

CONFIDENTIAL REPORT

FINAL REPORT

**OF A SERIOUS INCIDENT REQUIRING
INVESTIGATION (SIRI)**

prepared by
Code A

panel held on
12.08.15

Incident Number: WEB-37699

STEIS Number: 2015/20932

CLINICAL SERVICE CENTRE
Clinical Support

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EXECUTIVE SUMMARY

Brief incident description (a concise incident description)	
<p>Mr J had a chest x-ray on 06.05.15 which showed an abnormality in the left lower lobe (LLL). When comparison was made by the reporting Radiologist with a chest x-ray that Mr J had a year previously via ED, it was felt that this abnormality had been visible on this earlier image. The LLL abnormality has since been confirmed via CT biopsy as squamous cell carcinoma of the left lung lower lobe.</p>	
Incident date:	15.05.14 (date of attendance at ED)
Incident type:	Delayed diagnosis
CSC/Specialty:	Clinical Support, Diagnostic Imaging
Actual effect on patient / service (e.g. damage to myocardium)	Delayed diagnosis of lung carcinoma, resulting in potential missed opportunity for curative treatment
Actual severity of incident (outcome for patient and/or service)	Red

Level of investigation conducted
Full Serious Incident Requiring Investigation and Root Cause Analysis

Involvement and support of patients and/or relatives (E.g. meetings to discuss the incident / any family liaison appointed / sources of independent support)
<p>Mr J was seen in respiratory fast-track clinic by Dr B on 19.05.15 following a CT scan. Dr B explained to Mr J and his wife that he may have a cancer and that a CT (computed tomography) biopsy was required to confirm. It was also explained at this meeting that the abnormality seen on his chest x-ray on 06.05.15 may have been present on the chest x-ray taken a year previously in ED, and that this may have delayed his diagnosis. Dr B explained that an investigation would begin to ascertain whether this abnormality could have been seen earlier. A Duty of Candour letter explaining the investigation process and apologising to Mr J was sent to him in the post on 18.06.15 by Mrs H, Imaging Services Manager. Following presentation of the SIRI report at the Serious Incident Review Group (SIRG), scheduled for 25.08.15, Mr J will be invited to a meeting to discuss the report findings.</p>

Detection of incident (How and/or when the incident came to light)
<p>Mr J attended for a chest x-ray on 06.05.15, whilst this x-ray was being reported by a Consultant Radiologist comparison was made with his x-ray taken 1 year previously. It was noted that there was an abnormality visible on this earlier chest x-ray which may not have been followed-up or investigated.</p>

Conclusion (A discussion as to the outcome of the investigation and why the incident occurred. It must be evidentially linked to information in the report)
<p>There was a failure of the ED CT2 Doctor to identify a potential abnormality on the chest x-ray on 15.05.14 There was also a failure to provide a formal radiology report on this chest x-ray.</p>

Care and service delivery problems (Care Delivery: relates to direct provision of care arising during the process of care – usually actions or omissions by members of staff. E.g. (1) care which deviated beyond safe practice (2) the deviation had at least a potential direct or indirect effect on the adverse outcome for the patient, member of staff or 'general public'. Service Delivery: failures identified, which are associated with the way a service is delivered and the decisions, procedures and systems that are part of the whole process of service delivery)

Care Delivery Problems

Failure of the ED Doctor (CT2) to note an abnormality of the left lower zone on Mr J's chest x-ray taken during an ED attendance for a fall in May 2014.

Service Delivery Problems

Failure of diagnostic imaging to report on ED chest x-ray from 2014.

