# PHT Radiology: Response & Lessons learned

## In response to Section 31: Diagnostic and Screening Procedures (July 2017).

## 1. Background

1.1. The Care Quality Commission (CQC) highlighted poor governance procedures at the Queen Alexandra Hospital (QA) in relation to interpretation of Emergency Department (ED) chest x-rays (CXR) following an inspection in May 2017. The CQC expressed concern that there was insufficient oversight and audit of non-radiologist interpretation of CXRs, and the Trust was told it must take immediate action to review risk and identify possible harm to patients.

1.2. Inspectors returned to the Trust in July to conduct a focused inspection of the outpatients and diagnostic imaging department at QA, at which point it was identified that a backlog of circa 23,000 chest x-rays, from the preceding 12 months, had not been formally reviewed by a radiologist or appropriately-trained clinician as was required by the existing PHT Plain Film Reporting Policy

1.3. Inspectors were told there had been three serious incidents where patients with lung cancer had suffered significant harm because their chest x-rays had not been properly assessed.

1.4. Following the inspection CQC placed four conditions on the trust's registration:

- The trust must take steps to prioritise and deal with the backlog of unreported images (including those taken before January 2017), assess the impact on patients, and notify any patient who is adversely affected in the line with the requirements of the Duty of Candour.
- There must be robust processes put in place to ensure that any images are reported on and risk-assessed.
- Details of how the backlog will be addressed must be submitted to CQC.
- The trust must send CQC weekly reports on the size of the backlog, and times taken for reports to be produced.

## 2. Process of Backlog Clinical Harm Identification & Review

2.1. Following the Section 31 Notice it was decided, and agreed with the CQC, that the following process would be followed.

- The Emergency Department (ED) backlog of plain films would be reported, for a "clinically relevant timescale", agreed to be 18 months, including all plain films back to the 1st March 2016. The large majority of these films were Chest X-rays (CXR) and this was also the group around which there was most clinical concern. However there were also a significant number of Abdominal X-rays (AXR) and spinal X-rays.

- It was scheduled to commence the backlog reporting in September 2017, with a trajectory to complete this in February 2018

- Radiology film reporting required outsourcing to private companies (In Health and MSI) who commissioned trained reporting radiographers to carry out the work. This was done on site at QA due to the difficulties in exporting large numbers of CXRs electronically.

- Additional funding was secured from the Trust to support this backlog reporting

- Those with significant findings would be annotated and appropriate follow up would be arranged. For CXR, this process was simplified such that any patients with a possible missed cancer were classed as "Significant Finding 1" with other pathologies being designated "Significant Finding 2". The large majority of those in the latter group were patients with likely chest infections. Other pathologies included cardiac failure and small pleural effusions.

- For any patients where there was concern that harm may have occurred, a Datix form would be completed, an SI process started and a full panel review would be undertaken. Duty of Candour would be followed, in all cases where appropriate.

- A Radiology Helpline was established and manned with dedicated staff for a period following the public press release of the CQC Radiology report, to aid in identifying any additional cases of concern, and to support those members of the public requiring reassurance. Thereafter, the helpline number remained active with any calls being diverted to a Radiology senior manager for action.

- Several patients were identified during this process that had already been managed through other routes and therefore investigated. These patients notes were further reviewed to ensure that there had been no significant delay in the diagnosis, which might have caused them harm. If there was any doubt on the outcome, a Datix form was submitted for full panel review, as per the de novo reporting process.

- CXRs flagged as having a significant finding were reviewed initially by a Senior Radiographer, in order to establish whether these patients had been either treated appropriately (by review of the ED notes), or had had appropriate clinical follow up.

- In any case where the outcome was uncertain, films were then reviewed by a chest radiologist, to decide what course of action should be taken. In general, patients with findings suggestive of infection, who had not had subsequent imaging (Finding 2), were offered a follow up CXR to assess if changes had resolved. Patients where a missed cancer was suspected (Finding 1) were referred to the Chest Physicians for further review.

- The backlog harm review was complicated by the fact that the reports of one of the reporters (a trainee radiologist) were found to contain a number of inaccuracies. Following audit of a sample of reports, the outsourcing company in question undertook to re-report all (n=1000) the CXRs initially viewed by this reporter. These re-reports have subsequently all been completed.

## 3. Prospective reporting

3.1. In parallel to the retrospective backlog review of unreported films, prospective reporting of all ED images was agreed, commencing November 2017, once additional outsourced reporting had been secured.

3.2. A further business case was required to support this development and the work was again commissioned from the outsourcing companies.

