of maternity incidents occurring in the NHS which meet criteria for the **Each Baby Counts programme**.

The purpose of this programme is to achieve rapid learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. For these incidents HSIB's investigation replaces the local investigation, although the trust remains responsible for Duty of Candour and for referring the incident to us.

We work closely with parents and families, healthcare staff and organisations during an investigation. Our reports are provided directly to the families involved and to the trust. The trust is responsible for actioning any safety recommendations we make as a result of these investigations.

We have been operating in all trusts since 1 April 2019. Our longer-term aim is to make safety recommendations to national organisations for system-level improvements in maternity services. These will be based on common themes arising from our trust-level investigations.

Find out more in the **maternity investigations** section.

# EXECUTIVE SUMMARY

## The reference event

The patient, a 76-year-old woman, attended the emergency department (ED), with chest pain and shortness of breath.

Following tests in the ED, which included a chest X-ray, the patient was diagnosed as having had a heart attack. She was admitted to a cardiac ward and subsequently had a stent inserted in one of the blood vessels to her heart to improve blood flow. The patient was discharged home following the procedure and follow-up was arranged with the cardiac team.

The chest X-ray report was completed 12 days after the X-ray had been performed. The report identified a possible lung cancer. The report was sent to the ED because the chest X-ray had been requested from there. As the patient had been discharged from hospital several days earlier, a letter and email were sent to the cardiac team whose care she was under to inform them of the result. The letter was copied to the patient's general practitioner (GP). The letters were not received and, although the email arrived, the result was not acted upon.

Three months later, the patient went to see her GP. The GP documented symptoms of weight loss, cough, shortness of breath and left-sided chest pain. The GP accessed the tests taken during the patient's previous hospital admission and saw the chest X-ray report of a possible lung cancer. The GP requested a repeat chest X-ray which confirmed these findings. The patient was referred for an outpatient appointment with the respiratory team at the hospital for suspected lung cancer. At this appointment, tests including a CT scan were ordered.

Three days after the appointment with the respiratory team, the patient was admitted to hospital with increasing breathlessness. During this admission, the diagnosis of lung cancer was confirmed.
The patient became progressively more unwell and died just over two months later.

## The national investigation

Failures in communication or follow-up of unexpected significant radiological findings is a nationally recognised patient safety risk. HSIB contacted the hospital where the reference event occurred after it was reported as an incident on the national serious incident reporting database. Following initial information gathering and evaluation against the HSIB patient safety risk criteria (see section 3.2), the Chief Investigator authorised a national safety investigation. The investigation reviewed the processes for communication and follow-up of unexpected significant radiological findings to understand why such findings are not always received or acted upon. The factors that influence the communication of results were explored and opportunities to reduce the risk of this happening in future were identified.
The investigation paid particular attention to unexpected significant radiological findings from chest X-rays performed during a patient's stay in an ED. X-rays are the most common radiological examination and large volumes are requested from EDs. However, the conclusions of this investigation are applicable to the communication of radiological findings from other areas, and other types of diagnostic test results.

## Findings

- There is wide variation in practice in how unexpected significant radiological findings are communicated to clinicians. There is also considerable variation in how findings are acknowledged by clinicians, if they are at all. There is very little assurance that the actions indicated by the findings have been taken.

- Unexpected significant radiological findings may be communicated by telephone, electronic or paper-based systems, and involve a variety of policies and procedures. It is often a multi-step process, involving a number of individuals and information systems; this increases the risk of errors.

- Monitored acknowledgement of radiological findings is an important component of a reliable system and requires dedicated time and resource. Monitored acknowledgement is not in place in many trusts.

- Opening a report and generating a read receipt is an unreliable form of acknowledgement. A more robust risk control is for acknowledgement to be a separate, distinct action. That said, acknowledgement does not guarantee action has been, or will be, taken.
A system that provided assurance that necessary actions had been completed would best mitigate risk. Current IT infrastructure in many trusts means this is not feasible in the short term.

- There are often many steps before a patient is informed of an unexpected significant radiological finding. These steps provide opportunities for error.

- Inspection of trusts by the Care Quality Commission is limited in scope in relation to the communication and follow-up of radiological findings. Inspections do not look at whether a monitored acknowledgement system and other risk controls necessary for a reliable system are in place.

- There is no nationally agreed list of what constitutes an unexpected significant finding that should trigger an alert. Some trusts have developed lists to standardise when alerts should be triggered by radiologists and to create a common expectation for clinicians.

## HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATIONS

**Recommendation 2019/039:**
It is recommended that the Royal College of Radiologists, working with the Society and College of Radiographers and other relevant specialties through the Academy of Royal Medical Colleges, develops:

**1** principles upon which findings should be reported as *'unexpected significant', 'critical'* and *'urgent'*

**2** a simplified national framework for the coding of alerts on radiology reports

**3** a list of conditions for which an alert should always be triggered, where appropriate and feasible to do so.

**Recommendation 2019/040:**
It is recommended that NHS England and NHS Improvement's patient safety team takes steps to ensure providers are aware of the safety recommendations in this report and act to implement the key findings regarding risk controls such as a monitored acknowledgement system for critical, urgent and unexpected significant findings.

**Recommendation 2019/041:**
It is recommended that NHSX develops a method of digitally notifying patients of results. This should be used to inform patients of unexpected significant radiological findings after an agreed timeframe. It should be developed in conjunction with the Royal College of Radiologists. The notification system should be tested and evaluated.

**Recommendation 2018/042:**
It is recommended that the Care Quality Commission amends all appropriate core service frameworks to include risk controls identified in this report, to mitigate the risk of significant abnormal findings not being followed up.

## HSIB MAKES THE FOLLOWING SAFETY OBSERVATIONS

There is an established model of radiology departments requesting a CT scan for chest X-rays referred from GPs that show possible lung cancer. Two trusts are extending this to chest X-rays referred from the emergency department.

It would be beneficial for this practice to be evaluated.

**Observation to the Royal College of Radiologists:**
Given the likely wider use of artificial intelligence in the future, some standardisation of radiology reports may be required. It would be beneficial for this to be evaluated.

## SAFETY ACTIONS CARRIED OUT AND/OR IN PROGRESS

The Academy of Medical Royal Colleges has written a statement endorsing the need to ensure clinicians act on alerted radiological findings and that a monitored acknowledgement system is in place in all local organisations.

Whether this is a single centralised system or specialty-specific process is for local decision depending on the available infrastructure.

# CONTENTS

# 1 BACKGROUND

## 1.1 Communication of radiological findings

1.1.1 X-rays are one of the most common types of diagnostic examination; 22.9 million were carried out in the NHS in 2016/17 [1].

1.1.2 A radiologist is a doctor who is trained to interpret diagnostic images[2]. A radiographer is a registered healthcare professional trained to perform imaging examinations. When a patient has a radiological examination, a radiologist, or a radiographer who has undertaken training to enable them to report on examinations, will usually report on the images. The radiology report will summarise the findings and may make recommendations such as the need for further investigations. Sometimes images may be reported by a specialist doctor. This investigation focuses on the communication of reports from radiology departments.

1.1.3 When an image is described as having been *'reported'* it means the radiologist or radiographer has finalised the report and it is available for clinicians to review. It may also be sent directly to a clinician for action. It may be sent immediately by electronic means or take additional time if manual processes are used.

1.1.4 Depending on the requested urgency of the radiological examination and other factors, the radiology report may not be completed until some time after the examination. National reports have highlighted *'huge variation'* in reporting times [2]. A time gap between a patient's radiological examination and the completion of the radiology report means images may be reviewed by a non-specialist prior to the report. The reviewer may be the referring doctor or others involved in the patient's care and treatment. For example, the images will be reviewed by a doctor in the emergency department (ED) if the examination was requested there. This doctor will not usually have expert training in interpreting images and so may miss radiological findings, particularly if they are subtle or unusual. The expert opinion provided by the radiology report is the definitive interpretation.

1.1.5 When radiology reports are completed, the expectation is that those showing significant abnormal findings will be communicated to the referring clinician for them to take the appropriate action.

1.1.6 In 2007 the National Patient Safety Agency (NPSA) published a Safer Practice Notice [3] highlighting harm caused as a result of failure to act on radiological imaging reports. The Safer Practice Notice made recommendations to health professionals requesting imaging tests, radiology departments and medical and nursing directors. The recommendations included the need to develop *'safety net'* procedures for reports requiring *'particularly timely and reliable communication'*, such as when there are critical or unexpected significant abnormal findings.

1.1.7 The term *'fail-safe'* is used by the Royal College of Radiologists (RCR), and in much of the literature surrounding this safety issue, to describe safety net procedures. In safety-critical industries, *'fail-safe'* usually refers to processes which automatically identify and correct errors. However, when the term is used by the RCR, it refers to processes that contribute to, rather than assure, safety – that is, processes that help to ensure that a radiological finding has been seen by a relevant clinician.

1.1.8 In this report the term *'risk control'* rather than *'fail-safe'* is used to refer to such processes. This term better describes what is achieved by these processes, which is reductions in risk. The Australian Transport Safety Bureau's Safety Investigation Guidelines Manual defines risk controls as *'measures put in place to facilitate and assure safe performance of the operational components of the system'* [4]. It defines two types of risk control:

- preventive controls – measures put in place to reduce the likelihood of adverse events
- recovery controls – measures put in place to detect and correct adverse events [4].

[2] Non-radiologist doctors have the same initial undergraduate medical school and two years' postgraduate general medical experience as radiologists, but they do not have the formal five years of specialty training in radiology that radiologists undergo.

1.1.9 Informed by the NPSA Safer Practice Notice, the RCR suggested categories or clinical scenarios that would warrant risk controls to be in place. The suggested categories were:

- critical and urgent findings – where emergency action is required as soon as possible, or medical evaluation is required within 24 hours
- unexpected significant findings – defined as where the reporting radiologist feels the findings are important and an alert should be added to the normal communication method to ensure they are acted upon in a timely manner [5].

  In particular, findings may be unexpected when they are unrelated to the diagnosis made on the basis of the patient's presenting symptoms, for example, a patient presenting with an orthopaedic problem who has a chest X-ray which shows a possible lung cancer.

1.1.10 The RCR has published four standards documents regarding communication of results and risk controls since the NPSA Safer Practice Notice in 2007. Despite this, communication of critical, urgent or unexpected significant findings remains a problem [3]. The RCR's 2010 standards document detailed the requirements of a results acknowledgement system [6]. These requirements included the ability to record acknowledgement that the results have been read by an appropriate clinician.

1.1.11 In 2016, NHS England published Standards for the communication of patient diagnostic test results on discharge from hospital [7]. This document highlighted increasing contextual challenges regarding the communication and follow-up of test results. Challenges include:

- pressure to reduce inpatient length of stay, increasing the risk of tests not being reported before discharge
- increasing volume of requests for tests, which can contribute to information overload and communication breakdown
- increasing numbers of patients under the care of multiple specialist teams, which increases the risk of ambiguity about who is responsible for following up test results.

1.1.12 This investigation concentrated on *'unexpected significant'*[3] findings. Critical and urgent results, by their very nature, demand immediate communication (usually by a telephone call) so are at less risk of not being received [8]. Unexpected significant findings – such as possible cancers – do not require such immediate action so direct contact with the referrer, or clinician caring for the patient, is less likely. In addition, there is a particularly high risk that unexpected findings will not be followed up as the clinical team's focus is on the presenting issue or diagnosis [9].

1.1.13 A possible cancer is frequently reported as an unexpected significant finding [10].

1.1.14 This investigation focused on the communication of unexpected significant findings from X-rays and considered the unexpected finding of possible lung cancer as one example of how risk controls work in practice. Most cancers identified from X-rays are lung cancers from chest X-rays[4], as was the case in the reference event.

1.1.15 Lung cancer is the third most common cancer diagnosed in England, but accounts for the most deaths [11]. Estimated five-year survival rates (2010-2014) are among the lowest in Europe [11]. Because of the low survival rates, there has been a national focus on lung cancer resulting in changes to working practices. These offer potential for learning and elements may be adopted and adapted to suit other unexpected significant findings and local contexts.

## 1.2 Roles and responsibilities

1.2.1 The RCR [5] [6] states that radiologists' responsibilities include:

- ensuring reports are timely, clear and precise with the urgency for action clearly documented within the content of the report
- flagging a report which has urgent, critical or unexpected significant findings which he/she feels may not be acted upon in a timely manner
- verbally informing the referring clinician or member of the clinical team of an

[3] The term *'incidental'* findings is also used by clinicians and in published articles.
[4] Interview with radiology subject matter advisor.

unexpected acute finding which requires emergency clinical action

- being aware of, and adhering to, local alert policies if working as a teleradiologist[5].

Radiology departments' responsibilities include:

- defining and developing risk controls for the communication of critical, urgent and unexpected significant findings
- having a robust policy on how alerts will be communicated, notified and formally agreed with the referring teams
- ensuring the radiology information system (RIS) or other reporting application used is capable of communicating alerts electronically to hospital-wide radiology report reading and tracking systems such as PACS (picture archiving and communication system).

Referring clinicians' and their clinical teams' responsibilities include:

- reading and acting upon the result of every imaging test requested
- having an agreed process and policy on how to regularly access and read reports on imaging they have requested
- acting on all alerts in a timely manner
- keeping an audit trail of when these results are read and when they are acted upon
- carrying out regular audits to ensure they have read and acted upon all imaging requested.

Healthcare organisations' responsibilities include:

- defining and developing alert policies for the communication of critical, urgent and unexpected significant findings
- providing referring doctors with robust IT systems for electronic tracking, reading and acknowledgement of radiology reports
- having hospital-wide IT systems for tracking radiology reports which are capable of receiving and displaying alerts
- carrying out regular audits to ensure that radiology results are read and acted upon in a timely manner.

1.2.2 These responsibilities echo those in the NPSA's Safer Practice Notice [3]. The Notice also stated that referring health professionals should ensure *'safety net'* procedures were in place in case usual communication systems failed. This was noted to be particularly important in EDs and assessment areas.

1.2.3 The Safer Practice Notice recommended that radiology reports should ensure that critical findings are emphasised and obvious, and the degree of urgency for action by the referring health professional is clear.

1.2.4 The General Medical Council [12] and British Medical Association's [13] information on test results endorse the view that it is the responsibility of the referring clinician to read and act on results of tests they have ordered. The British Medical Association notes this may take the form of direct action or a transfer of responsibility to another clinician if there is clear instruction that the receiving clinician needs to take action.

1.2.5 The General Medical Council's guidance on delegation and referral [14] states that the transferring doctor should pass on to the healthcare professional involved *'the purpose of transferring care and/or the investigation, care or treatment the patient needs'* and *'check that the patient understands what information you will pass on and why'*.

1.2.6 In 2017, the Royal College of Emergency Medicine (RCEM) published a best practice guideline, Management of Radiology Results in the Emergency Department [15]. This states that within EDs, *'pragmatic issues exist with reviewing and actions resulting from investigations'*. The guideline recommends that EDs have a standard operating procedure to ensure a consistent approach to radiological results. When patients are admitted under the care of an inpatient specialty (clinical team with particular area of expertise), the guideline says follow-up of any abnormal radiological results should be by that team.

[5] The term teleradiology refers to the reporting of imaging examinations at a distance from where the examinations were performed, by reporters who are usually unknown to the referring doctors and local radiographers.

## 1.3 Harm caused by failures in communication or follow-up of radiological findings

1.3.1 Patient harm by failures in communication or follow-up of radiological findings is a long-standing and persistent problem. In 2007, the NPSA's Safer Practice Notice [3] drew attention to this issue. The Safer Practice Notice stated: *'The system for requesting radiology imaging tests and sending reports to the referring health professional is unreliable and has been proven to fail.'*

1.3.2 This issue is a concern for other countries too. A survey by the American College of Radiology in 2013 found that 23% of all radiologists were involved in at least one failed communication malpractice lawsuit [16]. Malpractice claims research identified that the second most common cause of litigation in America is failure to communicate radiological findings [17]. One American study found that doctors failed to acknowledge 36% of abnormal radiology results; 4% of these, many of which made reference to a possible cancer, were lost to follow-up [18]. The Joint Commission[6] made communication of critical test results a national patient safety goal [19].

1.3.3 The Safer Practice Notice described 22 serious incidents the NPSA had noted in the three years between November 2003 and May 2006 as a result of a failure to follow up imaging findings, most of which involved fatalities or significant long-term harm [3].

1.3.4 The Safer Practice Notice stated that in the 10 years up to May 2006, the NHS Litigation Authority (now NHS Resolution) identified 69 radiology cases on their database, some of which involved significant harm. Of the 662 radiology claims identified by NHS Resolution in the two years from April 2016, 24 were coded as failure to act on abnormal results. During the same period, over £2.5 million was paid out on settled claims where failure to act on abnormal results was listed as the main cause[7].

1.3.5 Despite the Safer Practice Notice in 2007, and four subsequent RCR publications regarding communication of radiological findings, serious harm continues to occur. Between 1 April 2017 and 14 May 2018 there were 41 serious incidents reported on the Strategic Executive Information System (StEIS) (the national serious incident database) involving a delayed lung cancer diagnosis as a result of radiological findings not being acted upon[8]. Thirteen (31.7%) related to imaging requested by the ED. HSIB reviewed key investigation findings on StEIS associated with treatment delays in 2017. In 27 incidents, informing the patient about unexpected radiological findings could have prevented serious harm.

1.3.6 In the UK, approximately 40% of patients with lung cancer are diagnosed following an emergency admission to hospital [20].

1.3.7 There are particular challenges with the communication and follow-up of results from the ED [21]. Given the frequent use of chest X-rays as a diagnostic tool, incidental findings of potential lung cancers are to be expected.

[6] The Joint Commission accredits and certifies health care organisations and programmes in the USA. Joint Commission accreditation and certification is recognised nationwide as a symbol of quality that reflects an organisation's commitment to meeting certain performance standards.

[7] The claims database was designed primarily as a claims management tool rather than for any other purposes. A claim may be multi-factorial and/or settled on a number of bases. NHS Resolution therefore advises that figures are treated with caution.

[8] The search looked for incidents that were categorised as *'Diagnostic incident including delay'* or *'Treatment delay'* and included the word *'lung'* as a keyword. This identified 58 incidents. Of these, 17 were excluded as they did not relate to communication or follow-up of radiological findings, leaving 41 incidents.


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# 2 THE REFERENCE EVENT

## 2.1 The patient's story

2.1.1 In the early hours of Saturday 15 July 2017, the patient (a 76-year-old woman) awoke with chest pain and shortness of breath. Her husband phoned 999 and she was taken to hospital by ambulance. The patient arrived in the emergency department (ED) at 07:40 hours and was assessed. Tests were requested including a chest X-ray and echocardiogram (ECG), a test used to check the heart's rhythm and electrical activity. The patient's symptoms and test results suggested she had had a heart attack and she was referred to the assessment suite for further assessment and admission to a ward.

2.1.2 At 10:18 hours a chest X-ray was performed. At 11:45 hours the patient was transferred to the assessment suite[9]. At 13:50 hours a junior doctor commented on the patient's chest X-ray in her medical records. The doctor documented *'lung fields clear'* which means no abnormality seen. At 14:00 hours a consultant reviewed the patient. The notes of this review did not refer to the X-ray. Details regarding the blood results and ECG findings were noted which supported the diagnosis of a heart attack. The patient was prescribed the standard treatment for a heart attack. She was also referred for further tests including an angiogram (a procedure used to check the health of blood vessels and how blood flows through them).

2.1.3 At 14:30 hours the patient was reviewed by the cardiology team and was transferred to a cardiology ward that afternoon. She remained on the cardiology ward for five days awaiting transfer to a neighbouring hospital (part of the same Trust) for an angiogram and angioplasty (a procedure to widen blocked or narrowed arteries). A further test to look at the internal parts of the heart using ultrasound (transthoracic echocardiograph) was carried out on 19 July.

2.1.4 The patient was transferred to the neighbouring hospital on 20 July and reviewed by the coronary care team that evening. The procedure (angiogram and angioplasty) was performed successfully the next morning. The patient was discharged that evening and a follow-up appointment was made for six weeks time. The discharge summary, sent to the patient's GP, did not refer to the chest X-ray taken in the ED and for which the radiology report was awaited.

2.1.5 On 27 July, six days after the patient was discharged home, the chest X-ray was formally reported by a radiologist. The radiology report stated:

*'Normal cardiopericardiac silhouette and mediastinal contour. Lungs are hyperinflated with features of COPD[10]. There is a 45mm opacity projected over the liver which may represent a right lung base mass.'*

In essence, the report indicates that the radiologist suspected a potential cancer in the lung.

2.1.6 This was an unexpected significant finding. In line with the radiology department's policy, the consultant radiologist emailed the radiology administration team to return the report to the ED for further action (see section 4.4). Later that day, the chest X-ray report was printed, taken to the ED and signed for by reception staff.

2.1.7 The following day (28 July) the ED consultant with responsibility for actioning unexpected significant findings reviewed the report. He established that the patient was admitted under the care of the cardiology team following her presentation at the ED. He emailed the chest X-ray findings to the consultant cardiologist who had been in charge of the patient's care. He also wrote a letter to this consultant, which was copied to the GP. The letter said:

*'This lady was seen in ED...on 15/07/17 then admitted to Ward 24 under your care for PCI[11] for an NSTEMI[12]. She has now been*

[9] The assessment suite looks after patients who require hospital admission. Patients are referred to the unit from the emergency department or their GP. They are seen by the medical and surgical on-call doctors before being admitted to a specific ward relevant to their condition, or another hospital or, if felt appropriate, discharged back to their home.