Contributory Factors (Factors which affect the performance of individuals whose actions may have an effect on the delivery of safe and effective care to patients and hence the likelihood of Care or Service Delivery problems occurring. Contributory factors may be considered to either influence the occurrence or outcome of an incident, or to actually cause it. Generally speaking, the removal of the influence may not always prevent incident recurrence but will normally improve the safety of the care system; whereas removal of root causes will be expected to prevent or significantly reduce the chances of recurrence)

Root Cause(s) (The prime reason(s) why the incident occurred; fundamental factors, removal of which will either prevent, or reduce, the chances of a similar type of incident occurring in similar circumstances in the future. Root causes should be meaningful – not sound bites such as communication failure – and there should be a clear link, by analysis, between root CAUSE and EFFECT on the patient)

Failure of the ED Doctor to note an abnormality on the ED chest x-ray in 2014

Failure of diagnostic imaging to report on the ED chest x-ray in 2014.

Lessons Learned (Key safety and practice issues identified, which may not have contributed to this incident but from which others can learn)

Key Themes (To be identified at the SIRI panel)

Recommendations (Courses of action that are recommended to address the problems identified and analysed during the investigation. They must be directly linked to the root causes and lessons learned and should be clear but not detailed – detail belongs in the action plan.

Review of the current Trust policy for evaluation of x-ray images and escalation of concerns to Trust Board via CSC risk register.

Review of current provision of chest x-ray interpretation teaching for ED doctors.

Discussion of this case at the Imaging Discrepancy Meeting

Dissemination and discussion of report findings at ED Clinical Governance meeting

Dissemination and discussion of report findings at Imaging Clinical Governance meeting

Arrangements for sharing learning (How lessons learned / changes in practice have been/will be shared locally/Trust-wide/with other organisations: by whom and by when)

Case to be discussed at the Radiology Discrepancy Meeting to raise awareness of all the Imaging Consultants

Case to be discussed at the Imaging and Clinical Support Clinical Governance meetings

Case to be discussed at the ED Clinical Governance meeting.

Case to be included in the ED Governance newsletter

MAIN REPORT

Incident description and consequence (concise incident description and outcome for patient, staff, service or organisation)	
<p>On 06.05.15 Mr J attended the Imaging Department at Gosport War Memorial Hospital for a chest x-ray, having been referred by his General Practitioner (GP) with weight loss, worsening breathing and chronic obstructive pulmonary disease (COPD).</p> <p>This chest x-ray was reported the next day by a Consultant Radiologist who felt that there was an abnormality present in the left lower zone.</p> <p>Whilst composing his report, the reporting Radiologist made comparison with a chest x-ray taken of Mr J via the Emergency Department (ED) on 15.05.14 when he attended following a fall. The CT2 ED Doctor who reviewed the image noted "NAD" (nothing abnormal detected) in the medical notes, and this chest x-ray was not formally reported by a Radiologist at the time of Mr J's attendance to ED. The Consultant Radiologist reporting on the most recent chest x-ray felt that the abnormality may have been visible on the earlier x-ray.</p> <p>Immediate actions taken by Radiologist on 07.05.15: Urgent respiratory clinic referral made Datix incident report completed Imaging Services Manager informed of potential missed abnormality on an x-ray GP informed of urgent respiratory referral</p>	
Incident date:	15.05.14
Incident type:	Delayed diagnosis
CSC/Specialty:	Clinical Support / Diagnostic Imaging
Actual effect on patient / service (e.g. damage to myocardium)	Delayed diagnosis of lung carcinoma, resulting in potential missed opportunity for curative treatment
Actual severity of incident (outcome for patient and/or service)	Red

Pre-investigation risk assessment		
A Potential Severity (1 – 5)	B Likelihood of recurrence at that severity (1 – 5)	C Risk Rating (C = A x B)
5	3	15

Background and context (Brief description of how the patient came to be with us and any contextual issues – such as staffing levels/new service arrangements – that may have impacted on the outcome)
<p>Referral for chest x-ray via GP with weight loss, worsening breathing and COPD.</p> <p>At the time of Mr J's chest x-ray in ED in May 2014, ED chest x-rays were being reviewed only by the ED Doctor, and their opinion recorded in the medical notes, unless a formal Radiologist report was specifically requested.</p>

Terms of Reference
<p>Aim</p> <p>The aim of the investigation is to establish the facts of the case. This will include <i>what</i> happened (which will be documented using a tabular time line), to <i>whom</i>, <i>when</i> and <i>where</i>. Once the facts</p>

have been established the aim of the investigating team will be to establish the reasons *why* this incident occurred, including contributory factors and root causes