## 4. Oversight of the Harm Review and management of subsequent change decisions

4.1 A Clinical Advisory Group (CAG) was established, chaired by the Medical Director, with clear terms of reference to oversee the learning and ensure that decisions made during the review were externally benchmarked. Membership included:

- PHT radiologists
- PHT Chest physicians
- PHT Radiology Services Manager
- External Radiologist (UHS)
- External Chest Physician (UHS)
- General Practitioner

4.2 The CAG met fortnightly, after an initial phase of weekly meetings whilst establishing the process

## 5. Lessons Learned

### Clinical Harm identified

5.1 Reporting of the backlog of plain films (to 1st March 2016) was completed on schedule in mid-February 2018.

5.2 The total number of films reported in the backlog was 30,221

5.3 27 potential missed cancers have been identified by CXR review, 22 of which were on images performed at QA, although not necessarily in ED.

5.4 Of these, 1 case had been followed up appropriately for possible infection, so was not “missed”. 3 further cases have been classified as “No Incident” following investigation.

5.5 13 have been through a full panel review and 8 have been graded as No Harm, 2 as Low Harm and **2** as Severe. A 3rd case was difficult to classify due to no cross-sectional imaging being available at the time; due to the significant delay to

diagnosis however, this is best regarded as Severe Harm. Therefore a total of **3** cases have been classed as Severe Harm. One case of "No Harm" was re-opened following further review at the lung MDT.

5.6 5 potential missed cancers on CXRs performed at the ISTC have also been flagged. These have either been investigated internally, and/or notified to the ISTC.

5.7 5 CXR cases are currently under investigation (6 including the reopened case). All of these patients have already been seen by the respiratory team and investigated appropriately – some many months ago. In several cases, abnormalities on the preceding CXRs were only noted once the subsequent imaging was reviewed. Some of the findings are extremely subtle, but all cases will have Datix filled in for thoroughness.

5.8 A further 1 case noted a previously unreported large abdominal aortic aneurysm on AXR. An investigation determined that No Harm ensued from the delayed diagnosis.

5.9 Prospective reporting of ED films "caught up" with the forward demand, so that all plain films are now being reported within a week of being taken.

5.10 Out of a total number of 30,221 CXRs reviewed from the ED backlog, **3** patients have been found to have suffered severe harm as a consequence of the failure to report their CXRs (0.01%). Whilst a small number of cases are still going through the full SI process it appears unlikely that the numbers of significant harm will rise dramatically beyond this level.

5.11 The limited harm identified in other patients, where a diagnosis of cancer was delayed was mainly due to one of several factors: the advanced state of disease at presentation; limited treatment options; or rapid disease progression, leading to very poor prognosis.

5.12 The accepted rate of "discrepancy" for trained reporters on CXRs is quoted as 3-5%. This includes all missed abnormalities, the most significant being a lung cancer. It would appear from the backlog review data that failure to report CXRs through the ED has not led to a significant increase in the levels of harm identified for those patients compared to if the films had been reported by a trained radiographer/radiologist.

5.13 From a total number of films reported of approximately 43,000 (backlog and prospective cases), significant findings have been identified in 1982 patients. This figure includes the suspected cancers outlined above. The large majority of these cases were for suspected infective changes.

5.14 403 patients were offered appointments for repeat CXR.

- 249 were normal or stable on recall, or showed findings not considered significant.

- 133 either declined, did not respond, or did not attend. Non-responders were telephoned on more than one occasion, where possible. A letter was also sent to their GP, containing a copy of the CXR report.
- 8 were living elsewhere; a letter was sent to their GP with relevant information
- 7 patients died before recall; notes and imaging review has not shown any suspicion that the findings on CXR contributed to death.
- 6 were referred to Respiratory for further clinical assessment.

5.15 Any significant findings are now being addressed via the ED Daily Checks folder in PACS, with cases reviewed by an ED consultant.

## 6. Resource & logistic implications

6.1 Without sufficient in-house reporting capacity, the project was dependent on outsourced plain film reporting

6.2 Costs incurred, to the middle of February 2018, was £196,690. Prospective reporting of ED films commenced in November 2017, so part of this in part represents the cost of prospective reporting.

6.3 Costs incurred in setting up and manning the Helpline were difficult to quantify. The Helpline received a total of **251** calls, of which **70** required a call back once looked into. Of these only **8** required active further investigation

## 7. Governance around PHT Radiology Plain Film Reporting Policy

7.1 An independent in-depth analysis of the historic circumstances leading up to, and the subsequent handling of decisions around the reporting of plain film X-Rays, was outside the Terms of Reference of this group and has been undertaken by an external company –Verita, the full report of which is to be published. The feedback from Verita regarding steps taken so far and further plans now in place to improve corporate and clinical governance is welcome and encouraging. The arrangements for the corporate identification, assessment and management of operational and strategic risk will continue to be developed, as will plans to enhance multi-disciplinary analysis of incidents, complaints, performance and audit to enable triangulation and improved learning. The review and revision of Trust governance systems to reflect the incoming clinical structure began with a governance workshop on 18 April 2018, and further work will reflect Verita's observations and recommendations.