[10] COPD stands for chronic obstructive pulmonary disease. This is a lung disease characterised by obstruction of lung airflow that interferes with normal breathing.

[11] The combination of coronary angioplasty with insertion of a stent (a tube inserted into the artery to help blood flow) is usually referred to as percutaneous coronary intervention (PCI).

[12] NSTEMI stands for Non-ST-elevation myocardial infarction. It is a type of heart attack. Myocardial infarction is the medical term for a heart attack. ST refers to the ST segment, which is part of the measurement of electrical activity in the heart used to diagnose a heart attack.

*discharged home to be followed up in the Cardiology clinic. I have received a report for her admission CXR[13] which states there is a 45mm opacity over the liver which may represent a right lung base mass. It is unclear from powerchart[14] whether this was picked up on admission so I am letting you know so that it is followed up appropriately.'*

2.1.8 The letter was generated on the computer system. Normally, it would then be printed and sent to the recipient. It is not clear whether the letter was printed or lost at some later point. Neither the consultant cardiologist nor the GP received a copy of the letter. However, the email sent to the consultant cardiologist was opened by him but he does not recall reading it (see section 4.4).

2.1.9 Almost three months later, on 20 October, the patient went to her GP. Her husband recalls his wife's only symptom at this time being back pain. However, the GP documented symptoms of shortness of breath, a cough and left-sided chest pain. The GP reviewed the patient's test results from her July hospital admission and noted there was a chest X-ray from the ED which identified a possible lung cancer. The GP ordered a repeat X-ray which took place on the same day. The report identified a:

*'5cm opacity at the posterior aspect of the right lower lobe. This appears to have slightly increased in size since the previous radiograph dated 15/07/2017. Mild bilateral increase reticular opacification in both lungs which is similar to previous radiograph... [There is] an impression of a further 5cm lesion in the left upper lobe on the lateral radiograph. Overall appearance is concerning for a primary bronchogenic lesions. Urgent referral to respiratory physician and further correlation with CT is advised. Urgent report faxed to GP.'*

In essence, the X-ray confirmed the previous finding of a possible lung cancer on the right side of the lung which had slightly grown in size. The X-ray also identified possible cancer on the left side, which indicated that the original cancer may have spread.

2.1.10 The GP informed the patient and her husband of the latest chest X-ray findings on 23 October and made an urgent referral for a respiratory clinic appointment within two weeks, as is the national standard for suspected lung cancer.

2.1.11 On 24 October, the patient's GP wrote to the radiologist who reported the first chest X-ray performed on 15 July. In the letter the GP said:

*'I am writing to draw your attention to an abnormal chest x-ray report which may have been missed. This patient came to see me last week complaining of dyspnoea[15], chest pain and cough, her chest x-ray has shown opacities[16], suspicious of primary lung cancer. Looking at ICE[17], it appears she had a chest x-ray requested from A&E in late July, which was reported by yourself as showing a possible 45mm right lower lung mass. The patient was unaware of this, and it doesn't appear that any follow up was arranged. I have explained to the patient that her chest x-ray in July was abnormal, and that I will be writing to the hospital to see if they need to look into this further. I also plan to report it on SIRMS (our local incident reporting system) as a significant event. The patient has been referred to the 2WW[18] Respiratory clinic.'*

2.1.12 The following day, 25 October, the consultant radiologist responded to the GP's letter. In his response, he confirmed that he had reported the X-ray on 27 July and that the report indicated a possible lung cancer. He said that he had asked for the report to be fast tracked to the ED. The radiologist explained that from the electronic patient record he could see that the ED consultant had written to the cardiology consultant on 28 July. The radiologist explained that he could find no further documentation of events. The radiologist said that he had completed an incident report regarding the failure to follow up the result, to initiate an investigation into what had happened.

[13] CXR is an abbreviation for chest X-ray.
[14] Powerchart is the name of the electronic patient record system used in the Trust.
[15] Dyspnea is the medical term for difficult or laboured breathing.
[16] Opacities is the medical term for non-transparent areas on an X-ray. Most lung cancers show up on X-rays as a white-grey mass.
[17] ICE is the name of an electronic record system used by the Trust, to which the GP had access.
[18] 2WW stands for two-week wait. It is a national standard for patients referred by their GP with suspected cancer to be seen within two weeks by the relevant specialist clinician.

2.1.13 On 6 November, the patient was seen by a consultant respiratory physician for an outpatient appointment. At this appointment, the consultant documented symptoms of worsening pain over the left lower chest, shortness of breath, occasional dry cough and slow weight loss. The consultant's documented impression was that the patient had lung cancer and he made a referral for an urgent CT scan[19]. He planned to see the patient in a fortnight to discuss the results. The clinic letter to the GP mentions the chest X-ray performed on 15 July. This letter stated:

*'The chest X-ray is not straightforward. There is the impression of a lesion at the right lung base tucked behind the diaphragm, but on the lateral view this is not as obvious as I would expect it to be. There is probably a lesion posteriorly which may be pleural based. There is also some distortion of the left hilum and on the lateral an impression of a lesion just behind the hilum.'*

2.1.14 Three days later, on 9 November, the patient was admitted to hospital with increased shortness of breath. A chest X-ray was requested, which showed a large left-sided pleural effusion (excess fluid in the cavity around the lungs). A chest drain was inserted that night to withdraw some of the fluid and make it easier for the patient to breathe.

2.1.15 The following day, 10 November, the patient had a CT scan. This showed lung cancer in the right and left lungs. The patient was told of the findings later that day. She was also informed that given her state of health, treatment would be palliative[20].

2.1.16 The patient had some further procedures to help relieve her symptoms over the next two weeks and was discharged home on 24 November. She continued to deteriorate over the next two months and had a further admission to hospital and two outpatient appointments during this time.

2.1.17 The patient died at home on 31 January 2018.

## 2.2 Impact

2.2.1 The patient died in January 2018, prior to the commencement of HSIB's investigation. Her husband was contacted by the investigation to hear his recollections of events and experiences. He had cared for his wife throughout her deteriorating health and up until she died in their home.

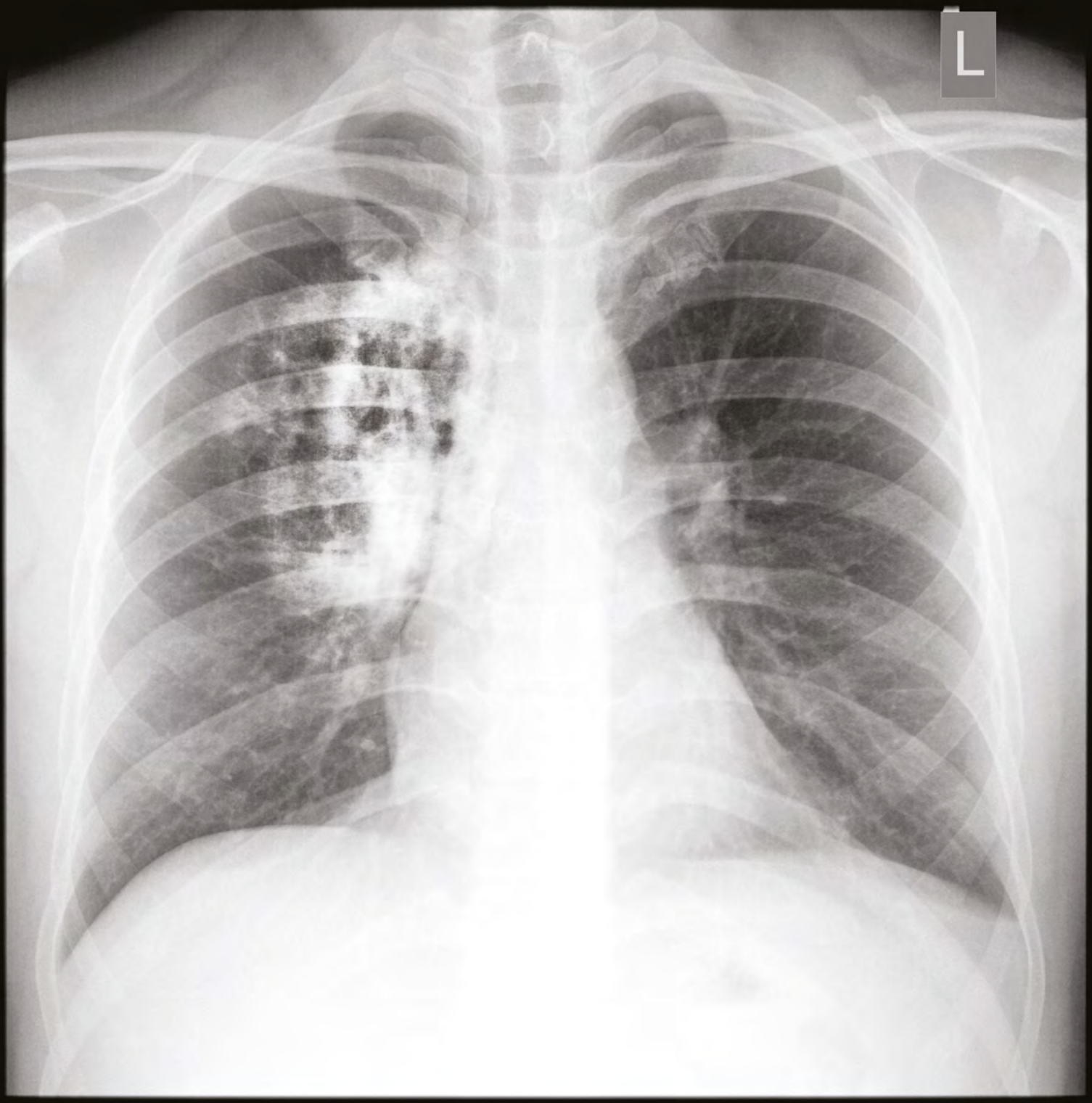
2.2.2 The patient's husband described his shock on learning of the chest X-ray report showing a potential lung cancer in July 2017 which had not been acted upon. He also described his surprise and concern at receiving a letter from the hospital in June 2018, five months after his wife's death, informing him of this and that an investigation was taking place into what had happened.

2.2.3 The patient's husband shared his sadness at the time lost as a result of his wife's X-ray not being acted upon. He spoke of regret that his wife had missed an opportunity for treatment which may have extended her life and their time together. He noted that his wife had had two previous episodes of cancer which had been successfully treated.

2.2.4 The Trust's internal investigation considered the impact of the delay on the patient's treatment options. The investigation report stated that as the patient had just had a heart attack, and her lungs were in poor condition due to COPD, it was unlikely that she would have been fit enough for curative treatment. The report concluded that:
*'An earlier palliative treatment intervention might have resulted in a better palliation [easing] of symptoms or offered a modest improvement in survival.'*

2.2.5 The patient's husband was very willing to be involved in the national investigation to help prevent the same thing *"happening to anybody else"*.

[19] Chest X-rays cannot give a definitive diagnosis of cancer because they often cannot distinguish between cancer and other conditions. Hence, a CT scan is requested to clarify diagnosis.
[20] Palliative treatment focuses on providing relief from the symptoms of a condition or disease, rather than curing it. Documentation in the patient's medical records of the conversations with her regarding her cancer diagnosis and treatment use this term.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# 3 INVOLVEMENT OF THE HEALTHCARE SAFETY INVESTIGATION BRANCH

## 3.1 Notification of reference event

3.1.1 Failures in communication or follow-up of radiological findings was identified by HSIB as a patient safety risk priority for investigation. The Trust where the reference event occurred was contacted after it reported the incident on the Strategic Executive Information System (StEIS) (the national serious incident database) and a scoping investigation was commenced. The purpose of scoping investigations is to explore the identified patient safety risk(s) and to consider the practicality and value of proceeding to a full investigation. The Trust welcomed HSIB's involvement and collaborated with information gathering.

## 3.2 Decision to investigate

3.2.1 Following scoping, the Chief Investigator authorised a full investigation based on HSIB's patient safety risk criteria:

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

3.2.2 Failures in communication or follow-up of significant radiological findings can be life-threatening. Incidents resulting in serious harm and death were highlighted by the National Patient Safety Agency (NPSA) in 2007 and recommendations made to address the issue but incidents continue to occur.

3.2.3 If radiological findings are of potential cancers, the earlier the diagnosis is made, the better the chance of successful treatment.

3.2.4 As well as the human cost, such incidents undermine patient confidence and trust in healthcare services. They also incur a financial burden and can seriously damage a hospital's reputation.

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

3.2.5 Imaging examinations include X-rays, CT scans, ultrasound and MRI. In the NHS both primary and secondary care services request these examinations. In 2016/17, more than 42 million examinations were carried out on NHS patients in England [1]. The large volume of imaging examinations adds to the imperative to ensure communication processes are reliable and that action in response to significant findings can be assured.

3.2.6 Data gathered from the national serious incident reporting system shows that despite published guidance and recommendations aimed at preventing these events, incidents continue to occur across all hospitals. Between 1 April 2017 and 14 May 2018 there were 41 serious incidents reported on StEIS involving a delayed lung cancer diagnosis as a result of radiological findings that were not acted upon.

3.2.7 Despite the recommendations made in 2007 by NPSA [3] and standards published since by the Royal College of Radiologists (RCR), communication and follow-up of significant radiological results has persisted as a patient safety risk.

3.2.8 There are contextual challenges regarding the communication and follow-up of test results. For example, pressure to reduce inpatient length of stay increases the risk of tests not being reported before discharge; the increasing number of patients under the care of multiple specialist teams increases the risk of ambiguity about responsibility for the follow-up of test results [7].

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

3.2.9 Over the last 10 years the NPSA and RCR have published a number of recommendations and standards to address this risk. The risk has remained, suggesting there are complexities associated with implementing the recommendations that need to be understood and acknowledged.

3.2.10 Initial information gathered by the investigation identified that different processes have emerged and evolved in different organisations to address the risk. There may be opportunities to share learning to positively influence processes and practices across organisations.

## 3.3 Terms of reference

After the scoping investigation, the following terms of reference for the full investigation were agreed:

- to understand the factors that impact upon the communication and follow-up of unexpected significant radiological findings, such as the IT systems in place and administrative resource provided
- to look at the variation in practice in how unexpected significant findings are communicated and follow-up assured
- to share learning from organisations that have implemented systems and processes to make the communication and follow-up of unexpected significant radiological findings more reliable
- to make safety recommendations to reduce the risk of failures in communication or follow-up of unexpected significant findings.

## 3.4 Evidence gathering and methodology

**Evidence**

3.4.1 Evidence gathered in this investigation included:

- a review of the patient's clinical records, Trust policies, procedures and practice regarding management of radiological results
- interview and telephone conversations with the patient's husband
- interviews with eight staff at the Trust where the reference event occurred
- interview with the patient's GP
- a review of the Trust's internal serious incident investigation report
- a search of StEIS for incidents occurring between 1 April 2017 and 14 May 2018 involving failures in communication or follow-up of radiological findings that resulted in a delay in lung cancer diagnosis. A review of key investigation findings on StEIS associated with treatment delays in 2017 was performed
- an information request to NHS Resolution regarding claims between 1 April 2016 and 31 March 2018 that specified failure to act on abnormal radiological results as the main cause for the claim
- a review of literature relevant to the safety ris.
- interviews, telephone calls and email correspondence with relevant national organisations and subject matter advisors, both clinical and non-clinical, regarding the communication and follow-up of significant radiological findings and possible improvements to reduce the safety risk to patients
- a patient survey, organised through the Academy of Medical Royal Colleges, to gain a patient perspective on potential alternative ways to communicate unexpected significant findings
- a meeting with representatives of medical royal colleges to gain their insights regarding failures in communication or follow-up of radiological findings
- visits to three trusts to observe their risk controls in action and a visit to a fourth trust to hear about its plan to request a CT scan, direct from radiology, for all X-rays identifying possible lung cancer.

**Methodology**

3.4.2 HSIB uses a standard methodology in all its investigations which may be supplemented by additional tools specific to the event under investigation. The standard methodology is as follows:

- gather all relevant evidence
- establish the factual circumstances leading up to the reference event
- analyse the evidence

- Identify the most significant safety factors and safety issues contributing to the safety risk being investigated.
- A safety factor *'is an event or condition that increases safety risk'*.
- A safety issue is a safety factor that *'is a characteristic of an organisation or a system, rather than a characteristic of a specific individual, or...environment at a specific point in time. Safety issues will usually refer to problems with...risk controls'* [4].
- Identify which safety factors are contributory to the reference event.
- Identify which safety issues are likely to contribute to future, similar events, nationally. These inform the wider investigation (see section 5).
- Make safety recommendations and safety observations to reduce identified safety risks.

3.4.3 A process map was drawn to identify the opportunities for error in the communication pathway between an unexpected significant finding being reported and it being acted upon. The process mapping exercise was also used to identify risk controls and influencing factors such as the local working conditions, organisational influences and regulatory context.

3.4.4 The Australian Transport Safety Bureau's model of analysis for safety investigations [4] was used to facilitate understanding of the event and inform the investigation.

# 4 FINDINGS AND ANALYSIS AT THE HOSPITAL WHERE THE REFERENCE EVENT OCCURRED

## 4.1 Missed diagnosis of possible lung cancer on chest X-ray

4.1.1 The first documentation regarding the patient's chest X-ray was at 13:50 hours on 15 July 2017. A junior doctor on the assessment suite wrote on the patient's medical records *'lung fields clear'*, that is, no abnormality seen.

4.1.2 The consultant head of the emergency department (ED) and the oncology consultant leading the Trust's internal investigation reviewed the X-ray after the incident came to light. They told the investigation that they were not surprised that the mass that indicated possible lung cancer was missed. This was because of the position of the mass behind the diaphragm, which would make it more difficult for a non-specialist to detect.

4.1.3 The head of the ED thought the doctor who requested the X-ray would also have reviewed it, although there is no documentary evidence to reflect this. If so, this doctor also missed the abnormality.

4.1.4 The consultant cardiologist who carried out the patient's angioplasty did not review her chest X-ray, as chest X-rays do not form part of the tests needed for angioplasty.

4.1.5 The very experienced consultant respiratory physician commented in his clinic letter of 6 November that the patient's X-ray was *'not straightforward'*.

**Summary**

4.1.6 Doctors caring for patients will often review X-rays prior to the formal radiology report. However, they do not have the expertise of radiology staff and may miss significant findings. This is a known safety issue and contributed to the reference event. The formal radiology report is, therefore, an important risk control.

4.1.7 The possible lung cancer on the patient's chest X-ray was not easy to identify because of its position behind the diaphragm. This was a contributory safety factor.

## 4.2 Wording of chest X-ray report

4.2.1 There are national standards published by the Royal College of Radiologists (RCR) that include guidance regarding the language and content of radiology reports. At the time of the reference event[21] the standards stated:

*'Radiologists should ensure that the reports are timely, clear and precise, and the urgency for action is clearly documented within the content of the report. Radiologists should clearly document advice on further management or action, where appropriate.[22]' [5]*

The standards also suggested that radiological results which, in the reporter's opinion require an alert, are reported in two categories:

- critical and urgent findings – when emergency action is required as soon as possible, or medical evaluation is required within 24 hours
- unexpected significant findings – cases where the reporting radiologist has concerns that the findings are significant for the patient and an alert is added to the normal communication method to ensure they are acted upon in a timely manner.

4.2.2 The Trust's policy, entitled Radiology Reporting Arrangements (November 2015), reflects much of the national guidance regarding content of reports. It states:

*'The report should be accurate, explicit, understandable, informative and relevant to the clinical findings…the report may include suggestions for further investigation or future management.'*

The Trust's radiology service does not currently use the critical, urgent and unexpected significant categories. The clinical director for radiology informed the investigation that it is planning to introduce these along with other changes in the communication of results (see section 4.5).

[21] In March 2018, after the reference event, further guidance on the reporting of imaging investigations was published by the Royal College of Radiologists [31].
[22] These were the standards at the time of the reference event. The Royal College of Radiologists published updated standards in March 2018.

4.2.3 In the reference event, the radiologist's report identified the possible lung cancer: '*There is a 45mm opacity projected over the liver which may represent a right lung base mass.*' The report did not include advice for the referrer on next steps or the urgency of the action needed. The Trust's clinical director for radiology told the investigation that while the action required could have been included or more clearly stated in the report, he doubted whether any referrer reading the result would not know what action to take.

4.2.4 Three of the radiology subject matter advisors (SMAs) were asked their opinion of the wording of the report. They said that a report of a possible lung cancer would usually include advice on action required. However, they noted that the finding was clearly stated and were in agreement that the important point was that the Trust's risk controls were activated, which they were. The report was returned to the ED within one day of being reported, in line with the Trust's radiology policy.

**Summary**

4.2.5 The Trust's radiology service procedures differed from the national standards in place at that time by not using critical, urgent or unexpected significant finding categories on radiology reports.

4.2.6 The radiologist's report did not include advice on next steps, but it triggered the Trust's risk controls and was successfully communicated to an ED consultant for action. The ED consultant wrote a letter to, and emailed, the cardiologist whose care the patient was under. There is no evidence that the wording of the report was a contributory safety factor to the lack of follow-up. However, it is a potential safety issue (see section 5.3a).