Objectives

To establish whether failings occurred in care and/or treatment
 To identify learning points and improvements rather than apportion blame
 To establish how a recurrence may be effectively reduced or eliminated
 To formulate realistic recommendation which address the root causes and learning points; to improve systems and services

Outcomes

To present the key findings in a report, as a record of the investigative process
 To prepare an action plan for implementation of recommendations made
 To provide a consistent means of sharing learning locally and nationally as appropriate
 To ensure that provision is made for monitoring the action plans developed

48 hour panel membership (Names will be removed when report is submitted to the PCT/SHA)

Name	Grade/designation
	Chair / Medical Director
	Consultant Respiratory Physician
	General Manager Clinical Support
	Senior Risk Advisor
	Superintendent Radiographer

The investigation team (Names will be removed when report is submitted to the PCT/SHA)

Name	Grade / Designation
	Superintendent Radiographer

SIRI panel membership (Names will be removed when report is submitted to the PCT/SHA)

Name	Grade / Designation
	Chair/Medical Director
	General Manager Clinical Support
	Senior Risk Advisor
	Superintendent Radiographer

Scope and level of the investigation (Describe briefly what the investigation covered - including start and end points - and list services/organisations involved)

Review of Datix incident report
 Review of images and radiological reports on PACS and CRIS
 Review of patient notes and clinic letters
 Review of emails between respiratory and imaging Consultants
 Review of IMR report compiled for panel meeting following the incident

Investigation type, process and methods used (E.g. root cause analysis of single incident, medical records review, staff interviews'. This should also include the tools used e.g. five 'whys', fishbone, incident decision tree)

Review of images with Consultant Radiologist and Respiratory Consultant to decide whether abnormality was visible on initial chest x-ray
 Root Cause Analysis

Statements / Interviews (Names will be removed when report is submitted to the PCT/SHA)	
Names and Grade	Involvement
Dr B, Consultant Respiratory Physician	Discussion about patient care and prognosis
Dr W, Consultant Radiologist	Review of x-rays
Dr H, ED Consultant	Discussion about review of initial ED x-ray

Involvement and support of patients and/or relatives (E.g. meetings to discuss the incident / any family liaison appointed / sources of independent support)
Mr J was seen in respiratory fast-track clinic by Dr B on 19.05.15 following a CT scan. Dr B explained to Mr J and his wife that he may have a cancer and that a CT (computed tomography) biopsy was required to confirm. It was also explained at this meeting that the abnormality seen on his chest x-ray on 06.05.15 may have been present on the chest x-ray taken a year previously in ED, and that this may have delayed his diagnosis. Dr B explained that an investigation would begin to ascertain whether this abnormality could have been seen earlier. A Duty of Candour letter explaining the investigation process and apologising to Mr J was sent to him in the post on 18.06.15 by Mrs H, Imaging Services Manager.

Involvement and support provided for staff involved (E.g. counselling / line management support / full debrief)
Discussion of the incident and Mr J's case will be discussed at the Radiology Discrepancy Meeting Support from the Educational Supervisor for the Emergency Department Doctor who reviewed Mr J's chest x-ray when he attended in 2014.

Chronology of events (A list of the key events or, if very lengthy, put in as Appendix 1)
Appendix 1

Detection of incident (How and/or when the incident came to light)
The incident came to light when Mr J attended for a chest x-ray via his GP due to worsening breathing symptoms, and the Consultant Radiologist reporting on it made comparison with a chest x-ray taken a year previously. He was concerned that the abnormality may have been visible on a chest x-ray taken a year previously, but had not been detected or acted upon.

Conclusion (A discussion as to the outcome of the investigation and why the incident occurred. It must be evidentially linked to information in the report)
Failure of ED CT2 Doctor to identify a potential abnormality on the chest x-ray on 15.05.14 Failure to provide a formal radiology report on this chest x-ray.