## 8. Changes and Recommendations supported by the CAG

8.1 The PHT plain Film Reporting Policy will be updated to include mandated reporting of CXRs taken as inpatients as well as in ED. Though the incidence of severe harm identified through this Harm Review was lower than anticipated, reporting of CXRs is now standard practice in other Trusts and PHT would be an outlier in not doing so.

8.2 There is a lack of published evidence and cost/benefit analysis generally to support this decision and the data from this Harm Review could be published to help inform national debate on the issue.

8.3 Priority must be given to training of advanced practitioner radiographers to undertake CXR reporting

8.4 The current follow up of infection diagnosed on CXR is inadequate and a robust protocol needs to be introduced to address this. This is particularly important with the increase in incidence of adenocarcinoma spectrum disease, which can mimic infection.

8.5 A new process is being drawn up for follow up of chest infection diagnosed in QA, either in ED, or as an in-patient. This will need to be agreed with the Clinical Commissioning Groups, as ideally this needs to be driven by the patient's GP, with follow up films being performed at the site most convenient for the patient.

8.6 A robust protocol should be introduced for follow up of suspected infective change detected on CXR.

8.7 Training of all staff groups in interpreting CXRs should be implemented, to minimise delays in detecting significant abnormalities, but also to avoid over-diagnosis of anatomical variations and technical factors (which can result in inappropriate requesting of CT scans).

## 9. Other Observation

9.1 There remains insufficient radiology staff resource to undertake CXR reporting. This situation will be amplified following introduction of the updated PHT Plain Film reporting policy.

9.2 Plans have been put in place to train 2 PHT Radiographers in chest X-Ray reporting. Training takes 2 years, and commenced in November 2017, so it is anticipated that fully-trained candidates would be in post by November 2019.

9.3 To report all CXRs prospectively will require more than 2 radiographers, so it is planned to develop further funded advanced practitioner posts to deliver the CXR reporting service. Due to the intensity of the training, and consequent time requirement from Chest radiologists, these posts will need to be staggered, and will also require a further business case.

9.4 It would be necessary to expand the scope of practice of existing appendicular reporting radiographers to include trauma axial reporting and non-trauma appendicular and axial reporting. This will also require additional funding.

9.5 PHT will be reliant on outsourcing companies to provide capacity for some time to come. The radiology department needs to receive the appropriate funding to purchase these services.

9.6 Where feasible, demand management of CXR requesting should take place, so that images are only requested when clinically appropriate and not as a "routine" screen on admission.

9.7 Other steps might include:

9.8 Setting consultants a number of plain films to be reported in job plans; this has the risk of impacting on other work, such as cross-sectional imaging reporting

9.9 Increasing the number of CXRs reported by post Fellowship PHT radiology trainees; this has the potential to impact on training and, in any case, many of this group undertake attachments away from PHT

9.10 Advertising for staff grade level radiology posts to undertake large amounts of plain film reporting; very few appropriately trained doctors are available to fill such posts

9.11 Recruit new consultant thoracic radiologists; this should be considered, as cardiac imaging demand is also expanding, and more consultants will be needed to oversee training of, and to work alongside other reporting grades

9.12 Increase the level of training in interpretation of CXRs for non-radiological staff

9.13 All doctors are trained to varying degrees in the interpretation of CXRs; it should be noted that the ability to interpret CXRs varies, even amongst consultant radiologists. Some lung cancers are extremely difficult to diagnose on CXR and it is likely that some cancers would be missed, even if all films were reported by Consultant Thoracic radiologists.

## 10. Key messages

10.1 Out of a total number of 30,221 CXRs reviewed from the ED backlog, 3 patients have so far been found to have suffered severe harm as a consequence of the failure to report their CXRs (0.01%)

10.2 There is a lack of published data on risk/benefit of plain film reporting available

10.3 The vast majority of CXRs were interpreted sufficiently well by non-radiologists to enable patients to be treated appropriately. It has not been possible to assess the number of patients who received best care based solely on the timely and accurate interpretation of their CXRs by the ED team

10.4 PHT's Plain Film Reporting Policy is being amended to come in line with typical practice in other Trusts, though there is limited data beyond this Harm Review to inform that decision

10.5 The retrospective backlog reporting and additional prospective reporting has had a significant cost impact. Significant increased funding is required to support changes to the Plain film Reporting Policy, with full consideration of the various staffing changes required to implement this

10.6 The findings of this report could be publicised to help inform rational risk-based decision making with regards to Plain Film reporting nationally