## 4.3 Delay in reporting of chest X-ray

4.3.1 In 2016, the Royal College of Emergency Medicine (RCEM) published best practice guidance entitled Management of Radiology Results in the Emergency Department [15]. The guidance states that: *'Emergency departments should have all their radiological investigations reviewed within a time frame of 48 hours of the request by either a radiologist or reporting radiographer.'*

4.3.2 The standards published by the RCR do not propose a timeframe in which radiology findings should be reported.

4.3.3 The Care Quality Commission (CQC) review of radiology reporting found *'huge variation in reporting times'*. In its recommendations, the CQC said the National Imaging Optimisation Delivery Board should advise on national standards for report turnaround times, so that trusts can monitor and benchmark their performance [2].

4.3.4 The Trust's policy, Radiology Reporting Arrangements, does not include any timescales for reporting of images. It does mention time in relation to the notification of results, stating that in cases of clinical urgency the referrer should be phoned as soon as possible and informed within one day for suspected cancer.

4.3.5 The patient's chest X-ray took 12 days to be reported, by which time her care had transferred from the ED to the cardiology team. The patient had been moved to the assessment suite, then to a cardiology ward, and then transferred to a neighbouring hospital for angioplasty and finally had been discharged home.

4.3.6 During interviews with Trust staff, the investigation was informed that 12 days to report on a chest X-ray was significantly longer than usual. The consultant head of the ED said that "on the whole" X-rays were reported in 48 hours.

4.3.7 The opinion of the clinical director for radiology was that that the delay was due to a recent change in the radiology IT system. There had been problems with the stability and speed of the system, which had taken several months to resolve. A substantial backlog had built up which took several months to clear. The clinical director confirmed that during this period reporting times did significantly increase, but he believed that X-rays from the ED were usually reported in three to five days.

4.3.8 The CQC report [2] and the radiology SMAs highlighted the importance of timely reports to minimise risk.

**Summary**

4.3.9 There is a lack of national standards regarding reporting times. The CQC has recommended that standards be set following its national review of radiology reporting.

4.3.10 There was a significant delay in reporting the patient's chest X-ray due to a backlog created by a change in IT systems. This was identified as a contributory safety factor to the event.

4.3.11 The investigation found the consensus of clinical opinion was that if the X-ray had been reported while the patient was still in hospital, the failure to follow up may have been avoided. It cannot be known if this would have been the case. Delayed reporting is a recognised safety issue.

## 4.4 Failures in communication and acknowledgement of the chest X-ray report

4.4.1 In 2016, the RCR published standards for the communication of radiological reports and alert notification [5]. The standards state it is the responsibility of the radiologist to *'flag reports when they feel a fail-safe alert is required'* and the responsibility of the organisation to '*ensure appropriate... fail-safe systems are in place'.* IT systems are seen as central to these risk controls to ensure there is *'a permanent audit trail of who has read the report and who has taken responsibility for acting upon it'.* This means having an acknowledgement system in place that provides confirmation that findings have been read and acted upon. The RCR provided specific standards on acknowledgement systems in 2010 [6].

4.4.2 The Trust's policy, Radiology Reporting Arrangements, includes a section on communication of results. It details when telephone communication is required (life-threatening findings) and when email may be used (urgent findings). The policy does not describe the process in place for returning results, such as unexpected significant findings, to the ED. However, the process seemed to be well-understood by the radiology and ED staff interviewed by the investigation. This process was described as long-standing custom and practice and is described below.

4.4.3 The Trust's radiology policy states: *'We are...unable to confirm that results have been received by the referrer, or have been acted upon.'* This is because the Trust did not operate a monitored results acknowledgement system at that time.

4.4.4 The RCEM's best practice guideline, Management of Radiology Results in the Emergency Department [15], states: *'For patients who are admitted under a non-ED team, then the responsibility for reviewing and subsequent actions arising from radiology reports should be clearly handed over to the team caring for that patient.'*

4.4.5 The evidence gathered indicates that the Trust's ED follows national guidance. The investigation found that only if the patient is discharged from hospital by the ED will the ED take responsibility for actions arising from the radiology report. In the scenario of a radiology report showing an unexpected finding of possible lung cancer, the ED will organise the next steps (request a CT scan, refer to the respiratory team and inform the patient). If the patient is admitted under the care of a specialty, the ED will pass the responsibility for these actions on to that clinical team. The communication may be by telephone, email or letter. There is no process in place to confirm that the communication is received or acted upon.

4.4.6 The Trust's radiology risk control process for unexpected significant findings is known internally as the *'bouncer'* process. This reflects the fact that results are bounced back to the referrer. The process was observed by the investigation and is as follows:

- The radiologist or reporting radiographer notifies the radiology administration team, either by email, or by putting a hard copy of the report in the Return to Accident Room (RTAR) tray in the radiology administration office.

- An administrator prints off radiology reports notified by email and documents patient details in the RTAR bouncer book.
- An administrator physically delivers the reports to the ED reception once or twice per day (09:00 hours and 16:00 hours). The ED receptionist puts the reports in a results tray and signs the bouncer book to acknowledge receipt of the reports and provide an audit trail.
- The ED consultant assigned to results management reviews and actions the reports.

4.4.7 In the reference event, the patient's chest X-ray report followed this process. The process as observed provided multiple opportunities for errors and for information not to be communicated (for example, for printed reports to be mislaid or not printed off, for a member of administration staff to forget to write in the bouncer book and so on).

4.4.8 The ED consultant who reviewed the radiology report established that the patient had been admitted under cardiology. She had undergone an angioplasty and had been discharged with a follow-up cardiology appointment in six weeks' time. The ED consultant therefore wrote a letter to the cardiology consultant in charge of the patient's care detailing the radiologist's findings. The letter was written electronically (and can be seen on the IT system) with the expectation it would be printed and sent in the internal post. It was also copied to the patient's GP to be sent by external post. The ED consultant also sent an email to the consultant cardiologist outlining the findings of the radiologist's report.

4.4.9 The ED, therefore, followed the Trust's process. However, the intended outcome was not achieved. Neither the consultant cardiologist nor the GP received the letter. It was not possible to identify whether the letters were ever printed, or if they were printed and not sent, or if they were sent but lost at a subsequent point.

4.4.10 The email sent by the ED was opened by the consultant cardiologist but he could not recall reading the contents so could not explain what had happened. He told the investigation that he had just returned from three weeks' annual leave to hundreds of emails. He estimated receiving 50 to 100 emails a day, so up to 700 a week. The consultant was also on call for emergency cardiac procedures during the week of his return.

4.4.11 The Trust does not have a system in place that requires acknowledgement of radiological findings by the clinician responsible for acting on those results. This event demonstrates the importance of that acknowledgement being by the clinician actioning the next steps required for the patient. This may not be the referrer of the test, to whom results are returned, and whose action may simply be to hand over the results to another team, as in this case.

4.4.12 There was no requirement for the cardiology consultant to acknowledge the findings. Thus, there was no recovery risk control (see paragraph 1.1.8) to flag up that he had not acted on the result. Given that humans are fallible, clinicians will, inevitably, have occasional lapses in attention causing them to forget about, overlook, or fail to register significant radiological findings. Therefore, systems need to be in place to mitigate this risk. A monitored acknowledgement system can provide an effective, reliable recovery risk control. However, to be reliable, acknowledgement of findings must be by the clinician caring for the patient or the person responsible for initiating the next steps.

4.4.13 When responsibility for actioning unexpected significant findings is handed over to another team so is the responsibility for informing the patient or carer of the results. If the information is not received or acted upon by that team, the patient will not be informed. This suggests there may be benefits in informing the patient independently (see section 5.3i).

**Summary**

4.4.14 The actions taken following the unexpected significant finding on the patient's X-ray followed the Trust's risk control process and the finding was successfully communicated to the test referrer. This process was not, therefore, a contributory safety factor to this event. However, the process itself was noted to have multiple opportunities for error. Preventive risk controls were identified as a potential safety issue.

4.4.15 The X-ray report was received by the ED. In accordance with national and local guidance, the ED handed it on to the cardiology consultant whose care the patient was under while in hospital. The added complexity involved when the referring clinician is not the one with the responsibility for actioning next steps was identified as a contributory safety factor to the event and a safety issue.

4.4.16 The consultant with the responsibility for actioning next steps was on call and had returned from a period of leave to a high number of emails. This high workload was identified as a contributory safety factor to the event. High workload is a recognised safety issue in many events; however the associated risk can be reduced by establishing appropriate risk controls.

4.4.17 The Trust did not operate a monitored acknowledgment system. Such a recovery risk control could have mitigated against human error. The lack of a recovery risk control was identified as a contributory factor to the event and a safety issue.

4.4.18 Responsibility for actioning results includes informing the patient. If results are not received by the relevant clinician or team, the patient will not know their results. There are likely to be benefits in informing the patient at an earlier point. Not informing the patient of their result was identified as a contributory safety factor to the event and a safety issue (see section 5.3i).

## 4.5 Actions resulting from the Trust's internal investigation

4.5.1 The Trust's internal investigation resulted in several safety actions to reduce the risk of recurrence. The key actions were:

**Safety Action 1**
Continue work already in progress to develop an electronic results acknowledgement system in accordance with Royal College of Radiologists standards.

**Safety Action 2**
A Cancer Imaging and Pathway Co-ordinator was appointed by the Trust.

**Safety Action 3**
Update the radiology reporting arrangements guidelines to include how unexpected significant findings (and other abnormal results) are communicated to the emergency department.

**Safety Action 4**
Write a local guideline on management of radiology results in the emergency department, based on the Royal College of Emergency Medicine guidance.

4.5.2 The Trust's development of an electronic results acknowledgment system is part of a larger improvement initiative, led by the Trust's clinical director for safety and quality, regarding the communication and follow-up of all results.

4.5.3 The clinical director told the investigation that the initiative had involved a review of incidents in 2017 to identify themes and risk controls to address these. The practicalities of the processes, and planned monitoring, were described to the investigation. The processes reflected RCR standards and some of the examples seen by the investigation in practice (see Appendix).

4.5.4 The clinical director explained that implementation had been slower than anticipated due to changes in IT systems to enable the Trust to become paperless. He estimated that the acknowledgement system would be in place by August 2019.

# 5 ANALYSIS AND FINDINGS FROM THE WIDER INVESTIGATION

This section considers the investigation's findings in relation to the identified safety issues with regard to the communication and follow-up of significant radiological findings within secondary care[23].

This investigation focused on unexpected significant radiological findings. These findings, as well as critical and urgent findings, form the group subject to additional risk controls. It is recognised that there are challenges with communication and follow-up of other radiological findings, but they are outside the scope of this report. Some of the findings will, however, be applicable to all radiological and other diagnostic test results.

## 5.1 Radiology report turnaround time

5.1.1 In the reference event, the chest X-ray which had been requested from the emergency department (ED) was reported 12 days after the examination was performed and after the patient had been discharged from hospital.

5.1.2 The radiology subject matter advisors (SMAs) who contributed to this investigation all highlighted the role of timely reports to minimise the risk of findings not being acted upon. They were in agreement that the ideal process is for imaging taken in the ED to be reported on straight away – known as *'hot reporting'* – so that the results are available to guide diagnosis and treatment while the patient is in the ED. As well as supporting diagnosis and treatment, hot reporting avoids all the communication steps (and resulting opportunities for error) involved when a radiology report is issued after the patient has been admitted to, or discharged from, hospital.

5.1.3 While hot reporting is the recognised ideal, SMAs pointed out the increased resource requirements needed to deliver it. Given the shortage of radiologists and reporting radiographers to meet current demand[24], hot reporting was not thought a realistic option in most UK imaging departments. One of the radiology SMAs suggested that technological advances in radiology, such as the use of artificial intelligence, may free up radiology capacity in the future or at least aid identification and prioritisation of abnormal studies. That said, the SMA thought the likely influence of these advances would be to free up capacity for radiologists to work on the increasing number of more complex imaging studies rather than, say, hot reporting.

5.1.4 In 2008 the National Imaging Clinical Advisory Group published best practice guidance on radiology reporting times [22]. This proposed that urgent imaging referrals are reviewed within 30 minutes and review of ED and inpatient imaging takes place the same day[25]. The Care Quality Commission's (CQC's) national review of radiology reporting within the NHS in England found a wide range of expected turnaround times for radiology reports within trusts. It also identified some trusts that were not routinely providing reports on all chest X-rays. Turnaround time for reporting was shortest for urgent referrals and ED patients. For EDs, the expected turnaround time varied from one hour to two working days. For X-rays requested by departments other than EDs, the turnaround time varied – at one trust it was up to three weeks [2].

5.1.5 Variation in reporting times is reflected in NHS England's statistics. In its 2016/17 diagnostic imaging statistical report, the average period from date of test to test report for chest X-rays requested by EDs varied between trusts and other healthcare providers from up to one day to over 10 days [1].

5.1.6 The CQC review recommended that national standards are set for report turnaround times. The recommendations include the need for frameworks to be developed to support trusts in managing turnaround times [2].

5.1.7 It is a legal requirement that all radiology examinations involving ionising radiation[26] should have a documented report [23].

5.1.8 The CQC review noted that one way in which trusts manage the reporting workload

[23] NHS care is provided in two main ways: primary care (GPs and community services) and secondary care (hospitals and specialists).
[24] The Care Quality Commission's national review of radiology reporting within the NHS in England [2] found an average vacancy rate across responding trusts of 14%.
[25] These timeframes are currently under review.
[26] X-rays, CT scans and nuclear medicine are examples of imaging using ionising radiation.

is by allowing auto-reporting[27] (imaging reported by non-imaging staff) in certain circumstances. For example, this might be used for images for patients attending follow-up appointments in fracture clinics where the initial X-ray has been reported by a radiologist or a reporting radiographer, and subsequent images are to assess healing.

5.1.9 The CQC review pointed out the risk of harm to patients from auto-reporting, stating: *'this is especially a risk for chest and abdomen X-rays, where general medical training does not constitute adequate training. Non-radiology staff may be able to spot large cancerous masses and other obvious pathologies, but may miss smaller, more subtle cancers that are more likely to respond positively to treatment.'* [2]

5.1.10 The reference event demonstrated the opportunities for error when reports are completed after patients are discharged from hospital or have moved between teams. As described in section 5.2 there are particular challenges for the ED. The shorter the reporting timeframe, the shorter the patient journey is likely to be, and the fewer teams involved. Reducing reporting times, the length of the patient journey, and the number of teams involved in turn reduces the opportunity for error created by communication between teams.

**Summary**

5.1.11 Immediate or *'hot'* reporting of imaging requested by EDs is the ideal from a patient safety perspective. This would mean findings were available in real time to guide diagnosis and treatment. The current shortage of radiologists and reporting radiographers make hot reporting an unlikely solution in the immediate future.

5.1.12 There is variation in turnaround times for radiology reporting between healthcare providers. The CQC review recommended national standards for reporting turnaround times. The standards, which at the time of writing are in the process of being agreed, will enable healthcare providers to benchmark and monitor performance.

5.1.13 Reducing reporting turnaround time will help mitigate the risk of significant findings not being acted upon by reducing the opportunity for error created by communication between teams.

## 5.2 Clinical responsibility for abnormal radiological findings

5.2.1 Follow-up of radiological findings requires clarity about who is responsible for acting on the results. The answer is not straightforward, and the complexity is a safety issue which increases the patient safety risk.

5.2.2 The National Patient Safety Agency's (NPSA) Safer Practice Notice [3] and other guidance [13] [14] [15] state that it is the responsibility of the clinician requesting the imaging test to ensure the results are '*viewed and acted upon accordingly'* [3]. The guidance also states that this responsibility may be delegated to another team. This means there can be multiple handovers before the required action for the patient is effected.

5.2.3 The potential for multiple handovers, and the opportunity for error this creates, is illustrated by the scenario of a chest X-ray ordered by the ED and reported as showing a possible lung cancer. The next steps on the diagnostic pathway are typically a CT scan and chest clinic appointment.

5.2.4 The Chair of the Safer Care Committee for the Royal College of Emergency Medicine (RCEM) explained the different possibilities if the patient is still in the ED or has been discharged by the ED. The possibilities depended on the certainty of the report. If the radiology report stated findings of a mass or potential malignancy, the ED in the Chair's Trust will inform the patient and then refer for a chest clinic appointment within two weeks as per national guidance. If the wording of the report was "looser" in terms of the significance of the findings, the Chair said handover may be to the CT booking team to book a CT scan or handover could be back to the GP to follow up.

5.2.5 The Chair of the Safer Care Committee for RCEM messaged ED leads across UK to ask

[27] Auto-reporting involves sending a standard response automatically to referrers, informing them that the examination will not receive a formal radiology report and that it is their responsibility to provide one.

how they managed a chest X-ray showing a possible lung cancer. She estimated the distribution list included about 120 leads and she received 29 responses:

- 21 said that in the scenario of possible lung cancer their ED organised the next steps (CT scan, chest clinic appointment and informing the patient)
- four said that either radiology organised the next steps or it would be handed over to the respiratory team to organise
- four said a mix of the above.

5.2.6 If the patient has been admitted under the care of a specialty team, the guidance [13] [14] [15] states that the ED may inform that team of the result and hand over responsibility for review and subsequent actions to them. That specialty will then hand over to the CT booking and respiratory team.

5.2.7 If the patient has been admitted under a specialty and then transferred to the care of another team, the ED will hand over to the team currently caring for the patient if known. Otherwise, the ED will hand over to the first admitting team who will then hand over to the second team, who will then hand over to the CT booking team and respiratory team. It is not uncommon for this chain to be longer as patients may be under the care of multiple teams as a result of having multiple health problems.

5.2.8 All these handovers may be by telephone, email, letter or fax. Only handover by telephone is certain to be acknowledged but may not provide an auditable record.

5.2.9 The principle of acting on unexpected findings if the patient was solely under the care of an ED and handover of responsibility if the patient was admitted under another specialty was common to all EDs. However, the details of how this worked in practice varied.

5.2.10 The process depended to a large extent on the capability of the IT system and whether the radiology reports were linked to, or within, an electronic patient record (EPR); if so, a doctor can review them directly. If not, reports may be sent (either electronically or in hard copy) to an ED secretary or member of the administration staff who would then attach it to the ED paper records or ascertain key details (such as who saw the patient and discharge information) ready for an ED doctor to review. This latter process involves multiple steps and therefore multiple opportunities for error. These steps are before the process of handovers described above take place. Examples of different processes are detailed in Appendix.

5.2.11 Handover of responsibility for acting on radiological findings to the team responsible for the patient's care is in accordance with RCEM guidance [15] and seems appropriate and pragmatic. The guidance describes the particular challenges for EDs in following up such results:

- Few EDs have outpatient facilities to see patients for follow-up.
- ED clinicians do not have a prior and ongoing relationship with the patient, which will affect communication and may affect clinical management, as the patient will need information and involvement in their ongoing care.
- EDs often lack full details of the patient's history, which may affect follow-up and clinical management decisions (for example, whether the imaging finding has been investigated in the past, or there are other clinical conditions that contraindicate further investigation).

5.2.12 Handovers of care, while pragmatic, involve risk. The British Medical Association guidance on clinical handover describes it as *'one of the most perilous procedures in medicine'* [24]. The more handovers there are in a process leading to an action, the greater the risk that the action will not be taken.

5.2.13 Timely action is especially relevant when the unexpected significant finding is a possible cancer. There is a defined diagnostic pathway for lung cancer, meaning the actions required following a suspicious chest X-ray are known and standardised. Additional steps in cancer diagnostic pathways have been identified as a source of unnecessary delay that should be minimised where possible [25].

5.2.14 In addition to the risk associated with the actual process of handover, the investigation was informed that it can be difficult to identify or confirm whose care the patient is under and who, therefore, should have responsibility for acting on the radiology result. The difficulty could be for multiple reasons:

- The electronic patient administration system may not be updated in a timely way, so the clinician detailed on the system may not be the one now caring for the patient.
- It may be difficult to access the clinician by telephone or messaging.
- The patient may be under the care of several specialty teams and it is not clear or agreed who has overall responsibility.

5.2.15 The Chair of the Safer Care Committee for RCEM commented that, from a patient perspective, *"the system we currently have in place doesn't make sense…we have put in place the most ridiculously complicated steps"*. Each of these steps are susceptible to human and other forms of error. The probability of error is increased with each additional step, making the current process inherently error prone. The threat to safety and reliability associated with multiple steps in a process is well recognised [26].

5.2.16 The Chair of the Safer Care Committee for RCEM noted the considerable patient safety benefits of the radiology department directly acting upon findings of possible lung cancer by initiating the next steps. She also pointed out that most radiologists are very involved in the multidisciplinary team (MDT) meetings for cancer patients so have an established relationship and regular communication with relevant teams.

5.2.17 The radiology SMAs informed the investigation of trusts where responsibility for acting on some chest X-ray findings of possible lung cancer stayed with the radiology department. In these examples, responsibility was mostly restricted to GP referrals.

5.2.18 In the course of the investigation, four trusts were visited to obtain details of their risk control processes. During these visits, the investigation asked about the process for chest X-rays showing findings of possible lung cancer. In all four trusts the radiology department initiated the next steps for GP referrals, but each did it in a different way (see Appendix).

5.2.19 A key component of initiating the next steps is informing the patient. The investigation was provided with examples of this being done by the GP, respiratory team or CT booking team.

5.2.20 The National Clinical Director for Diagnostics and the Patient Safety Advisor to the Royal College of Radiologists (RCR) thought some radiology departments were also taking responsibility for organising a CT scan for inpatients and those discharged from the ED. They noted that for inpatients, the clinician caring for the patient could cancel the scan if they thought it was not clinically appropriate. The National Clinical Director said his Trust was about to implement this in response to the national guidance on achieving a timed lung cancer pathway [27]. Another of the radiology SMAs[28] was planning to pilot this for patients discharged from the ED.