Notable practice (Exceptional actions taken; not those actions which should just be <u>normal</u> daily practice)

Care and service delivery problems (<u>Care Delivery</u> : relates to direct provision of care arising during the process of care – usually actions or omissions by members of staff. E.g. (1) care which deviated beyond safe practice (2) the deviation had at least a potential direct or indirect effect on the adverse outcome for the patient, member of staff or 'general public'. <u>Service Delivery</u> : failures identified, which are associated with the way a service is delivered and the decisions, procedures and systems that are part of the whole process of service delivery)
Care delivery problems Failure of the ED Doctor (CT2) to note an abnormality of the left lower zone on Mr J's chest x-ray taken during an ED attendance for a fall in May 2014.

Service delivery problems

Failure of diagnostic imaging to report on ED chest x-ray from 2014.

Contributory factors (Factors which affect the performance of individuals whose actions may have an effect on the delivery of safe and effective care to patients and hence the likelihood of Care or Service Delivery problems occurring. Contributory factors may be considered to either influence the occurrence or outcome of an incident, or to actually cause it. Generally speaking, the removal of the influence may not always prevent incident recurrence but will normally improve the safety of the care system; whereas removal of root causes will be expected to prevent or significantly reduce the chances of recurrence)

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Failure of the ED Doctor to note an abnormality on the ED chest x-ray in 2014
Failure of diagnostic imaging to report on the ED chest x-ray in 2014.

Lessons learned (Key safety and practice issues identified, which may not have contributed to this incident but from which others can learn)

Key Themes (To be identified at the SIRI panel)

Recommendations (Courses of action that are recommended to address the problems identified and analysed during the investigation. They must be directly linked to the root causes and lessons learned and should be clear but not detailed – detail belongs in the action plan.)

All future ED chest x-rays to have a formal radiology report.
Review of current teaching of ED Doctors to review chest x-rays for disease.
Discussion of this case at the Imaging discrepancy meeting
Review of this case at the Imaging Clinical Governance meeting
Review of this case at ED Clinical Governance meeting

Arrangements for sharing (How lessons learned / changes in practice have been/will be shared locally/Trust-wide/with other organisations: by whom and by when)

Case to be discussed at the Radiology Discrepancy Meeting to raise awareness of all the Imaging Consultants
Case to be discussed at the Imaging and Clinical Support Clinical Governance meetings
Case to be discussed at the ED Clinical Governance meeting.
Case to be included in the ED Governance newsletter

Distribution List

Individuals Patient – Mr J

Internal Groups/Committees Serious Incident Review Group (SIRG)

External Clinical Commissioning Group (CCG)

Author

Name	Code A	Job Title	Superintendent Radiographer	Date	30.07.15

Appendix 1

Chronology of Events	
Date and Time	Event
05.05.15	Mr J was seen by Dr SG at his family surgery with weight-loss, worsening breathing and chronic obstructive pulmonary disease (COPD). He was given a request form for a chest x-ray
06.05.15 3.40pm	A chest x-ray was performed at Gosport War Memorial Hospital
06.05.15 5.00pm	Mr J's chest x-ray was reviewed and reported by a Consultant Radiologist, SC, who stated: <i>"Comparison has been made to a previous film. Within the left lower zone there is an ill-defined 5cm mass which would be in keeping with a primary bronchogenic carcinoma. No other lung lesion is identified. Suggest respiratory fast track referral. Copy Faxed to GP. Copy to Faxed Chest Clinic."</i> Whilst writing his report, SC made comparison with a chest x-ray Mr J had one year previously during an Emergency Department (ED) attendance following a fall. Consultant Radiologist SC felt that the abnormality may have been visible on this earlier image. The ED x-ray did not receive a formal radiology report at the time, and the CT2 doctor who reviewed the x-ray in ED noted "NAD" (nothing abnormal detected) in the medical notes.
07.05.15 4.00pm	Dr B, Respiratory Consultant reviewed the chest x-ray following Mr J's referral to clinic, and emailed SW, Radiology Chief of Service, alerting him to the potential missed diagnosis, and her concern that the abnormality may be cancer.
07.05.15 4.15pm	As part of the investigation process, Mr J's original chest x-ray from 15.05.14 is reviewed by another Consultant Radiologist, SW, who confirmed that an abnormality was visible on the x-ray.
08.05.15	Datix incident report completed by Consultant Radiologist SC
12.05.15	First amber incident meeting held, decided to maintain at amber pending results of CT.
14.05.15	Mr J is seen at his GP surgery by Dr R to inform him of the referral to respiratory fast-track for further investigation of the abnormality noted on his chest x-ray.
19.05.15	Mr J is seen in Fast-Track Respiratory clinic. He underwent a CT (computed tomography) scan which was reported straight away by Consultant Radiologist Dr W. The report conclusion states: <i>"Primary LLL (left lower lobe) bronchogenic carcinoma amenable to CT biopsy.."</i> Mr J was then seen in clinic the same day by Dr B, Consultant Respiratory Physician. Dr B informed Mr J under Duty of Candour obligation that an investigation into the circumstances surrounding his diagnosis would be