5.2.21 NHS England's optimal lung cancer pathway [11] states that for unexpected findings on chest X-rays, such as from the ED, a CT scan should be performed within 24 hours if clinically indicated. The radiology department taking responsibility for this step would expedite the scan.

5.2.22 The investigation asked the radiology SMAs about the potential for all radiology departments to have responsibility for next steps where possible lung cancer was identified in ED-referred chest X-rays. The Patient Safety Advisor to the RCR pointed out that once discharged from the ED, these patients are under primary care. Where the process of arranging next steps is already set up for GP-referred X-rays, this would be an extension of that system. He said that if trusts did not have this process in place or were needing to use lots of external companies to report their chest X-rays, organising next steps on the patient pathway is more difficult.

5.2.23 One of the radiology SMAs noted an issue with the radiology department potentially

[28] The Medical Director for Professional Practice for Clinical Radiology at the Royal college of Radiologists.

organising next steps, such as a CT scan, for patients referred from the ED. The radiologist would not know if the ED doctor had identified the potential cancer on their review of the X-ray and already requested a CT scan and/or chest clinic appointment. There is, therefore, a risk of confusion and duplication. This risk could be mitigated by inbuilt checks within imaging ordering software to prevent duplication of appointments. However, the radiology SMA highlighted that where requesting of imaging remains paper-based, these mitigations all take time along with the booking procedures, emphasising the need for appropriate administrative resource.

5.2.24 Another issue pointed out by the same SMA was that the need for the radiology department to take responsibility for organising next steps is the result of the current mismatch in capacity and demand. He pointed out that, ideally, if a patient had a chest X-ray in the ED, it would be reported while they were still in the department and their CT scan would take place straight away with the patient being informed directly. Similarly, he suggested the ideal for GP referrals would be a timely report, followed by a GP-organised rapid access CT scan, as part of a fast-track cancer service such as the Danish model described in Vedsted's work [28] and the Manchester RAPID project [29].

5.2.25 A radiologist at one of the site visits pointed out that patients referred for a chest X-ray by their GP are aware that a potential lung abnormality may be found. The GP is aware that next steps will be organised by radiology if this pathway is in place. In contrast, when a possible lung cancer is found on a chest X-ray requested by the ED, it is often a truly unexpected finding as the patient may have attended the ED for completely unrelated reasons. If the ED organised next steps rather than the radiology department, there is little gain as the ED staff will have limited knowledge of the patient and the person who would inform them is unlikely to have met them. However, the ED would have sufficient knowledge of the patient to know whether next steps were appropriate. That said, if radiology organised this and informed the GP in its report, the GP could cancel this if inappropriate, provided the cancellation process was timely and reliable with minimal steps. Harvey et al [30] showed that CT scans recommended by radiologists following an abnormal chest X-ray give a substantial percentage of significant findings, including diagnoses of cancer.

**Summary**

5.2.26 Identifying who has clinical responsibility for radiological findings is not straightforward. There can be multiple steps and multiple handovers between findings being reported and the action required being effected.

5.2.27 Although there are common principles for the management of unexpected significant findings from imaging requested by EDs, the operational processes in place vary. The variation is largely driven by the IT systems in place and in particular by whether the radiology reports are linked to, or sit within, an EPR.

5.2.28 In the context of possible lung cancer, there are examples of radiology departments taking responsibility for follow-up of the findings. The lung cancer diagnostic pathway is standardised and there has been a national focus on reducing the time to diagnosis, which has provided impetus for innovation and pathway design.

5.2.29 There are patient safety benefits to radiology departments taking responsibility for the action required in this clinical scenario. This has resource implications which need to be accounted for. There would also need to be clarity regarding who informs the patient.

5.2.30 The model for lung cancer may be applicable to findings of other cancers too, or other conditions, where there is a standardised pathway, but this has not been the focus of this investigation.

## HSIB MAKES THE FOLLOWING SAFETY OBSERVATION

There is an established model of radiology departments requesting a CT scan for chest X-rays referred from GPs that show possible lung cancer. Two trusts are extending this to chest X-rays referred from the emergency department.

It would be beneficial for this practice to be evaluated.

## 5.3 Communication and acknowledgement of unexpected significant findings

5.3.1 The RCR standards [5] state that there are three elements of communication regarding a radiology report, as follows. These elements relate to notification of findings:

- Language or content of the report – the report needs to be clear, the critical elements emphasised and the action that needs to be taken by the referrer clearly stated.
- Transport mechanism of the report – once finalised, the report should be communicated to the referring clinician in a timely manner.
- Alerts – when findings are important, an alert should *'supplement the normal systems of communication'* to ensure that they are acted upon in a timely manner.

The RCR also published standards for acknowledgement of results [6] to ensure that notifications are received and read. Alerts and acknowledgement are key elements of risk control processes.

### 5.3a Language and content of reports

5.3a.1 The purpose of an imaging report is *'to provide an accurate interpretation of images in a format that will prompt appropriate care for the patient'* [31]. The RCR states that the usual format of a report should include:

- clinical details (unless requesting details are accessible for review)
- a description of the findings
- a conclusion or summary of the key findings
- advice on the next step of management (when appropriate).

5.3a.2 In common with the RCR standards [5] the NPSA Safer Practice Notice published in 2007 stated that reports *'should ensure that critical findings are emphasised and obvious, and that the degree of urgency for action by the referring health professional is clear'* [3].

5.3a.3 The radiology SMAs told the investigation that there was *"massive"* variation between radiologists regarding the language and content of reports. Variation was described in relation to the level of information provided in the report and circumstances in which advice on next steps was deemed appropriate. This variation was said to be informed by personal style and habit formed over years, the local working context, such as the preference of referring clinicians, and in response to experience.

5.3a.4 One of the radiology SMAs said radiologists wrote either long or short reports with little agreement about what was best. This radiology SMA said that in general, whatever the length or content of the body of the report, important findings appear in the conclusion and clinicians look to this section of the report for these. This situation is reflected in European publications – the European Society of Radiology comments: *'The impression or conclusion section is… critical, and it should be assumed that in some cases it is all that will be read.'* [32]

5.3a.5 The Patient Safety Advisor to the RCR noted the standards produced by the College, which emphasise that reports should be *'actionable'* [31]. An actionable report '*should answer the clinical question asked by the referrer…[and] be worded so that it prompts appropriate action for the patient'*. The format described includes 'a conclusion or summary of the key findings'.

5.3a.6 One of the radiology SMAs pointed out that the American College of Radiology has proposed structured reports, with areas expected to be commented upon in each section and standardised language [33]. The radiology SMA said the advantages included:

- consistency – meaning referring clinicians know what to expect
- support for less experienced radiologists as the format prompts consideration and comment on areas of imaging
- ease of interpretation for artificial intelligence (AI) systems. These are being developed to identify critical and unexpected significant findings in reports and whether these have been communicated[29] [34].

5.3a.7 The radiology SMA described one potential disadvantage. Requiring highly skilled, experienced radiologists to report in a set

[29] This technology uses a natural-language understanding (NLU) algorithm. It is a potential quality control measure and may assist in ensuring more consistent documentation of important abnormal findings.

format may have the effect of *"switching off the brain"*; that is, it may lead radiologists to disengage their full attention. This SMA also said that such a requirement made potentially less allowance for professional judgement regarding what is helpful to include.

5.3a.8 The Patient Safety Advisor to the RCR considered the concept of structured reports to be a sensible one. He pointed out that some private companies have instituted this. He noted it is easier to mandate this in a private company than in the NHS.

5.3a.9 The Medical Director of Professional Practice for the RCR thought that while there may be merits to structured reports, the patient safety gains were unproven and unlikely to be significant, and the resistance was likely to be substantial. The review of serious incidents on the Strategic Executive Information System (StEIS) did not identify any case where the language of reports was a contributory factor to the failures in communication and follow-up of findings. For these reasons, the investigation did not deem a safety recommendation appropriate. However, given the likely wider use of AI in the future, some standardisation of reports may be required.

**Summary**

5.3a.10 There are professional standards regarding the content of radiology reports. However, professional judgement and other factors determine how this translates in practice, meaning there is considerable variation between radiologists within a trust and within external providers. Clinicians, therefore, receive many different reports in terms of language and content.

5.3a.11 Structured reports promote consistency. However, the safety gains are unproven and the investigation did not find evidence that report structure was a safety issue in failures to follow up unexpected significant findings. The use of AI to identify and communicate significant findings may be the most compelling argument for structured reports as they would facilitate AI development.

## HSIB MAKES THE FOLLOWING SAFETY OBSERVATION

**Observation to the Royal College of Radiologists:** Given the likely wider use of artificial intelligence in the future, some standardisation of reports may be required. It would be beneficial for this to be evaluated.

### 5.3b Means of communicating the report

5.3b.1 Technology plays a pivotal role in the communication of reports. Radiology reports are created in radiology reporting applications. In NHS hospitals, the Radiology Information System (RIS) is the one predominantly used but reporting applications can be part of other imaging technology systems, such as the picture archiving and communication system (PACS) or electronic patient records (EPR). Radiology reports are transmitted electronically from radiology reporting applications to other IT systems such as PACS, EPR and primary care results systems, where reports are read by clinicians [5].

5.3b.2 In 2007 the NPSA Safer Practice Notice set out the requirements of an electronic system to communicate imaging results to clinicians and these requirements have been further described by the RCR [5]. In 2019 the requirements have not changed but they are not in place, or not fully functional, in many trusts (see section 5.3h).

5.3b.3 This investigation focused on secondary care. The RCR standards state that imaging in secondary care is captured by digital technology and the results accessed through IT systems such as PACS or EPR [5]. Evidence from interviews with clinical staff and SMAs supported this. However, the IT systems in use varied between trusts, as did the interfaces between systems and functionality – for example, between the radiology reporting application (predominantly RIS), PACS and the trust's EPR or patient administration system.

5.3b.4 The SMAs advised the investigation that the ways in which the IT systems were utilised also differed between trusts. For example,

the investigation was informed of radiology departments that used their RIS to flag critical, urgent or unexpected significant report findings which then automatically generated an alert email to referrers. Other departments had systems capable of generating electronic alerts but had chosen not to use them because it had not been agreed how the alerting system would work or who would monitor and manage responses, or because there had not been *'sign-up'* from clinical teams to use such a system. This is discussed more in section 5.3e.

5.3b.5 A theme that emerged from interviews with SMAs was the need for a standardised, reliable way to receive timely results. The NPSA Safer Practice Notice and RCR standards state that IT systems used for reading, tracking and acknowledging radiology reports should be part of the EPR, or have one-click access to the EPR, so that clinicians can read reports in the context of other clinical information about that patient (blood results, clinic letters and so on). Many trusts do not have an EPR system in place, meaning it is common for radiology reports to be printed for attachment to paper medical records [5] with the inherent risks and delays this incurs.

5.3b.6 The Chair of the RCEM's Safer Care Committee described the difficulties of tracking results in her Trust, which relied on searches to pull lists of reports, complicated by the lack of reporting timeframes. Discussing the ideal system, she said that there should be a dedicated area within the EPR where all radiology findings could be viewed with critical, urgent or significant unexpected findings clearly highlighted. This is exactly the system proposed at the Trust where the reference event occurred, as a result of the working group set up to look at this issue.

**Summary**

5.3b.7 The requirements of an electronic system to communicate imaging results were detailed in the NPSA's Safer Practice Notice in 2007. These requirements have not changed but are not in place in many trusts.

5.3b.8 Radiological reports are accessible through IT systems. However, the functionality of these systems varies, especially in relation to tracking of results and facilitating risk control processes. This is an important aspect in reducing the risk of communication breakdowns and failure to follow up radiological findings.

### 5.3c Risk controls

5.3c.1 Risk controls involve additional steps to supplement the normal systems of communication [5] [6]. Their aim is to ensure important findings are communicated and acted upon in a timely way.

5.3c.2 The NPSA Safer Practice Notice [3] and RCR standards [5] state that risk controls should be in place for findings that *'require particularly timely and reliable communication'* such as critical, urgent or unexpected significant findings [3] [5].

5.3c.3 Neither the NPSA Safer Practice Notice [3] nor the RCR standards [5] define precisely which findings constitute critical, urgent or unexpected significant findings. The RCR standards state that this is a matter of professional judgement on the part of the radiologist, and to be agreed locally with referring teams.

5.3c.4 Risk controls – which may be preventive or recovery (see paragraph 1.1.8) – typically include activities such as:

- Sending copies of reports to a patient's GP or cancer MDT (recovery)
- alerts being generated to prompt particular actions. Alerts may be electronic (for example, email) or manual (for example, printed reports or verbal communication in person or by telephone) (preventive)
- requiring acknowledgement of results (preventive) and monitoring that acknowledgement (recovery)
- actioning of the next steps on the patient pathway, for example, organising a CT scan in the event of a possible lung cancer (preventive).

5.3c.5 RCR standards state that a key aspect of IT systems if they are to support risk controls is that they are *'capable of receiving and displaying fail-safe alerts'* and

provide *'electronic tracking, reading and acknowledgement of radiology reports'* [31].

5.3c.6 In April 2017, a Coroner issued a Prevention of Future Deaths report[30] concerning a failure to follow up an unexpected significant radiological finding. As a result, a Task and Finish Group was set up by NHS England, chaired by the National Clinical Director for Diagnostics, to consider the issues raised[31].

**Summary**

5.3c.7 Risk controls aim to ensure critical, urgent and unexpected significant findings are communicated and acted upon in a timely way.

5.3c.8 IT systems play a key role in how risk controls operate in practice.

5.3c.9 Failure to act on an unexpected significant finding led to a Coroner's Prevention of Future Deaths Report, which led in turn to a Task and Finish Group being set up to address the Coroner's recommendations.

### 5.3d Copying reports

5.3d.1 The NPSA Safer Practice Notice [3] included examples of risk controls. One such example was copying reports to the GP, cancer MDTs, or other identified health professionals.

5.3d.2 While appearing to give added assurance, several of the radiology SMAs commented that copying reports to cancer MDTs and GPs without it being clear what action has been taken, or is expected, is not helpful as a risk control. These SMAs noted that the practice can be counterproductive for the following reasons:

- Diffusion of responsibility meaning that each person copied in has (possibly) false assurance that someone else is acting on the finding. A study where the patient's GP was informed of findings alongside the radiology requester supported the view that diffusion of responsibility increases the risk of failure to follow up [35].

- Information overload in an already overloaded system.

- GPs copied in to an abnormal report do not know whether action has been taken or not. They may then embark on trying to find out who has done what, which is time-consuming in a service already challenged for time.

- Requirements to copy reports to multiple people and different groups creates added confusion and complexity for teleradiology companies trying to comply with multiple alert systems for multiple hospitals.

5.3d.3 The radiology SMAs believed that reliability was best achieved by alerts going to the person – or generic inbox – responsible for acting on that result with acknowledgement required of receipt and action taken. They also agreed GPs should be kept informed of patients' test results, but that information must come with clarity about any action required.

5.3d.4 If a GP is asked to take specific action, this is not a risk control, it is a request. If no action is requested of the GP, copying reports may act as a last line of defence simply because the GP has that information, but it is not an effective risk control as the GP will assume necessary actions have been taken.

5.3d.5 Guidance from the National Institute for Health and Care Excellence states that where chest X-rays show incidental findings suggestive of possible lung cancer, *'a second copy of the radiologist's report should be sent to a member of the lung cancer MDT…The MDT should have a mechanism in place to follow-up these reports'* [36]. If follow-up means ensuring necessary next steps have been taken, then this is a risk control. If, however, it is unclear who is taking responsibility for next steps, and for monitoring that these have happened, this leads to confusion and diffusion of responsibility as discussed above.

**Summary**

5.3d.6 Copying reports to individuals or groups is only a risk control if there is clarity about who is responsible for actions to be taken and who is responsible for the assurance that those actions have been taken.

[30] Coroners have a statutory duty to issue a Prevention of Future Deaths report to any person or organisation where, in the opinion of the Coroner, action should be taken to prevent future deaths.

[31] The Task and Finish Group included representatives from NHS Improvement, NHS England, NHS Digital, CQC, and the Royal College of Radiologists. The Group concluded in January 2019 as it was agreed their findings and recommendations had been incorporated in this report.

### 5.3e Alerts

5.3e.1 Use of alerts is a key preventive risk control, that is, alerts reduce the risk of a significant finding not being seen. A number of studies, reviewed by Callen et al, have shown alerts to be effective [21]. RCR standards [4] suggest two categories in accordance with the NPSA. These are where there are critical and urgent findings (defined as, respectively, emergency action required as soon as possible or medical evaluation within 24 hours) or unexpected significant findings such as a possible cancer. RCR standards state that ideally alerting systems *'should be IT based to reduce error and increase efficiency, but if facilities are not available, alternative manual processes should be in place'* [5]. Both IT- based and manual processes require administrative support.

5.3e.2 Electronic alerts are created by the radiologist clicking an alert flag on the RIS. The alert is sent out as an abnormal flag as part of the radiology report. This abnormal flag should be received and displayed by IT systems used for reading and acknowledging radiology reports, ideally as part of an EPR. The PACS should also be able to display alerts.

5.3e.3 The Patient Safety Advisor to the RCR explained that there were different alerting systems. He gave examples of different systems such as red, amber and green colour coding for images; defined text (such as *'critical', 'urgent'* and *'unexpected significant'*) being put on different categories of report which then automatically generated an alert message; or codes being used at the end of reports to generate an alert message.

5.3e.4 The Patient Safety Advisor to the RCR highlighted the problems of lots of different alert processes for teleradiologists and networked radiology services. He noted that a radiologist working for a teleradiology company may be reporting images for 10 different trusts, so may have to learn 10 different alert processes.

5.3e.5 RCR standards state that IT applications used for reading and acknowledging radiological findings should have functionality to allow clinicians to create a worklist of all findings. Clinicians should be able to filter out alerts, so they can deal with them as a priority before the others. The alert should also be displayed in the PACS on the digital imaging and users should be able to filter the PACS for alerts [5].

5.3e.6 RCR standards point out that alerts can be supplemented with digital *'push notification'* to the referrer's smartphone or email address. The details (such as where push notifications should be sent and the type of patient they would be sent for) need to be agreed between clinical teams and radiology departments. For example, in the ED, push notifications may be sent to the clinical shift leader's smartphone for each individual patient. For GP referrals, push notifications may be sent to the duty doctor at a particular time of day informing them there are imaging results with alerts awaiting their review [5].

5.3e.7 Manual processes for communication of alerts require telephone calls, emails, or faxes being sent to the referrer or MDT co-ordinator. Notification by telephone may be performed by the radiologist or delegated to administrative staff within the radiology department. RCR guidance states that when delegated to radiology administrative staff, the relevant reports should go to a worklist within the reporting application (such as RIS) which staff can access. Staff should document within the system when they have communicated the alert and who they have communicated it to [5]. RCR guidance states: *'Radiologists should be supported by… administrative staff 24/7 to provide fail-safe communication on their behalf, particularly if manual processes of fail-safe notification are required.'* [5]

5.3e.8 The SMAs and Task and Finish Group agreed that alert notifications were helpful in prioritising results for clinicians. However, the radiology SMAs noted a range of problems associated with alerts. One such problem was the variation in use of alerts. This was reflected in the RCR audit of UK radiology departments [37]. The SMAs explained that there was variation between radiologists based on knowledge, experience and personal preference – some radiologists

being much more cautious and therefore issuing alerts where others wouldn't. There was also variation between hospitals based on local practice and in response to referring teams' wishes. Furthermore, the radiology SMAs pointed out that fear of litigation can influence the generation of alerts, with it being perceived as more protective to the radiologist to issue an alert rather than not.

5.3e.9 The radiology SMAs agreed that over-use of alerts can be counterproductive by overburdening clinicians who may then take less notice of them. Conversely, one of the SMAs noted the risk of alerts leading to a culture where clinicians only read alerted findings and ignore, or delay, review of radiology reports that have no alerts associated with them on the assumption that such reports contain normal findings.

5.3e.10 The radiology SMAs explained the different ways alerts were managed in response to local context such as IT systems and specialty teams' ways of working. The investigation heard that alerts may be sent:

- by email to an individual clinician's inbox
- by email to a generic email inbox set up by a specialty team, which an allocated individual is responsible for accessing and acting on each day
- by automated message to the EPR inbox of a named clinician or 'pool' that can be accessed by a number of designated staff
- by automated message, or physical delivery, to a radiology administrator who emails, or physically delivers, to the referrer or clinician currently caring for the patient.

5.3e.11 The radiology SMAs agreed that it was safer for alerts to go to a generic, managed email or designated results pool on an IT system (ideally within an EPR) rather than to an individual clinician. They noted the risks of the latter: the clinician may not be working that shift or on leave, or the imaging requester may be a locum not regularly in the trust. The SMAs also highlighted the issue of information overload by email, meaning a single email can easily be missed as in the reference event.

**Summary**

5.3e.12 There is variation in what triggers an alert, how it is coded, and how it is managed. This presents particular challenges for teleradiology or networked radiology services.

5.3e.13 Both IT and manual processes are in use in trusts.

5.3e.14 Alerts are helpful in prioritising patients, but this may lead to other findings being ignored. Alternatively, over-use of alerts can lead to alerts being non-prioritised.

5.3e.15 Alerts should go to a generic pool rather than an individual clinician and there should be dedicated clinical resource to manage it.

### 5.3f Standardisation of alerts

5.3f.1 The Task and Finish Group set up by NHS England considered the key components of a reliable alerting system. The operational processes in place necessarily vary depending on IT infrastructure and other factors. The group agreed that there were key components which could be standardised. Standardisation is well recognised to be an important element of safe, reliable care [26].

5.3f.2 The investigation saw examples of trusts that have defined what constituted critical, urgent and unexpected significant findings, and should therefore trigger an alert. This has been done to standardise when alerts should be used by radiologists and create a common expectation for clinicians.

5.3f.3 Radiology SMAs had mixed views about the value of lists to define when an alert is used. One view was that lists were of limited value because of the difficulty in defining the range of scenarios or thresholds for using an alert, and the professional judgement that informs this. Another view was that lists were helpful, as a nationally agreed set of findings that should be flagged would:

- provide consistency
- create a shared expectation for clinicians
- be a framework for audit.

5.3f.4 A list of conditions that should always be considered for alerting need not curtail

professional judgement. Ultimately, it is the radiologist's, or reporting radiographer's, decision when to use an alert. One of the radiology SMAs pointed out that, with a defined list of conditions, the alerting system may then harness AI to prompt reporters when appropriate to add an alert.

5.3f.5 One of the American College of Radiology's goals is to standardise communication. It convened a working group [8] to consider findings that required non-routine communication (because of their urgency or unexpected nature) and the role of IT support. The working group considered the descriptive terms *'critical', 'urgent'* and *'unexpected'* as potentially causing confusion. It defined three categories of findings and an associated timescale for communication of the findings to be achieved:

- **Category 1:** Communication Within Minutes – direct verbal communication with the referrer generally required as promptly as possible.
- **Category 2:** Communication Within Hours – direct verbal communication may take place but other mechanisms, as defined locally, may be sufficient.
- **Category 3:** Communication Within Days – direct verbal communication not required but confirmation of receipt and appreciation of significance required (via electronic acknowledgement system).

5.3f.6 The working group devised a list of findings under each category. It stated that the list was not intended to be definitive or prescriptive but was to help standardise reporting and communication of findings.

5.3f.7 The Task and Finish Group noted the increasing importance of standardising practice, such as use of alerts, given the move towards networked radiology services[32].

5.3f.8 Standardisation of alerts will involve principles of use and a list of conditions which would need to be developed with the involvement of all relevant specialties. Given the increasing role of reporting radiographers, it would also be beneficial to include the Society and College of Radiographers in the development. Furthermore, it would be helpful to involve NHSX to facilitate integration into digital systems. NHSX was founded in February 2019 and its focus is digital transformation and capability within the NHS. NHSX will oversee NHS Digital.

5.3f.9 The CQC review identified that of the trusts that responded to its questionnaire, 76% were outsourcing at least some of their work to external companies [2]. Alert processes, therefore, need to be workable for them. The Patient Safety Advisor to the RCR concurred with the view of the Task and Finish Group that the alert process needed to be standardised.

5.3f.10 The investigation saw a proposal document sent to radiologists and clients by the medical director of a large, national, networked radiology group in 2017[33] regarding alert codes. The group's analysis showed there was *'wide variation'* in coding. Two levels of coding were identified in use by trusts:

- At level one there was an alert for a critical, urgent or unexpected significant finding.
- At level two there was facilitation of patient management by directing the case to various MDTs or clinicians.

5.3f.11 The document stated that at level two, there were in excess of 100 codes used across the more than 100 NHS hospitals the group served. The codes often flagged the reports to various MDTs and clinics to aid patient management in accordance with local policy and protocol. The document stated: *'The variation is introducing risk from human error due to omission or incorrect codes being applied and is working counter to the original intention of the NPSA notice.'*

5.3f.12 This networked radiology group noted the two common themes across most systems. For level one coding, an alert code was added for a critical, urgent or unexpected significant finding; and another alert code was added for cancer. The group proposed the introduction of a simplified, unified alert system to be used across all clients:

[32] Networked radiology services vary in their configuration. For example, they could be regional or based on type of work (emergency or routine).
[33] S. G. Davies. Alert Codes: Communication to Radiologists and Clients. 19 September 2017.

- RED FLAG (for all alerts) with optional text which the group has defined.

- CANCER ALERT with optional text which the group has defined.

  The group's proposal was that clients added their local secondary codes as addenda to the reports. The group stated the proposed changes did not replace the requirement for urgent or critical findings to be communicated by contacting the referring trust and speaking to the relevant clinician.

5.3f.13 Multiple codes, across multiple trusts, creates difficulty and risk for teleradiologists and networked radiology services. The proposal to hand back to trusts responsibility for the addition of local codes to support patient management, while reducing the risk of error, necessarily means additional work for the trust.

**Summary**

5.3f.14 The Task and Finish Group agreed that elements of the alert processes could be standardised.

5.3f.15 There is no nationally agreed list of findings that should result in an alert. Some trusts have created their own to standardise practice.

5.3f.16 The American College of Radiology has produced a list of findings which require additional communication because they are urgent or unexpected as part of its work to standardise practice.

5.3f.17 Standardisation of alerts requires the involvement of all specialties and it would be beneficial to involve NHSX.

5.3f.18 The majority of trusts are reliant on teleradiology to manage their workload. Current alert processes create difficulties and risk for these networked radiology services.

## HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION

**Recommendation 2019/039:**
It is recommended that the Royal College of Radiologists, working with the Society and College of Radiographers and other relevant specialties through the Academy of Royal Medical Colleges, develops:

**1** principles upon which findings should be reported as *'unexpected significant', 'critical'* and *'urgent'*

**2** a simplified national framework for the coding of alerts on radiology reports

**3** a list of conditions for which an alert should always be triggered, where appropriate and feasible to do so.

### 5.3g Acknowledgement of radiological findings

5.3g.1 The RCR issued standards in 2010 describing the expected capabilities of a results acknowledgement system [6]. These included the ability to:

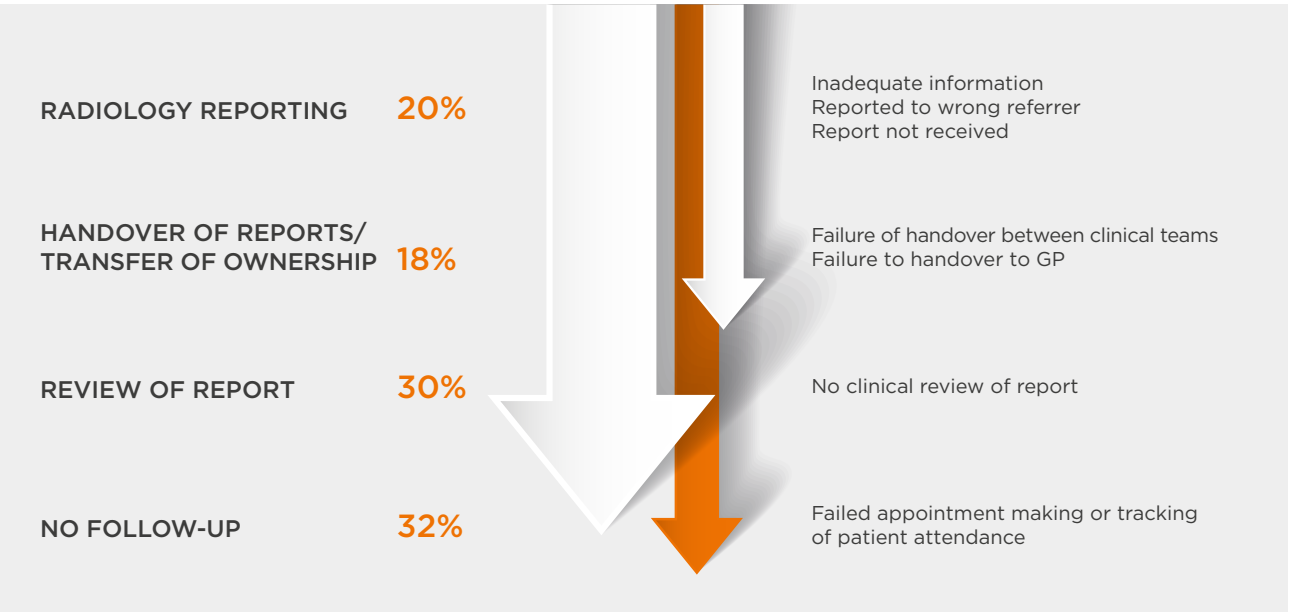
- record acknowledgement that findings have been read by an appropriate clinician

- create an electronic list of findings for the referring clinician with the reports flagged as critical, urgent or unexpected at the top

- generate automatic alerts to provide early notification of unread reports after an agreed time period.

5.3g.2 The radiology SMAs emphasised the gap that currently exists between notification of significant findings (alerts) and confirmation that they've been seen, and responsibility taken for acting upon them (acknowledgement). This theme was also evident from the review of serious incidents on StEIS (Figure 1). Analysis suggested that there were significant problems associated with what was notified and to whom, which accounted for 20% of delays. Ambiguity associated with who was responsible for follow-up of results accounted for 18% of delays. Other breakdowns (62%), including the lack of a clinical review and no follow-up planning, are not necessarily indicative of a failure of communication but are associated with a lack of acknowledgment and action.

**FIG 1 THEMES FROM STEIS REVIEW OF REPORTED SERIOUS INCIDENTS**




A systematic review of the safety implications of missed test results for hospitalised patients argued the need for acknowledgement systems in addition to alerts. The review highlighted one study of radiology follow-up using an email alert system for important but not urgent imaging findings which showed that 20% of electronic reports were not viewed by the referring physician [21].

5.3g.3 From a patient perspective, acknowledgement that every radiology report (both normal and abnormal results) has been read is a reasonable expectation. However, this is not routine in practice (see section 5.3h) and acknowledgment of every critical, urgent and unexpected significant finding would reduce the risk of these being missed.

5.3g.4 The radiology SMAs explained that most RIS and EPR systems include a results acknowledgement function. This is not used, or its use is not monitored, by most trusts (see section 5.3h). One of the radiology SMAs pointed out that this reflects the lack of supportive local conditions which would facilitate this activity, in particular, IT systems which allow clinicians to see radiology images and reports alongside other clinical information about the patient, for example within an EPR. IT systems also need to be up to date, for example with details such as the name of the patient's current consultant. In addition, there needs to be staff resource to monitor acknowledged results and, importantly, follow up unacknowledged ones. This points to the need for a results co-ordinator supported by reliable IT systems (see section 5.3h).

5.3g.5 Some systems, called *'read acknowledgment'*, accept the report being opened as acknowledgement[34], while others require the report to be opened and an acknowledgement to be actively sent, that is, a two-step process. RCR standards [6] state: '*There must be a distinction between 'viewed' and 'acknowledged' (a two-step process).'* The investigation visited trusts where this was in place (see Appendix).

5.3g.6 Acknowledgment of results suggests, by implication, that responsibility has been taken for acting on the findings, and this will lead to the required outcome for the patient [37]. However, this does not, provide complete assurance, as the action required may not be completed at that point in time, may be forgotten, or may require a request for action by others, such as the CT booking team.

5.3g.7 Ideally, completion of the actions would automatically trigger information being fed back, or stored against the alert, providing

[34] Read acknowledgement systems record that a radiology report has been opened and take this as acknowledgement that the findings will be acted upon, the assumption being that opening the report equates to reading it and taking the necessary action.
[35] Systems where completion of expected actions *'downstream'* feeds information back *'upstream'* to signal that the actions have occurred are known as *'closed-loop'* systems. Such systems are central in designing reliable processes.

confirmation that results had been acted upon[35]. The investigation found no evidence of an IT system currently in place that has this functionality. Furthermore, it may not be possible for an IT system alone to deliver this, especially within the current NHS infrastructure, and given the diversity and complexity of possible actions required in response to significant abnormal findings.

5.3g.8 The reference event demonstrated two important points in relation to acknowledgment systems. Firstly, acknowledgement must be by the clinician responsible for carrying out the next steps for the patient. Had an acknowledgment system been in place, it would have been the cardiology consultant, not the ED consultant, who needed to respond. Secondly, acknowledgement systems must entail a two-step process where acknowledgement is separate from opening the report. A read acknowledgement system (one-step process) would have indicated that the cardiologist had seen and taken responsibility for the findings as he had opened the email regarding them.

5.3g.9 Acknowledgement systems need to allow forwarding of a report to transfer the required acknowledgement to another clinician.

**Summary**

5.3g.10 Currently, in many trusts, there is no assurance that radiological findings, including critical, urgent or unexpected significant findings, have been read.

5.3g.11 The IT systems in most trusts have an acknowledgement capability but in most trusts this is not used and, when it is, it is usually not monitored.

5.3g.12 Acknowledgement of results needs to be a two-step process.

5.3g.13 Acknowledgement of results does not necessarily mean action has been or will be taken, but does track responsibility for inaction.

## 5.3h Audit of radiology communication systems for critical, urgent and unexpected significant findings

5.3h.1 The NPSA Safer Practice Notice [3] and RCR standards state the importance of radiology departments and clinical teams carrying out *'regular audit'* of their communication tracking systems. The RCR included audit templates within its standards documents [5] [6].

5.3h.2 In 2015, the RCR conducted an audit of all UK radiology departments [37]. The audit was to establish compliance with RCR standards. The standards being audited were: whether there was a policy for communication of critical, urgent and unexpected significant findings; and whether organisations had service-wide electronic tracking of radiology reports (that is, they were able to tell whether radiology findings had been read or not). The key results were:

- 67% of invited departments responded (154/229).
- 88% of departments that responded indicated that they had a policy in place for the communication of critical, urgent and unexpected significant findings (136/154).
- 17% of departments had an electronic acknowledgement system (26/154).
- 42% of the departments with an electronic read acknowledgment system had someone regularly monitoring the read rate (11/26). Therefore, in 58% of departments, although available, the result acknowledgement system was not being monitored (15/26).
- 34% of departments had an automated one-click electronic alert system (53/154). Of those, 66% were able to send the alerts to all referring clinicians including GPs (35/53), and 34% to hospital clinicians only (18/53).
- The majority of the departments with an electronic alert system also had a variety of other risk controls, such as contacting referrers by telephone, email or fax[36], and also notifying the relevant MDT co-ordinators.
- 71% of responding departments outsourced some or all of their radiology reports (110/154). In 19% of those departments, alerts issued by the outsourced reporter were passed on electronically to referrers (21/110). In 21% of departments, secretaries were relied upon to pass on alerts (23/110), thus creating additional steps and opportunities

[36] Of note, fax machines will be phased out shortly – see **https://www.gov.uk/government/news/health-and-social-care-secretary-bans-fax-machines-in-nhs**

for error. The audit does not state the other means used for passing on alerts.

5.3h.3 The audit confirmed evidence from SMAs that the processes in place to ensure radiology findings have been acted on are *'very different in different Trusts'*[37]. The audit concluded that there was *'wide variation in practice'* with regard to both the communication and monitoring of radiology reports. Most UK radiology departments were not compliant with published guidance.

5.3h.4 Just over a third of responding departments were using electronic systems for alerting clinicians to critical, urgent or unexpected significant findings. However, only a minority of departments used electronic tracking to ensure reports had been read and acknowledged. And this only provides limited assurance that action has been taken. There is, therefore, in the majority of trusts, no feedback loop between reporting findings and acknowledgement of those findings to provide a degree of assurance that they have resulted in the necessary action for the patient.

5.3h.5 One recommendation from the audit was that *'manual safety-net procedures should also form part of the feedback process, as electronic alerts are currently not entirely reliable'*. Related to this, the audit proposed: *'Each trust/organisation should ensure that a named individual/individuals within the hospital has/have responsibility for monitoring that all reports are read and that escalation policies are in place for unacknowledged reports.'* [37]

5.3h.6 The radiology SMAs noted that reducing the risk of failures in communication or follow-up of radiological findings requires the involvement of all referring clinicians. They pointed out that the RCR has led the work on trying to set up systems to assure receipt and follow-up of findings, but specialties need to decide their preferred option given local context. The system that works for one specialty won't be the same for another, as the ways of working together and how the team functions will vary depending on the patient caseload, volume of imaging requested, and how work is organised. The radiology SMAs considered that, despite the inherent complexity, safety gains could be made with a greater focus on specialties designing their specific systems – with local radiology departments – to assure reports were read, acknowledged and acted upon.

5.3h.7 The National Clinical Director for Diagnostics emphasised the time that is needed to follow up results. He pointed out that electronic administration systems may not be accurate in terms of who has responsibility for the patient, meaning it can take time to identify the correct clinician, in addition to the time needed to contact that person.

5.3h.8 The investigation met with representatives from different specialties[38] at the Academy of Medical Royal Colleges to share themes identified by the investigation. The investigation was also keen to hear representatives' perspectives on opportunities for improvement. The themes identified by the investigation reflected the experiences of those present. There was particular emphasis on:

- The lack of progress since the publication of the NPSA Safer Practice Notice and repeated incidents involving failures in communication and follow-up of significant findings. The need for any future recommendations *"to have teeth".*
- The problem of identifying the consultant responsible for the patient's care (electronic administration systems often not updated in a timely way).
- Reporting times – the longer the delay in reporting, the greater the risk of failure in communication and follow-up. The biggest risk was said to be when findings were reported after the patient had been discharged from hospital.
- Variation in alerts and when they are applied to findings. The value – and difficulty – of defining unexpected significant findings that should be alerted.
- The patient's GP needing to be informed of results at the same time as the patient – particularly for unexpected significant findings – so they are aware of the situation when/if patients come to them to discuss results.

[37] Patient Safety Advisor to the RCR.
[38] Representatives were present from the Royal Colleges of:
- Surgeons • General Practitioners • Physicians
- Radiologists • Emergency Medicine • Intensive Care Medicine.

- Informing the patient as soon as possible once the findings are reported and advising what will happen next.

- Specialties needing to engage and develop risk control processes.

5.3h.9 Since the NPSA Safer Practice Notice in 2007, all guidance regarding risk controls has been produced by the RCR. This guidance may have limited reach in other specialties, but nevertheless there is still a need to ensure alerted radiological findings are acted upon in all areas.

5.3h.10 The difficulty of ensuring radiological findings are seen and acted upon may be assuaged by results co-ordinators who understand the different workflows and have the information *'at hand'* to assign responsibility and track actions. Schiff, drawing on approaches in reliability science, concludes that: *'Just as someone needs to 'own' each critical result, someone needs to be responsible for tracking outstanding results and identifying problems and system improvement opportunities.'* [38]

5.3h.11 The radiology SMAs concurred that results co-ordinators would add value to current risk control processes. Comparison was made with cancer MDT co-ordinators who provide a means to ensure patients' results are tracked and actions taken so they move along their diagnostic pathway in a timely way. NHS England's National Clinical Director for Diagnostics pointed out that these posts resulted from financial investment in cancer services and the same sort of investment would be required to create such posts in relation to radiological findings.

5.3h.12 The investigation was informed of (and observed) staff roles that were, in effect, results co-ordinators. These staff carried out different tasks but a common one was monitoring acknowledgement of results and chasing unacknowledged ones (see Appendix). These acknowledgement monitoring roles were either centrally based in radiology or within specialties. Such individuals could co-ordinate and communicate across multiple teams and multiple systems of care in a way that current IT systems were not designed to. The complexity of a patient's journey through the healthcare system requires a means of making sense of situations, so that the necessary adjustments and adaptations can be made to achieve the desired outcomes. This is a key feature in the Safety II approach to healthcare [39].

5.3h.13 The investigation observed some '*results co-ordinators'* checking whether next steps had been taken as part of the monitoring process, albeit in an ad hoc way. Ideally, this would form part of a dedicated results co-ordinator role to provide the best assurance that actions required have been taken. However, the resource implications of this and the IT infrastructure in place in many trusts may make such an arrangement impracticable. Dalal et al [40] point out that electronically linking acknowledgement functionality to typical actions that clinicians take to follow up, such as referral to other specialties, scheduling future tests and messaging patients securely, would safeguard against failure to follow up. One site visited was working towards this by making referral forms one-click away from the acknowledgement button.

**Summary**

5.3h.14 The audit by the RCR in 2015 confirmed wide variation in alert processes. The majority of radiology departments were shown not to be compliant with UK guidance on communication of critical, urgent and unexpected significant findings. Risk controls are particularly weak in terms of acknowledgment of findings.

5.3h.15 The audit recommended that there needed to be named individuals who have responsibility for monitoring that all reports are read, and that escalation policies are put in place for unacknowledged findings.

5.3h.16 Reducing the risk of failures in communication or follow-up of critical, urgent and unexpected significant findings requires the commitment of all referring specialties.

5.3h.17 As a minimum, a *'results co-ordinator'* role is needed to monitor acknowledgement and chase unacknowledged abnormal findings. Creating these roles would have resource implications. Results co-ordinators may be based centrally in radiology or within specialties. Their roles could be extended to include tracking whether next steps had been taken, but current IT infrastructure in many trusts means this is not feasible.

## SAFETY ACTIONS CARRIED OUT AND/OR IN PROGRESS

The Academy of Medical Royal Colleges has written a statement endorsing the need to ensure clinicians act on alerted radiological findings and that a monitored acknowledgement system is in place in all local organisations.

Whether this is a single centralised system or specialty-specific process is for local decision depending on the available infrastructure.

## HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION

**Recommendation 2019/040:**
It is recommended that NHS England and NHS Improvement's patient safety team takes steps to ensure providers are aware of the safety recommendations in this report and act to implement the key findings regarding risk controls such as a monitored acknowledgement system for critical, urgent and unexpected significant findings.