	held.
21.05.15	2 nd incident review meeting held. Decided that SIRI panel meeting required.
22.05.15	CT biopsy of Mr J's tumour was performed.
27.05.15	Whole body PET (positron emission tomography) scan performed for staging and to assess any lymph node involvement.
03.06.15	Lung MDT to review CT biopsy and PET scan. Biopsy confirmed squamous cell carcinoma left lower lobe. Dr B, Respiratory Consultant to request Endoscopic Ultrasound to ascertain node involvement, possible spread of the carcinoma and therefore suitability for surgery. Staged as probable T2b N2 M1a squamous cell carcinoma left lower lobe.
11.06.15	Amber incident panel meeting held to discuss incident and grading.
12.06.15	Referral made to Urology to investigate prostate activity seen on PET CT and raised PSA (13.1) which might indicate prostate pathology.
16.06.15	Endoscopic Ultrasound to perform Fine Needle Aspiration (FNA) of subcarinal node to determine whether lymph nodes were involved.
16.06.15	Amber panel meeting held. On discussion with Dr B, Respiratory Consultant it was felt that Mr J's tumour may have been suitable for resection if diagnosed on his original chest x-ray 1 year ago, therefore a full Serious Incident Requiring Investigation (SIRI) process should take place.
18.06.15	Duty of Candour letter sent to Mr J via post.
29.07.15	Update received by LB Superintendent Radiographer from Lung Cancer Nurse Specialist caring for Mr J. He was due to start sequential chemotherapy and radiotherapy on 23.07.15
12.08.15	Final SIRI panel meeting held, case scheduled for Trust Serious Incident Review Group (SIRG) on 25.08.15. Following this an invitation will be sent for Mr J to discuss the findings of the SIRI investigation if he wishes to do so.

Appendix 2

Action Plan (These must be directly linked to each recommendation)

No	Recommendation	Level	Action Required	Proposed date for completion	Lead for Implementation	Responsible for Monitoring
1.	Review current Trust policy for evaluation of x-ray images and escalation of concerns to Trust Board via CSC risk register		Radiology and Clinical Support management teams to review current processes for reporting of ED x-rays	December 2015	N C	J H
2	Review provision of chest x-ray interpretation teaching for ED doctors		ED Educational Supervisor to review x-ray teaching for ED Doctors	Begin by December 2015, then on-going	S H	S H
3	Discussion of case at Imaging Discrepancy Meeting		Discussion and sharing of learning amongst Radiologists	September 2015	S W	Completed
4	Dissemination and discussion of report findings at ED Clinical Governance meeting		Discussion and sharing of learning amongst ED medical teams	December 2015	S H	K S, ED Governance Coordinator
5	Dissemination and discussion of report findings at Imaging Clinical Governance meeting		Discussion and sharing of learning amongst Imaging Clinical Governance team	December 2015	N C	J H