### 5.3i Involving the patient

5.3i.1 The evidence linking patient involvement with health outcomes, patient experience, and costs has grown substantially over the past decade [41]. It has been suggested that radiology reporting practices would be improved if radiologists were to discuss the results of an examination directly with the patient [42]. Patient access to results electronically can also serve as an important mechanism for detecting errors and inconsistencies [43]. There is evidence that patient access to diagnostic test results can decrease the likelihood of failed follow-up due to a broken link in the chain of communication [44] [45].

5.3i.2 Responsibility for informing patients of their radiological findings lies with either the clinical team caring for the patient, the last clinical team to see the patient, or the GP. As has been described, there can be many handovers of information before this happens. These communication processes are fragile and prone to failure. Informing the patient independently, at the same time as alerting the referring clinician, was proposed in 2007 by the NPSA Safer Practice Notice [3].

One of the recommended actions for registered health professionals was to:

- *'Provide patients with details of when test results are expected and how they will be communicated, giving contact details for enquiring about any concerns or delays.'*

One of the recommended actions for radiology departments was to:

- *'Consider providing standard letters to patients if an examination is abnormal. These could be generated at the same time as an alert is sent to the referring health professional.'*

5.3i.3 The investigation contacted the Project Manager responsible for the NPSA Safer Practice Notice. She said that patient groups, and professional bodies such as the RCR, were consulted in the development of the recommendations.

5.3i.4 The Project Manager informed the investigation that the Safer Practice Notice proposed that patients should be informed of their results by letter, rather than any other medium, for three reasons:

- the volume of results meaning more direct communication, such as by telephone, was likely to be impractical
- clarity of written information that can be shown to other health professionals such as GPs
- confidentiality – letters can be addressed directly to a patient.

5.3i.5 Social changes since the Safer Practice Notice, such as widespread mobile phone ownership and increasing use of texts for medical appointments and some results, mean a text message or other electronic notification may now be preferable over letters.

5.3i.6 RCR standards published since the Safer Practice Notice have not included involving the patient as one of the strategies to reduce the risk of significant findings not being acted upon. However, the radiology SMAs raised the importance of patient involvement and this formed part of the discussions by the Task and Finish Group. Possibilities were

discussed such as reminders at the time of the test being performed, either face to face or via posters in the waiting room, of the need to receive a result. The use of patient web portals or secure access to GP or secondary care records which could, in future, include radiology reports was also raised. It was noted that there would need to be careful consideration of the impact of imparting a serious or potentially serious diagnosis this way, so support mechanisms may be required.

5.3i.7 NHS England's Five Year Forward View [46] included the ambition for patients to be able to access their health records, reflecting the increasing demand for patients to have all information about their care. Another example of this is the guidance published in September 2018 by the Academy of Medical Royal Colleges [47]. This guidance endorses as best practice that outpatient clinic letters should be written to the patient (in patient-centred language) and copied to the GP rather than, as currently happens, written to the GP (in medical terminology) and copied to the patient.

5.3i.8 The investigation met with representatives from NHS Digital and with the Chief Clinical Information Officer for Health and Care, who explained that the newly established NHSX has oversight of NHS Digital. The Deputy Chief Medical Officer for NHS Digital noted the potential for patients to have independent access to all their test results. He spoke about the NHS App, which will enable patients to access a range of healthcare services and their medical records from a smartphone or tablet.

5.3i.9 While increasing patients' access to their healthcare records is beneficial for results such as unexpected significant radiological findings, patients need to be actively informed. There is potential for the NHS App to include the ability to send notifications to patients. The NHS Online Digital Delivery Lead explained that this would require an application processing interface to allow communication between the App and radiology information systems, together with a set of standards for use. The Deputy Chief Medical Officer pointed out that responsibility and accountability for implementation would remain with the provider organisation.

5.3i.10 Informing patients independently, by an automated process, was discussed with representatives of some of the medical royal colleges and other healthcare bodies at several meetings, including a Strategic Clinical Reference Group in January 2019. The Group noted the importance of risk controls being in place for the communication and follow-up of all test results, not just radiological findings, together with audits to measure their effectiveness. It was supportive in principle of patients being informed independently as an additional risk control. It was, however, concerned about the impact this would have on GP workload, as GPs were likely to be the first port of call for support and information. This additional workload would be unnecessary in nearly all cases where existing processes were working as intended and appropriate action was being taken leading to the patient being informed. It was suggested, therefore, that there should be a delay between the radiological finding being alerted and the patient being informed by independent means. This would avoid unnecessary workload and give the opportunity for patients to be informed personally first. Evaluation of any agreed process should include the impact on GPs.

5.3i.11 The Joint Honorary Secretary of Council for the Royal College of General Practitioners wrote: '*We are strongly of the view that the person or organisation that orders an investigation is responsible for any management and actions that would flow from an abnormal result.'* GPs should *'only be involved by exception and where there has been express communication and agreement between the hospital department and the GP'*.

5.3i.12 The content of any automatically generated digital communication to patients was also discussed at these meetings. The need was stressed for sensitive wording, clear advice on what action to take if they had not already been informed of the unexpected significant finding, and who to contact for support. It was noted that patient representatives should be involved in the design of this communication.

5.3i.13 Automatically informing patients of an unexpected significant finding is the safest way of ensuring the patient is aware of the result. This, therefore, acts as a preventive risk control. It should not, however, be a patient's

responsibility to ensure necessary action is taken. Nevertheless, it is a good last line of defence because patients have the most vested interest in following up their results. The value of informing patients as a priority is noted by Kwan et al who comment on the increasing use of EPR-linked patient portals facilitating direct patient access to radiology reports [48]. One of the most basic assumptions of any safety-critical industry is *'no news is most certainly not good news'* [49]. In the past, in healthcare, the opposite has been assumed. Automatically informing patients of their results helps to bring healthcare in line with other safety-critical industries.

5.3i.14 In the reference event, the patient's husband recalled that they were told the chest X-ray was normal. He did not recall being told this was a preliminary result and would be further reported by a radiologist. Irrespective of whether they were informed or not, had the patient been contacted about the abnormal result, the delay in diagnosis may have been avoided. The most important person to be informed of the abnormal result was not told.

5.3i.15 If patients were automatically informed of unexpected signicant findings it would minimise the risk of harm from failures in communication or follow-up. How workable this is, and whether it is acceptable to patients to receive such information, would need to be evaluated.

5.3i.16 Women undergoing cervical and breast screening are informed of their results by letter. Therefore, the precedent of being informed of results in a standardised way already exists, albeit in a different scenario where the possibility of a finding is not entirely unexpected.

5.3i.17 Early in the investigation a patient perspective was sought on potential additional ways of communicating unexpected significant findings. The Academy of Medical Royal Colleges agreed to contact its Reference Group, which is made up of patient and lay members. A briefing was provided about the HSIB investigation and a number of questions were posed[39]. At that stage of the investigation, independent contact with patients at the same time the finding was reported was being considered by either a standardised letter or a telephone call by a non-clinician. Patients were asked about the acceptability of these approaches. As the evidence gathered during the investigation suggested it would be more efficient and reliable to independently inform patients by an automated means after an agreed timeframe, many of the questions posed became redundant. Nevertheless, the responses were still valuable in highlighting patients' fears about their results being lost, their right to know them and their desire to be told them, ideally, by a clinician. However, responses demonstrated that patients would rather be informed by whatever means if it meant reducing the risk of not being informed. This was typified in the following comments:

*"The risk [of] getting lost or delayed in the system seems too great and although this would be coming out of the blue, if handled well it puts the patient in the driving seat."*

*"It's their health and their body."*

*"I feel that the news should be given by a trained clinician – GP or radiologist."*

*"As long as they can point them in the right direction, give sufficient info and reassurance then the patient is better informed than not."*

*"I would rather know immediately than find out later, when it is too late."*

5.3i.18 Patients' wishes could, perhaps, best be met by a delayed, automatically generated digital notification of unexpected significant findings. The delay would allow existing processes the opportunity to work through, meaning nearly all patients would be told by a clinician first. At the meetings where the length of the delay was discussed, a maximum of two or three weeks was proposed. The notification would act as a risk control if the patient had not been informed of the findings, and would minimise duplication by informing patients that if they have already been told no action is required by them.

5.3i.19 There will be patients who, for a variety of reasons, will not benefit from digital notification. It is important that the needs of these patients are considered, and strategies identified to ensure that they are not disadvantaged.

[39] The briefing and questionnaire were issued on 28 September 2018. The closing date for responses was 21 October 2018 and 33 responses were received.

**Summary**

5.3i.20 Currently patients are informed of unexpected significant findings by the clinical team caring for the patient, the last clinical team to see the patient or the GP. Before this happens, there can be many handovers with many opportunities for error.

5.3i.21 There is an ongoing cultural shift to give patients full access to their clinical information. The NHS App's functionality could be developed to include patient notifications. Test results could be part of these.

5.3i.22 Patients could be informed of unexpected significant findings by an automatically generated standardised response, at an agreed time after findings are reported. The workability and acceptability of this would need to be evaluated. The needs of patients unable to benefit from digital notification need to be considered.

5.3i.23 The patient survey showed that patients would ideally like to be informed of unexpected significant findings by a clinician. However, there was a general willingness to accept being informed of findings in a non-personal way if it would help mitigate the risk of not being informed at all. Patients' wishes could, perhaps, best be met by a delayed, automatically generated digital notification, which would allow existing processes the opportunity to work through, meaning patients could expect to be told of unexpected significant findings by a clinician first.

## HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION

**Recommendation 2019/041:**
It is recommended that NHSX develops a method of digitally notifying patients of results. This should be used to inform patients of unexpected significant radiological findings after an agreed timeframe. It should be developed in conjunction with the Royal College of Radiologists. The notification system should be tested and evaluated.

## 5.4 Assessment and regulation of radiology services

5.4.1 The investigation considered the role and influence of assessment and regulation on the implementation of RCR standards.

5.4.2 Radiology services may be assessed through the Imaging Services Accreditation Scheme (ISAS) and are regulated through CQC inspections.

### 5.4a Imaging Services Accreditation Scheme

5.4a.1 ISAS is jointly organised by the RCR and the Society and College of Radiographers. ISAS developed the Service Accreditation Standard in consultation with imaging services across the country. The Standard was first published in 2009 and was last revised in 2016. It is divided into five domains which contain statements, or criteria, requiring evidence to demonstrate how the criteria is met. It covers all aspects of an imaging service.

5.4a.2 Accreditation with ISAS is voluntary. Although the evidence required for accreditation maps with CQC key lines of enquiry, accreditation is not dependent on compliance with national legislation or regulation.

5.4a.3 The Clinical Domain of the Standard includes the criterion: *'There are systems in place… to manage unexpected findings and potential medical emergencies.'* One of the radiology SMAs, an ex-assessor with ISAS, explained that while evidence is required of systems being in place, the finer details of the risk controls, and any shortcomings therein, may not be explored as there are no specific requirements.

5.4a.4 Trusts choosing to pursue accreditation must pay for it. There is a one-off application fee and thereafter an annual fee which is dependent on the size of the organisation and number of geographical sites involved.

5.4a.5 The accreditation scheme informs trusts that a significant amount of work is required to evidence meeting the Standard's criteria – in particular, time is needed to review and document processes in place. This was reflected in comments by the radiology SMA who is a former ISAS assessor and has led a radiology service through accreditation.

5.4a.6 Twenty-two NHS trusts across the country have received accreditation[40] for their radiology departments [50] out of 168 trusts in England[41].

5.4a.7 The limited uptake of accreditation by trusts, and the lack of imperative to be accredited

by ISAS, suggests this is not currently a significant driver for improvement.

**Summary**

5.4a.8 ISAS accreditation is voluntary and there has been limited uptake by trusts. Consequently, ISAS has limitations as an effective vehicle to drive national change.

### 5.4b Care Quality Commission

5.4b.1 The CQC is the independent regulator of health and adult social care in England. It monitors, inspects and regulates services against fundamental standards of quality and safety. Inspectors gather evidence to help them answer five questions: is the service safe, effective, caring, responsive and well-led? Each of these questions represents a domain within the overall inspection framework. Within each domain there is a further set of questions called key lines of enquiry.

5.4b.2 The CQC inspects a total of 10 services – eight core services and two additional services – within an NHS trust . These are the services that most providers deliver. Based on evidence gathered during its inspection, a rating of Outstanding, Good, Requires Improvement or Inadequate is given. The CQC usually gives a rating for each of its five key questions and an overall rating for the service and the NHS trust[42].

5.4b.3 For NHS trusts, the maximum interval between CQC inspections depends on a trust's previous ratings of core services and the latest information the CQC has from its monitoring activities. The maximum is five years for core services rated as Outstanding. At least one core service is inspected at any one time, so it may take several years to inspect all the core services of a trust.

5.4b.4 In 2017, the CQC inspected several trusts where there were serious concerns about reporting time for radiology examinations. The inspections *'flagged wider concerns about delays in reporting'* and the risk posed to patients. As a result of the inspections, the CQC carried out a national review of radiology reporting within the NHS in England. Its findings and recommendations were published in 2018 [2].

5.4b.5 The CQC's recommendations included the need for national standards to be set for report turnaround times, and for trust boards to have *'effective oversight'* of any backlog of radiology reports. In addition, the CQC report stated that it had strengthened its approach to assessing radiology services so it could *'monitor the reporting of imaging examinations as part of [its] inspections to make sure that radiology services are providing a safe, responsive, effective, caring and well-led service for patients'. The report continued: 'Action needs to be taken now to agree what good looks like in terms of radiology reporting. This will allow departments to benchmark their performance.'* [2]

5.4b.6 The investigation reviewed the revised CQC inspection guidance for radiology in relation to risk controls. The *'Safety'* domain includes a prompt to inspectors to ask: *'Are there clear processes to escalate unexpected or significant findings both at the examination and upon reporting?'* This specifically relates to whether there is an alerting process within a trust. A link is included to RCR 2016 guidance on communication of reports and alert notification [5].

5.4b.7 The CQC's key lines of enquiry do not require inspectors to consider the following risk controls:

- evidence (for example, an audit) that the process of issuing alerts for unexpected significant findings is effective as per RCR guidance [5]
- whether there is a monitored two-step acknowledgement system (as per RCR guidance in 2010) or how trusts assure themselves that results are read and acted upon
- whether there is clinical time allocated to results follow-up – particularly in specialties such as the ED, which will receive a high volume of test results

[40] The investigation was advised by the Executive Director for Professional Practice, RCR, that 32 departments had been accredited by November 2018.
[41] Source: NHS Choices.
[42] The core services as of 2018 are:
- urgent and emergency services (A&E) • medical care (including older people's care)
- surgery • critical care • maternity • outpatients
- services for children and young people • end of life care.

Additional services:
- diagnostic imaging • gynaecology and termination of pregnancy.

- whether there is administrative resource to follow up unacknowledged results
- the ease of access for clinicians to view reports alongside patient clinical information (such as EPR)
- whether specialties monitor their acknowledgement of results
- whether there is a process to check if the necessary action for a patient has happened.

5.4b.8 Inclusion of these elements in the core service frameworks for all appropriate services may focus attention on this patient safety risk.

5.4b.9 The majority of CQC inspectors will not have expertise in radiology. Several of the radiology SMAs said that without such knowledge it may be difficult to identify the weaknesses of processes in place. However, this can be mitigated by prompting inspectors to ask about important risk controls in the key lines of enquiry.

**Summary**

5.4b.10 The HSIB investigation found that the core service frameworks used during CQC inspections could be strengthened to ensure evidence is gathered regarding important risk controls such as monitored acknowledgement of results.

## HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION

**Recommendation 2018/042:**
It is recommended that the Care Quality Commission amends all appropriate core service frameworks to include risk controls identified in this report, to mitigate the risk of significant abnormal findings not being followed up.

# 6 SUMMARY OF THE INVESTIGATION FINDINGS, SAFETY RECOMMENDATIONS AND OBSERVATIONS

## 6.1 Findings

- There is wide variation in practice in how unexpected significant radiological findings are communicated to clinicians. There is also considerable variation in how findings are acknowledged by clinicians, if they are at all. There is very little assurance that the actions indicated by the findings have been taken.

- Unexpected significant radiological findings may be communicated by telephone, electronic or paper-based systems, and involve a variety of policies and procedures. It is often a multi-step process, involving a number of individuals and information systems; this increases the risk of errors.

- Monitored acknowledgement of radiological findings is an important component of a reliable system and requires dedicated time and resource. Monitored acknowledgement is not in place in many trusts.

- Opening a report and generating a read receipt is an unreliable form of acknowledgement. A more robust risk control is for acknowledgement to be a separate, distinct action. That said, acknowledgement does not guarantee action has been, or will be, taken. A system that provided assurance that necessary actions had been completed would best mitigate risk. Current IT infrastructure in many trusts means this is not feasible in the short term.

- There are often many steps before a patient is informed of an unexpected significant radiological finding. These steps provide opportunities for error.

- Inspection of trusts by the Care Quality Commission is limited in scope in relation to the communication and follow-up of radiological findings. Inspections do not look at whether a monitored acknowledgement system and other risk controls necessary for a reliable system are in place.

- There is no nationally agreed list of what constitutes an unexpected significant finding that should trigger an alert. Some trusts have developed lists to standardise when alerts should be triggered by radiologists and to create a common expectation for clinicians.

## 6.2 Safety Recommendations, Observations and Actions

### HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATIONS

**Recommendation 2019/039:**
It is recommended that the Royal College of Radiologists, working with the Society and College of Radiographers and other relevant specialties through the Academy of Royal Medical Colleges, develops:

**1** principles upon which findings should be reported as *'unexpected significant', 'critical'* and *'urgent'*

**2** a simplified national framework for the coding of alerts on radiology reports

**3** a list of conditions for which an alert should always be triggered, where appropriate and feasible to do so.

**Recommendation 2019/040:**
It is recommended that NHS England and NHS Improvement's patient safety team takes steps to ensure providers are aware of the safety recommendations in this report and act to implement the key findings regarding risk controls such as a monitored acknowledgement system for critical, urgent and unexpected significant findings.

**Recommendation 2019/041:**
It is recommended that NHSX develops a method of digitally notifying patients of results. This should be used to inform patients of unexpected significant radiological findings after an agreed timeframe. It should be developed in conjunction with the Royal College of Radiologists. The notification system should be tested and evaluated.

**Recommendation 2018/042:**
It is recommended that the Care Quality Commission amends all appropriate core service frameworks to include risk controls identified in this report, to mitigate the risk of significant abnormal findings not being followed up.

## HSIB MAKES THE FOLLOWING SAFETY OBSERVATIONS

There is an established model of radiology departments requesting a CT scan for chest X-rays referred from GPs that show possible lung cancer. Two trusts are extending this to chest X-rays referred from the emergency department.

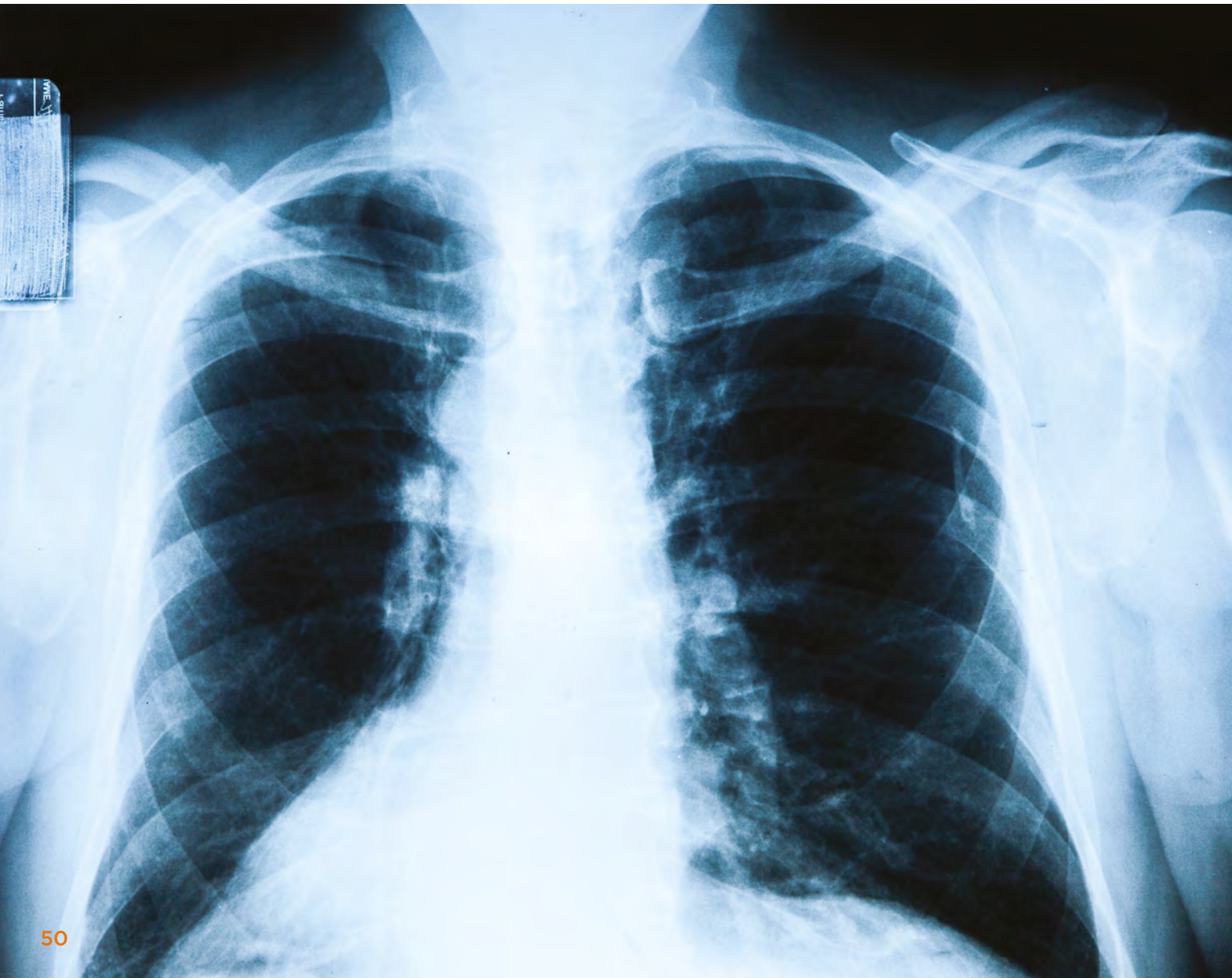
It would be beneficial for this practice to be evaluated.

**Observation to the Royal College of Radiologists:** Given the likely wider use of artificial intelligence in the future, some standardisation of radiology reports may be required. It would be beneficial for this to be evaluated.

## SAFETY ACTIONS CARRIED OUT AND/OR IN PROGRESS

The Academy of Medical Royal Colleges has written a statement endorsing the need to ensure clinicians act on alerted radiological findings and that a monitored acknowledgement system is in place in all local organisations.

Whether this is a single centralised system or specialty-specific process is for local decision depending on the available infrastructure.



# APPENDIX: PRACTICE EXAMPLES

## A.1 Site visits

A.1.1 The investigation visited three trusts with different IT infrastructure which had monitored acknowledgement systems in place for alerted findings. The investigation observed their risk control processes in situ. By doing this, the investigation gained a better understanding of the workflow and factors that impact on the processes. The trusts were based in Cambridge, Nottingham and Brighton.

A.1.2 The investigation observed the process for unexpected significant findings. Consideration was given to the specific example, as per the reference event, of a chest X-ray requested by the emergency department (ED) showing an unexpected finding of a possible lung cancer.

A.1.3 The investigation also visited a trust based in Redhill to learn about its plan to request a CT scan, direct from radiology, for all X-rays identifying possible lung cancer. In addition, the investigation talked to consultants based in Birmingham about their fast-track CT clinic, the evaluation of which has been published [51]. HSIB investigators also conducted telephone conversations with staff from other trusts who made contact with HSIB following publication of the Interim Bulletin on HSIB's website. These conversations provided further evidence of the challenges associated with implementing risk controls and informed this report.

A.1.4 The practice examples detailed in this section are not intended as exemplars but rather to share how trusts with different infrastructures are trying to improve the reliability of radiology results follow-up. The names of the trusts visited have been included in this report to aid cross-learning and contact between trusts.

## A.2 Addenbrooke's Hospital (Cambridge University Hospitals NHS Foundation Trust)

A.2.1 The investigation met with three ED consultants, an ED secretary, a consultant radiologist, and the Chief Clinical Information Officer (CCIO) for the Trust.

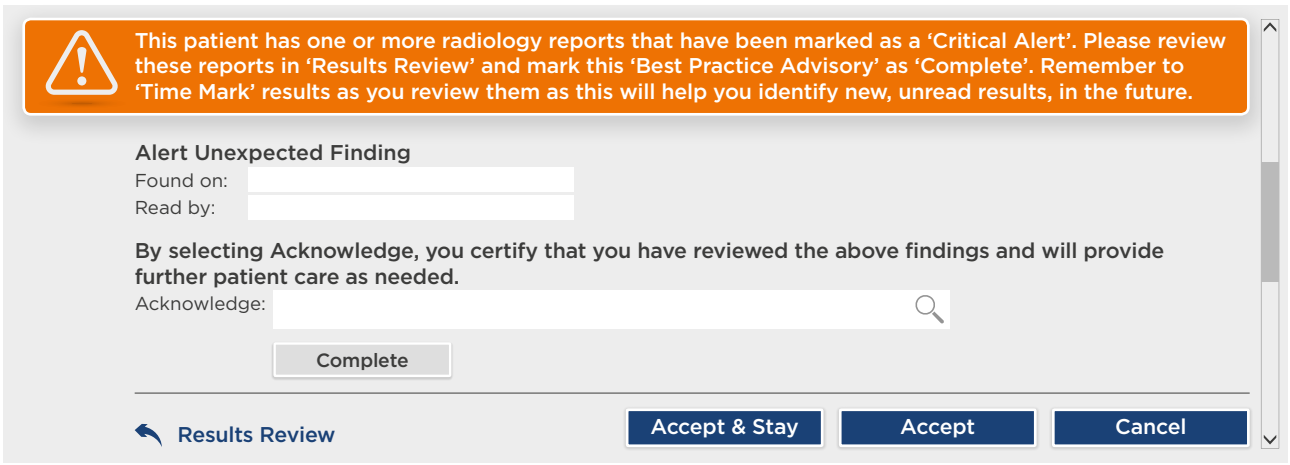
A.2.2 The Trust introduced an electronic patient record system (EPR) in 2014 and radiology reports are integrated within this. A clinician can, therefore, open a radiology report and in one click view this alongside the patient's clinical records and other information such as test results, upcoming tests and outpatient appointments.

A.2.3 The investigation was told that when the EPR system was introduced, it was set up slightly differently for different departments based on their needs and workflows.

A.2.4 The CCIO noted the importance of team – rather than individual – responsibility for results given the working patterns of doctors. He said it was easy to set up constituted pools for teams to access patient records, including radiology reports, for review and to follow up results. If doctors are on leave, or have left the Trust, this means results are still actioned in a timely way.

A.2.5 Alerted results are sent automatically to a results *'In Basket'* in the EPR and an alert message also appears on the patient's electronic clinical record (Figure 2).

**FIG 2 ALERT MESSAGE ON A PATIENT'S ELECTRONIC CLINICAL RECORD**



A.2.6 The hospital has an acknowledgement system in place for alerted results. This is currently monitored on a weekly basis by the CCIO. This is a duty the CCIO has taken upon himself to do, rather than being an agreed part of his job or accepted Trust process.

A.2.7 The process is as follows:

- The CCIO pulls a report every Sunday of unacknowledged, alerted radiology reports. He estimated that 20% of alerted reports were unacknowledged.
- Each report is checked alongside the patient's clinical records and other information to see if appropriate action has been taken. For example, if the radiology report recommended a CT scan, the CCIO will check if a CT scan appointment has been made.
- If there is evidence that appropriate steps have been followed, no further action is taken. The alert remains, unacknowledged, on the patient's records.
- If there is no evidence that appropriate action has been taken in two weeks, the CCIO will identify the consultant caring for the patient and email them regarding the unacknowledged report. No further action is taken. He estimated eight out of 10 consultants respond to his email. This means that for an estimated two out of 10 there is no response and no further action taken to follow up the unacknowledged result.

A.2.8 Commenting on the process, the CCIO noted that over time the number of unacknowledged reports had reduced. Furthermore, he pointed out that from monitoring use of the results area, it was evident that *"more and more senior clinicians are spending time looking at results"*.

A.2.9 The investigation was informed that the hospital plans to require acknowledgement of all narrative results in the near future. This includes radiology and other results such as histopathology and virology. The plan is for each specialty to be responsible for monitoring their performance by generating an automated report each week (or agreed time period) of unacknowledged reports. These unacknowledged reports will require someone to check evidence of actions and chase up as necessary.

A.2.10 The CCIO explained that the oversight of this proposed system has not yet been agreed. It may involve a performance dashboard for scrutiny at a higher level.

A.2.11 The investigation observed a consultant in the ED going through the process of review and acknowledgement of abnormal results (including unexpected significant findings). The investigation also met with an ED secretary to observe and hear about their role in results management.

A.2.12 The process is:

- Radiology reports (along with all other tests) are accessed via a results *'In Basket'* on the EPR. Each day an ED secretary goes through the radiology reports and sifts out the normal ones.
- Those sifted as normal are then reviewed by a second secretary providing a second, independent check. Those agreed as normal are acknowledged by clicking a *'Done'* icon, which acts as acknowledgement of the report. The secretary advised that she had received training for this role and built up experience over years. She pointed out that if she had any doubt at all she left the result for consultant review.
- If the radiology report shows abnormal findings (including those alerted as unexpected and significant), the secretary checks if the patient is in hospital. If so, the secretary identifies the consultant responsible for the patient's care and forwards the report for acknowledgement and follow-up to them. If the patient has been discharged from the ED, the secretary checks the appropriate action has been taken, for example a fracture clinic appointment if the report identifies a fracture. If there is evidence of appropriate action taken, this will be acknowledged.
- The secretary explained that prior to EPR, a similar process existed with paper results. As she noted, the paper system was far less secure as it relied on internal post and there was, for example, the risk of paper being mislaid or a delay in paper notes being available.
- Each day, an ED consultant is assigned to an *'admin, training and teaching'* (ATT) shift. The shift is usually 09:00 hours to 17:00 hours. During this shift, the consultant will review and

follow up abnormal results (such as unexpected significant radiological findings), troubleshoot queries coming through ED receptionists (such as from GPs regarding information received on patients discharged from the ED) and plan or deliver teaching sessions.

- The investigation observed an ED consultant going through abnormal results, alongside the patient's clinical information, and checking whether action had already been taken (such as a further test arranged or clinic appointment made). Where appropriate action had been taken, the consultant acknowledged the result by clicking a *'Complete'* icon. The result then disappeared from the results In Basket.

- If the patient had been admitted to hospital but was now discharged, the consultant responsible for their care was identified and the result forwarded to them for acknowledgement. On occasion, when felt appropriate, the ED consultant bleeped a clinical team to have a telephone conversation about the result.

- The investigation observed queries being brought to the ED consultant intermittently from the ED receptionists for the consultant to follow up.

- In the scenario of a chest X-ray for a patient discharged from ED showing a possible lung cancer, the ED consultant said she would either telephone the patient to advise them of the need for further investigation, or telephone and speak to the GP to discuss who would do this. The ED consultant would refer the patient to the respiratory clinic for a two-week appointment and inform the multidisciplinary team co-ordinator. The consultant said that the ED would not request a CT scan as they would not want the CT results to go back to them, so they leave this for the respiratory team to arrange.

- The ED consultant explained that if there are outstanding actions needed for a result by the end of the ATT shift, the result will remain in the In Basket to be dealt with the next day. Information about action required is messaged to the consultant rostered for ATT the next day.

A.2.13 The ED consultants and secretary, and radiology consultant, all commented on the benefit of easy ('one-click') access to patient information alongside the radiology (and other tests) report. They said that this made it easy to track patients and actions taken in response to test results. The ED consultants also noted the value of dedicated time rostered each day for this important clinical activity. One summed this up as being *"key to an effective system"*.

A.2.14 The consultant radiologist said that for GP-referred chest X-rays showing a possible lung cancer, they would refer to the respiratory team for an appointment and inform the GP of the result, who would then inform the patient. As with the ED, radiology would not request a CT scan.

A.2.15 The consultant radiologist told the investigation that she kept a list of the results she had issued an alert on, and checked that the required action had happened, such as further test arranged or clinic appointment made. She pointed out that acknowledgement doesn't necessary mean actions have happened and as it was *"easy to track patients on the system"* she followed up in this way. The consultant said that she thought many of her colleagues did this too. Although not a formal system, this vigilance demonstrates a worry about what can go wrong and preparation for possible problems which are recognised features of high-reliability organisations [38].

**Summary**

A.2.16 The EPR, and ability to view radiology reports within this, means clinicians can easily track patients and their results and identify action taken or outstanding.

A.2.17 The hospital has a two-step acknowledgement system in place for alerted results. This is monitored by one individual who has chosen to take responsibility for this. The follow-up of unacknowledged results is limited.

A.2.18 The hospital plans to implement an acknowledgement system for all results. The oversight of this has not been finalised.

A.2.19 The ED has a process for acknowledgement of all results. The process involves filtering of normal results by a secretary.

A.2.20 Processes in place are supplemented by the vigilance of individual radiologists following up alerts they've issued and by individual consultants in other specialities. This is enabled by the IT infrastructure.

## A.3 Brighton and Sussex University Hospitals NHS Trust

A.3.1 The investigation met with: an ED consultant; the Imaging Information and Performance Manager; the Clinical Lead (and consultant radiologist) for the division within which radiology services are located; a Reporting Pathway Co-ordinator; and the Safety Lead for radiology (and consultant radiologist).

A.3.2 The Trust has an electronic alerting system for critical, urgent and unexpected significant findings. The nature of the findings is also included on the report. The Trust has a monitored two-step acknowledgement system for alerted results.

A.3.3 The alerting process is:

- The reporting radiologist/radiographer adds a code to the report which automatically generates an email to the clinician's inbox (Figure 3). The subject header of the email says *'Critical', 'Urgent'* or '*Unexpected significant'* finding. The Imaging Information and Performance Manager said that generic email addresses had been offered but were only taken up by one specialty to allow monitoring by the secretary.
- Critical and urgent findings are communicated to the referrer or his/her senior by telephone at the time of reporting, as well as being sent by email as an alert.
- The email requests that the reader clicks *'reply'* and *'send'* to confirm acknowledgement. The sent reply is automatically registered by the software.
- If the clinician receiving the alert has a query, such as *'this is not my patient'*, the email includes an email address to direct queries to.
- Reminder alerts are sent on day seven, 14, and 21 if the report is unacknowledged.

**FIG 3 EXAMPLE OF AN ALERT EMAIL**


A.3.4 In 2015 a six-month review of imaging was carried out to identify the percentage of reports that were alerted. For X-rays, 0.3% were alerted, which equates to 231 reports. The highest number of alerts was issued for CT scans (3.5%).

A.3.5 The Imaging Information and Performance Manager said that, although the processes now were safer than the paper and manual processes that preceded them, his aim was to embed the acknowledgement of reports within a system that allowed clinicians to see the reports alongside all other patient information. This would make it easier for clinicians to put the results in context and identify whether findings had been acted upon. He noted that this capability had been developed for the ED and offered a solution for the rest of the Trust. The manager pointed out the risk associated with the reliance on emails with the current alerting system. He pointed out that emails can easily be overlooked, especially given the volume of email correspondence consultants have to manage.

A.3.6 The Imaging Information and Performance Manager pointed out the risk that still exists with acknowledgment of radiology reports, that is, clinicians may click to confirm acknowledgement without fully reading or actioning findings. Essentially, it was a way of reducing the risk to as low as reasonably practicable. Requiring acknowledgement provides a means of ensuring critical, urgent and unexpected significant results are brought to clinical attention but does not guarantee that action will be taken.

A.3.7 The Trust does not have a full EPR. The majority of patient information, including inpatient medical notes, is in paper records making it difficult to track patients through the system and identify whether appropriate action has been taken in response to radiological findings.

A.3.8 The investigation was informed how the risk control processes had evolved over time. For example, an unexpected significant finding of a possible cancer used to be alerted and an additional code applied to the report. This automatically sent an email to the lead for cancer multidisciplinary team meetings to assign for discussion at the relevant group. This was a risk control suggested by the National Patient Safety Agency's Safer Practice Notice. However, because of the variation between radiologists about when an alert may be used, and differences in criteria between cancer groups, the practice ceased in 2015. The process was simplified and streamlined to one code being applied for an unexpected significant finding of possible cancer, with the clinician being responsible for deciding if referral was appropriate.

A.3.9 Radiology takes responsibility for initiating the next steps for GP-referred chest X-rays showing a possible lung cancer. The process is:

- Where lung cancer is suspected, GPs request a chest X-ray using a specific form. The expectation is that the GP will have advised the patient that a CT scan may be required and that they will be contacted by the hospital if so. The Imaging Information and Performance Manager and Reporting Pathway Co-ordinator said that patients sometimes seemed unaware they may be required to undergo a CT scan when they were contacted. Overall, however, they said the process worked well. An information leaflet, designed to explain the process, was developed for GPs to give to patients at the time of requesting their X-ray.

- If the chest X-ray shows a possible cancer, a CT scan is requested in the GP's name and the X-ray report advises the GP of this.

- A member of the radiology administration staff informs the patient of the need for a CT scan and the date of the appointment.

- The CT scan report is sent to the GP and, depending on the findings, the GP is asked to refer the patient for a chest clinic appointment within two weeks.

A.3.10 The Imaging Information and Performance Manager explained that in the past, unacknowledged reports had been escalated to senior clinicians in the organisation. However, these clinicians did not have time to chase up individual reports and it became apparent that there was a need to dedicate staff resource to this activity – at least until such time that the IT infrastructure made it easier to track patients.

A.3.11 Reporting pathway co-ordinators, who form part of the radiology administration team, monitor and chase up unacknowledged alerted results. The co-ordinators keep a spreadsheet of the actions they take. The Reporting Pathway Co-ordinator who met with the investigation team estimated that approximately three hours each day are spent on this activity. She shared recent examples such as:

- Physically going to the ED to speak to administration or clinical staff to help identify where a patient was located, and who the responsible consultant was, so that she could send the report to them.

- Making telephone calls to secretaries asking them to clarify with consultants if action indicated by the radiology report had been taken and requesting they acknowledge the report.

- Contacting secretaries and/or the doctor on call to check required action for a patient had been taken when an *'out of office*' or 'I've left the Trust' reply came back in response to an alert sent to a consultant's email address. These replies generate an error message on the IT software which the co-ordinators review.

- Informing GPs of unexpected significant findings for patients discharged from hospital.

A.3.12 The Trust is in the process of implementing electronic requesting of tests. The divisional Clinical Lead noted that this will help with issues such as being able to read the signature of referrers. It will also mean that inclusion of essential information such as contact details can be made obligatory before a request can be submitted.

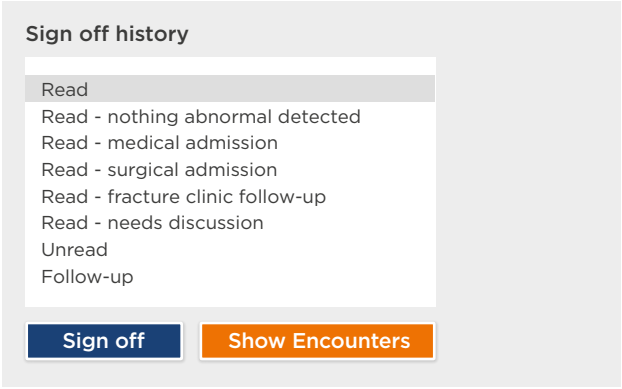
A.3.13 The Trust does not have a prescribed list of conditions that should trigger an alert. The Clinical Lead discussed the pros and cons of such lists. He saw the benefits of standardising, particularly for teleradiology companies. However, he pointed out the difficulty of compiling a meaningful list and the risk of blame if a reporting radiologist/radiographer failed to alert something on the list. The Safety Lead for radiology highlighted the training requirements for both in-house radiologists/radiographers and teleradiology companies that would need to accompany the introduction of a list. He thought defining the meaning of critical (emergency action required as soon as possible), urgent (medical evaluation required within 24 hours), and unexpected significant (cases where the reporting radiologist has concerns that the findings are significant for the patient and will be unexpected by the referrer) was more useful. These definitions were in the Trust's radiology policy for communication of results.

A.3.14 The Safety Lead for radiology emphasised that alerts need to be a *"safety net"* to help teams check important results in a timely manner, but did not diminish the need for specialties to have a system in place for review of results. He added that relying on radiology alerts alone was not a reliable or safe system: *"The more they expect us to chase the more we'll get it wrong."* He noted that one of the problems with increasing the number of conditions triggering an alert was that it risked alerts losing their significance. The Safety Lead thought it would be good practice for all results (normal and abnormal) to be acknowledged once the IT infrastructure was in place to enable this. That is, infrastructure which allows clinicians to see all their results, along with relevant clinical information, in a single place, and enables them to easily mark the results as read and/or actioned.

A.3.15 The ED opted out of the email alerting system because the volume of test results meant a different process was required. Approximately two years ago, the ED consultants and IT team worked together to develop an in-house software solution – a portal that pulls clinical data from many other IT systems. This enables the ED to review radiology reports alongside all electronic clinical information (such as clinic letters, discharge summaries and blood results), making timely acknowledgement more achievable. The Imaging Information and Performance Manager said that previously a doctor would need to log into lots of different IT systems to get different bits of information, making it very time consuming. The Director of IT described the portal as the *"single pane of glass"* through which all clinical information could be accessed. The plan is to roll out its use across the Trust.

A.3.16 The ED consultant noted the ease of making changes during the development of the system as the IT team was in house. The investigation observed the two-step acknowledgement of alerted findings and the consultant using the drop-down options (Figure 4) that list common outcomes of review and reason for acknowledgement. There is also a clinical notes section to record actions taken.

**FIG 4 DROP-DOWN OPTIONS GIVING RATIONALE FOR ACKNOWLEDGEMENT**




A.3.17 The ED consultant estimated the review of results took three to four hours each day. He said there would be about 200 reports (which included normal and abnormal radiological findings) to review each day.

A.3.18 The system allowed results to be filtered in different ways such as by date, by unread results, by normal results and by critical, urgent and unexpected results.

A.3.19 The ED consultant queried the benefit of reviewing reports that were normal and not requiring any action. He pointed out that X-rays will have been reviewed by an ED doctor already and the radiologist/radiographer review was to check nothing was missed. In his opinion, a third review by an ED doctor brought no gain, took up pressured time and potentially created distraction from those images that were abnormal and needed

attention. The consultant had proposed that a statement be added by reporting radiologists/radiographers to completely normal reports saying *'no action required'* so that these could be filtered out of review. This had been agreed for musculoskeletal X-rays where the ED doctor has not identified a fracture from their review and the radiologist/radiographer report confirmed this. The ED consultant believed this could usefully be extended to other X-rays that were normal, such as chest X-rays.

A.3.20 The divisional Clinical Lead's view was that it was *"probably not helpful"* to expect the ED to acknowledge all reports. He agreed there were some normal reports that could be filtered out allowing attention to be focused where it was most needed. He noted that discussions were ongoing about where this might apply beyond musculoskeletal X-rays when the absence of a fracture is confirmed.

A.3.21 The ED consultant highlighted the issue of delays in reporting, particularly for chest X-rays, which meant that missed diagnoses may come to light several weeks after a patient's attendance in the ED.

A.3.22 The ED consultant said that if an unexpected significant finding of a possible lung cancer was found on a chest X-ray, an electronic referral was made to the respiratory clinic and the GP informed. The ED does not request a CT scan or inform the patient.

A.3.23 The investigation heard that junior doctors had been responsible for looking at radiology results, but this was under review at the time of the site visit due to a breakdown in the process which had resulted in a backlog of results.

A.3.24 In common with other trusts, the ED took responsibility for acting on radiological findings for patients discharged by them. If the patient had been admitted to hospital under the care of a specialty team, it was expected that the speciality team would take responsibility for acting on radiological findings.

A.3.25 It seemed that the process of forwarding results to the relevant specialty team had not always happened. There was agreement that this was necessary to reduce risk, particularly as unexpected significant findings are often unrelated to a patient's current condition so not a focus of the clinical team.

A.3.26 The ED consultant explained that when results were forwarded, the ED would acknowledge the result so there would be no way of knowing if it had been read by the clinician with responsibility for acting on it. The consultant recognised the risk posed by this and thought there may be a way to amend the IT system, so acknowledgement remained a requirement of the responsible clinician.

**Summary**

A.3.27 The Trust has a monitored two-step acknowledgement system for alerted radiological findings.

A.3.28 Staffing resource is dedicated to monitoring and chasing up unacknowledged alerted reports.

A.3.29 The ED has a process for review and acknowledgement of results. A small number of reports are filtered out from needing review by agreement with the radiology service, which adds a *'no action required'* comment to the report.

A.3.30 The Trust does not have a fully integrated EPR. An in-house solution has been developed for the ED. It is planned to roll this out to the whole Trust for reviewing and acknowledging results.

## A.4 Queen's Medical Centre (Nottingham University Hospitals NHS Trust (NUH))

A.4.1 The investigation met with a consultant radiologist[43], two members of the radiology administration team, two members of the ED administration team and a consultant in acute medicine who is the Chief Clinical Information Officer (CCIO) and was instrumental in setting up the risk controls.

A.4.2 NUH joined with eight other trusts to form the East Midlands Radiology Consortium. One aim of the consortium is to help manage workload by pooling resources. To achieve this aim, the trusts share some of the same IT software, which enables them to view and report each other's radiology studies where this is desirable.

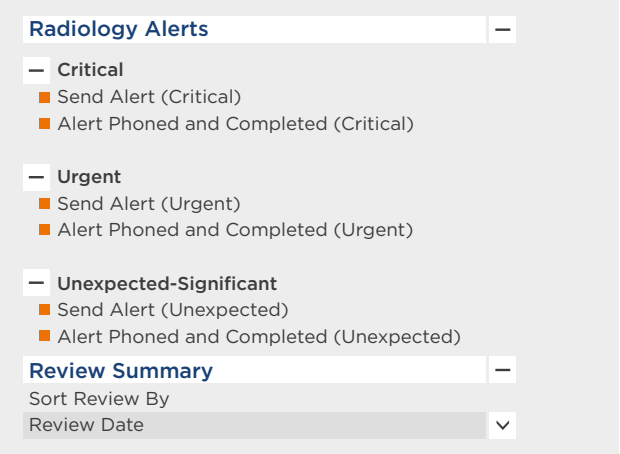
A.4.3 NUH has a *"best of breed"* clinical IT system. This means rather than a single clinical system, containing EPR and other clinical

[43] The radiologist is the national lead for imaging for a national programme called Getting It Right First Time (GIRFT). The programme is designed to improve clinical quality and efficiency within the NHS by reducing unwarranted variations. GIRFT also encourages the sharing of best practice between trusts and proposes improvements within specialties.

information, a number of different systems are used. The investigation observed four different interconnected IT systems in use, each containing different clinical information and serving different functions. The hospital still uses paper medical records for inpatients. Once patients were discharged from hospital, their records were scanned into an IT system and so were available to view electronically. Patient electronic observations, inpatient handover and task management information are stored on a different IT system. The CCIO said that although there were different IT systems in use, considerable work had taken place to enhance the usability of each and he thought, overall, the *"best of breed"* strategy works well.

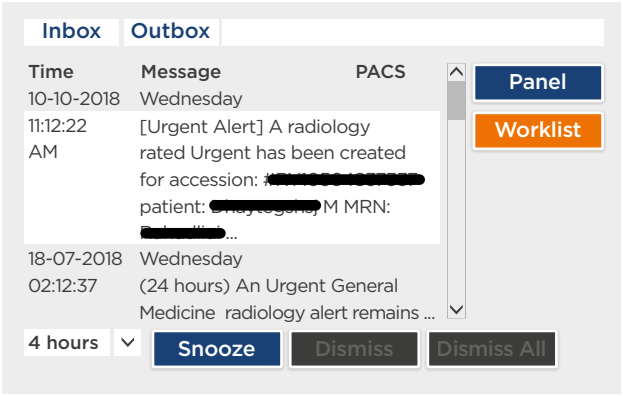
A.4.4 The Trust has guidelines that detail which radiological findings should trigger an alert, but there is also scope for individual clinical judgement on the part of the reporting radiologist/radiographer. The investigation observed the consultant radiologist creating an alert. There are two tick-box options for alerts (Figure 5) and the radiologist/radiographer must tick one of them: either that an alert has been sent or that a telephone conversation has taken place with the referrer or clinical team which has resulted in acknowledgement of the result. The consultant radiologist described the IT software used to generate alerts as very simple, *"just one click"*. When the new PACS (picture archiving and communication system) was first introduced across the radiology consortium the consultant said it was sometimes very slow and unstable, resulting in a backlog of X-rays waiting to be reported. This situation has now improved.

## FIG 5 ONE-CLICK RADIOLOGY ALERTS




A.4.5 Alerted results appear as a *'pop-up'* on the referrer's computer screen (Figure 6). By clicking on the pop-up, the clinician is taken to the full report. Further pop-ups are automatically activated until the alert is acknowledged; the frequency depends on the alert activated.

## FIG 6 RADIOLOGY ALERT 'POP-UP'




A.4.6 Alerted results are also automatically sent electronically to a clinician's email inbox (Figure 7) with a link to the report. Reports are not integrated within an EPR and to access clinical information the clinician must cut and paste the patient's hospital number into other IT systems.

## FIG 7 EMAIL SENT TO REFERRING CONSULTANT (IDENTIFIED FROM THE REQUEST FORM)

**Unexpected and Clinically Significant Radiology Alert**

A radiology alert rated Unexpected-Significant has been issued from Nottingham University Hospital Trust for one of your patients, with the radiology study accession no. RXXXXXXXXXXXX.

Please log on to acknowledge the alert.

A.4.7 The Trust's guidelines for the alert process state that specialties need to ensure they have administrative support to check for unacknowledged alerts. Identified administration staff also receive the pop-up alerts and are expected to monitor that they have been acted upon.

A.4.8 Teleradiology companies reporting findings that require an alert will contact the radiology administration team via email to advise them of this.

A.4.9 The consultant radiologist said that for GP-referred chest X-rays showing a possible lung cancer, a CT scan is requested directly by the reporting radiologist or radiographer. The fact that a CT scan has been requested is included on the report. An email is also sent to

a generic *'lung cancer chest X-ray to CT'* inbox monitored by specialist nurses. The X-ray result is also alerted.

A.4.10 In March 2018, the hospital implemented a monitored acknowledgement system for alerted radiological findings. The consultant radiologist described it as a *"huge relief"* to have this in place. She said that prior to this, there had been serious incidents as a result of reported findings not being acted upon because they had not got to the right person or been overlooked for various reasons. She noted the large volume of tests from areas such as the ED, which requests about 210 X-rays a day.

A.4.11 Unacknowledged alerts Trust-wide are chased up daily by unit co-ordinators – these staff are based in radiology and take responsibility for different types of imaging (one co-ordinator is responsible for X-rays, another for MRI and another for CT scans). The unit co-ordinators spend 25-30 hours per week chasing up unacknowledged reports.

A.4.12 Timescales have been set for acknowledgement of alerted results. A critical finding, which will have been phoned to the referrer or clinical team, should be acknowledged within 24 hours; urgent and unexpected significant findings within three days. After this time, the unit co-ordinators escalate to named managers in each specialty to follow up with relevant staff. There are also designated consultants they can escalate to if the matter cannot be resolved by the manager.

A.4.13 The investigation met with two members of the ED administration team who are instrumental in managing the acknowledgement of alerted findings for the department.

A.4.14 The process is:

- Alerted findings go to designated members of the ED administration team and the consultant referrer named on the request form.
- An ED consultant and ED registrar is rostered every day to deal with alerted radiological findings. A member of the administration team assigns the alerted reports to the rostered consultant or registrar as appropriate: all CT/MRI/chest X-rays go to the consultant; general/simple X-rays go to the registrar.
- If the patient was admitted under the care of another specialty, the ED consultant or registrar will ask the ED administrator to send the report to the relevant ward if the patient is still in hospital. If the patient has been discharged, the report is emailed with a *'read receipt'* to the patient's consultant. This is noted, and the report acknowledged. The administrator keeps a log if no read receipt is received and the email (and report) is forwarded to the consultant's secretary to chase up.
- When the ED consultant or registrar has reviewed the report, they comment on actions they have taken and may request actions by the administrator (such as sending a copy letter to the GP or the report to the inpatient team). They will then acknowledge the report. The administrator checks comments and completes any requested actions, recording these on a separate database so there is a record of their actions which can be cross-checked against the alert.
- If a chest X-ray shows a possible lung cancer, the ED organises a CT scan and a multidisciplinary team two-week referral if the patient was discharged by them. (If the patient was admitted to hospital, the report will be sent to the team responsible for their care to organise the CT scan and referral, if appropriate.)
- Radiological findings not alerted are not reviewed.

A.4.15 The hospital is in the process of rolling out acknowledgement of all radiology results across all specialties[44]. Initially, this will apply to all inpatients, eventually outpatients too. This means both abnormal (which includes critical, urgent and unexpected significant findings) and normal results will need to be acknowledged. Commenting on this, the acute medical consultant told the investigation that *"there is no 'normal' radiology result – these are all reports of a clinical opinion, it is not as discrete as a laboratory result being within a defined normal range"*. He gave examples of results that were not alerted (and that previously he may not have reviewed) but which indicated the need for some form of patient follow-up which is now being arranged but previously wouldn't have happened.

A.4.16 The acknowledgement of all results was piloted in July 2018 in the acute medical receiving

[44] The investigation was informed that, eventually, it is anticipated all results would be acknowledged (such as pathology and microbiology) using the orders and results module in the electronic health record system.

unit (a unit into which GPs can directly refer patients). Results of the pilot, such as range and average time to acknowledge, had not been collated at the time of the investigation's visit.

A.4.17 The investigation met with the acute medical consultant to observe him using the system for acknowledgement of results. Referrers can also view all patients on their ward(s) and see whether any have unacknowledged results. So, if an individual referrer was on leave, the outstanding result could be seen by others (Figure 8).

A.4.18 The acknowledgment is a two-step process: the report must be opened, and a box must be ticked to confirm acknowledgement of having read the report. Comments can be added regarding action taken or rationale for report acknowledgement.

A.4.19 Unacknowledged results that have not been alerted will not be chased up in the same way as alerted results. The acute medical consultant told the investigation that the plan is for a performance dashboard to be created that shows acknowledgement of results for monthly review at governance meetings. He also discussed the possibility of acknowledgement of results being part of doctors' appraisals.

**Summary**

A.4.20 NUH is part of a radiology consortium which was set up to help manage capacity and demand.

A.4.21 The Trust has a *"best of breed"* approach to clinical systems, with multiple interconnected systems performing various different functions.

A.4.22 The hospital has a monitored two-step acknowledgement system for alerted radiological findings. Significant staffing resource is dedicated to monitoring and chasing up unacknowledged results.

A.4.23 The hospital is rolling out acknowledgment of all radiological findings following a pilot on an acute medical unit.

## A.5 University Hospitals Birmingham NHS Foundation Trust

A.5.1 The investigation spoke to a consultant radiologist and a consultant respiratory physician[45] about the Trust's fast-track CT service. This service is for GP-referred chest X-rays showing suspected lung cancer. The consultant respiratory physician was very involved with setting up the service and its evaluation. He noted the national focus on improving the time to diagnosis for lung cancer which provided impetus for trialling new pathways [11] [27].

A.5.2 A fast-track CT scan is requested as a triage to identify those who need a clinic appointment and to speed treatment decisions for those who do not. The process is as follows:

- Patients are offered a direct appointment for a CT scan within one week of the suspicious chest X-ray. Radiologists reporting these chest X-rays add a standard text to a radiology report which then triggers the CT appointment via the CT booking clerk.
- Patients are informed of the need for a CT scan by a member of the radiology administration staff, who has had brief communication skills training for this task. The administration staff member also takes information necessary to ensure it is safe to proceed with the CT scan.
- The CT scans are reviewed in a weekly meeting with a chest physician, radiologist, and lung cancer nurse specialist. Only those patients with a CT scan indicating a lung cancer are offered an urgent lung cancer clinic appointment.
- Those patients not recalled to clinic are sent a letter reassuring them that nothing of immediate concern was found on the scan but advising them to make an appointment with the GP to discuss the results in more detail.

**FIG 8 LIST OF WARD PATIENTS. A RED CROSS DENOTES UNACKNOWLEDGED ALERTED RADIOLOGY RESULTS (PATIENT NAMES HIDDEN)**

[45] The consultant respiratory physician was one of the authors of the published article regarding the fast-track CT pathway. He is also the Clinical Director of Audit and Accreditation for the Royal College of Physicians and Chair of the British Thoracic Society Specialist Advisory Group.

- The GP receives a letter informing them of this and a copy of the CT report. If the GP has ongoing concerns, the patient is referred to the respiratory clinic via the normal routes.

A.5.3 This process of fast-track CT scan referral direct from radiology was evaluated for its effect on clinic efficiency, waiting times and patient satisfaction. The findings, which have been published, were that this pathway led to more effective use of clinic appointments, reduced time from referral to diagnosis and, as a result, increased patient satisfaction [51]. The pathway also reduces the risk of failure to follow up results by reducing the number of steps in the patient's pathway and therefore reducing the opportunity for error.

A.5.4 The benefits of using a CT scan to triage patients to lung cancer clinics are mirrored elsewhere. The Cancer Vanguard (Greater Manchester Cancer) found that approximately 75% of patients could be discharged from the cancer pathway after their initial CT scan, reducing demand in outpatient clinics [27].

A.5.5 The consultant respiratory physician pointed out the resources involved with this system, particularly in relation to radiology administration staff. These staff members orchestrate the process by contacting patients, booking CT scans and managing the follow-up appointments and communication as indicated.

A.5.6 The investigation asked the consultant respiratory physician about extending the service to patients discharged by the ED. He said that *"in principle"* he thought this was a good idea and would avoid the scenario of possible lung cancer findings not being followed up. The consultant noted that issues such as who the CT results would go to and who would pay for the scan (the Trust or local commissioners) would need to be agreed.

**Summary**

A.5.7 As an initiative to improve time to diagnosis for lung cancer, a fast-track CT service was set up for GP-referred patients whose chest X-ray shows possible lung cancer.

A.5.8 Patients are contacted about the findings and need for CT scan by a member of radiology administration staff who has received brief communication skills training.

A.5.9 Only patients with a CT scan indicating lung cancer are offered an urgent lung cancer clinic appointment.

A.5.10 Evaluation of the service found that this pathway led to more effective use of clinic appointments, reduced time from referral to diagnosis and, as a result, increased patient satisfaction.

## A.6 Surrey and Sussex Healthcare NHS Trust

A.6.1 The investigation met with a consultant radiologist[46] and a consultant respiratory physician to hear about the plan for the radiology service to request a CT scan for all chest X-rays showing possible lung cancer. This will include GP-referred X-rays, those requested by the ED and those requested by a clinical team for a patient currently in hospital.

A.6.2 The planned process is:

- The consultant radiologist identifies a possible lung cancer on a chest X-ray.
- If this is an unexpected finding, an electronic alert will be generated (by adding a code to the report) and the result will be sent to the EPR inbox of the clinician who requested the test, advising them that a CT scan has been requested.
- The consultant radiologist will electronically request a CT scan in the name of a respiratory consultant (it has been agreed they will be in the name of the respiratory consultant involved in setting the process up).
- The lung multidisciplinary team co-ordinator is automatically electronically notified of the CT request. The co-ordinator tracks that CT results have been received and acted upon.
- The CT scan is booked by a member of administration staff and the patient is informed of the appointment.
- The CT scan result is sent electronically to the respiratory consultant named as the test requester, and is automatically copied to the consultant's colleague (to provide cover in case of absence), and the lung multidisciplinary team co-ordinator.

[46] This consultant is also National Clinical Director for Diagnostics, NHS England.

- The CT report is reviewed and, depending on the findings, a chest clinic appointment made. For patients currently in hospital, there will be a conversation with the clinical team caring for the patient about whether a respiratory review or clinic appointment is most appropriate.

A.6.3 The consultant radiologist explained that for patients in hospital, the clinical team could cancel the CT scan if the clinical condition of the patient meant it was not appropriate.

**Summary**

A.6.4 To improve time to diagnosis for lung cancer, the radiology service plan to request a CT scan for all chest X-rays showing possible lung cancer.

## A.7 Key themes from practice examples

A.7.1 Monitoring of acknowledgement for alerted findings, and chasing up unacknowledged findings, takes significant time and resource. Chasing to ensure the required actions have been taken involves communicating across multiple teams and multiple systems of care in a way that IT systems cannot easily do.

A.7.2 IT infrastructure that allows clinicians to see radiology reports with easy access to other clinical information is critical to support acknowledgement and actioning of results.

A.7.3 The EDs had processes in place to review reports. The processes involved filtering out normal results, albeit by different means, so that clinicians' time was given to abnormal findings. This practice was reflected in conversations with other trusts the investigation spoke with. The example of one of the trusts visited, which was working with radiology to agree reports that required no further action, may be a useful model to draw on.

A.7.4 The two trusts that were aiming to roll out acknowledgement of all results were planning to monitor acknowledgement through performance dashboards at clinical governance meetings. Details regarding whether, and who, would be responsible for chasing up unacknowledged reports had not been finalised. The Trust that had piloted acknowledgement of all results had done so in the medical unit where the consultant who led the acknowledgement project worked. The results, therefore, may not be representative of how acknowledgement would work in other areas of the Trust. The pilot had not been fully evaluated at the time of the site visit as the process was still being embedded.

A.7.5 The principle of EDs taking responsibility for patients they have discharged but not for those admitted to hospital was reflected in the trusts visited. In the scenario of a chest X-ray showing a possible lung cancer:

- If referred by a GP, radiology for the most part was initiating a CT scan but one trust was referring to the respiratory team to do this.
- If referred by the ED, only one radiology service was planning to initiate a CT scan. The rest were giving responsibility for next steps to the ED.

  Of note, in the latter scenario, the investigation spoke with another trust that was planning to pilot the radiology department requesting a CT scan.

# 7 GLOSSARY

This section lists some of the frequently used abbreviations that are cited in this report.

| | |
|---|---|
| **AI** | Artificial intelligence |
| **CQC** | Care Quality Commission |
| **ED** | Emergency department |
| **EPR** | Electronic patient record |
| **MDT** | Multidisciplinary team |
| **NPSA** | National Patient Safety Agency |
| **PACS** | Picture archiving and communication system |
| **RCEM** | Royal College of Emergency Medicine |
| **RCR** | Royal College of Radiologists |
| **RIS** | Radiology Information System |
| **StEIS** | Strategic Executive Information System |
| **SMA** | Subject matter advisor |

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HEALTHCARE SAFETY INVESTIGATION BRANCH

# FURTHER INFORMATION

More information about HSIB – including its team, investigations and history – is available at **www.hsib.org.uk**

If you would like to request an investigation then please read our **guidance** before submitting a safety awareness form.

**@hsib_org** is our Twitter handle. We use this feed to raise awareness of our work and to direct followers to our publications, news and events.

## CONTACT US

If you would like a response to a query or concern please contact us via email using **enquiries@hsib.org.uk**

We monitor this inbox during normal office hours - Monday to Fridays (not bank holidays) from 0900hrs to 1700hrs. We aim to respond to enquiries within five working days.

To access this document in a different format – including braille, large-print or easy-read – please contact **enquiries@hsib.org.uk**