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1. Executive Summary

- As a result of the commencement of a major review of x-ray reporting at two hospitals in Ireland involving a long term locum consultant radiologist at Lorn and Islands District General Hospital (LIDGH) in Oban and the coincidental expression of concerns by a GP practice regarding the accuracy of a number of x-ray reports by the same radiologist, it was decided to institute a Critical Incident Review of x-rays and ultrasound scans performed at LIDGH between 16 October 2007 and 15 May 2008.

- The review took the form of a Look Back of all chest x-rays, barium examinations and x-rays of children under 12 performed within the review period. The review was undertaken by an independent external consultant radiologist and consisted of the re-reporting of a total of 1697 images. The aim of the review was to identify if there had been any missed pathology within the radiological reporting process and to ensure that patients had received appropriate care. The results of the Look Back confirmed that there were no cases where any pathology missed in the original radiological report had a significant and detrimental effect on patient care, management or safety. (See Section 4.)

- Of the 1697 images reported by the external radiologist, 45 (2.6%) were judged to be Category 3, i.e. possible significant missed pathology. All of these reports were clinically reviewed by the Locality Acute Clinical Director (a consultant physician), the Community Health Partnership (CHP) Clinical Director (a GP) and the relevant referring clinician. It was determined by these reviews that on no occasion, was detriment caused to any patient as a result of the possible missed pathology within the original x-ray report.

- The referring clinicians of all ultrasounds undertaken within the review period (totalling 435) were requested to clinically review the cases and to consider whether these should be repeated. 92 patients were referred for repeat scans, 63 of whom accepted the offer. All of these scans were undertaken between July and October 2008 by Raigmore Hospital Radiologists or by the Oban Ultrasonographer. The Look Back confirmed that two ultrasound scans identified ongoing morbidity which was likely to have been present at the initial investigation where there had been an effect on clinical management and outcome. In both cases this led to prolonged discomfort of the patients but did not affect their eventual recovery. (See Section 4.)

- The overall incidence of potential missed pathology falls within the limits of professional acceptability previously laid down by the Royal College of Radiologists and other professional bodies.
2. **Introduction and Background**

2.1 **Setting the Scene**

From June to November 2008, a review of x-ray and ultrasound investigations reported by two consultant radiologists at Lorn & Isles District General Hospital (LIDGH) in Oban was undertaken by NHS Highland. The review was prompted by notification of a review to be undertaken in Ireland relating to the clinical practice of the long term locum radiologist working in Oban between October 2007 and May 2008.

The review re-assessed all chest x-rays and barium enemas performed on adults, all x-rays performed on children aged under 12 years and ultrasound investigations reported by consultant radiologists at LIDGH from 16 October 2007 to 15 May 2008. The review was carried out to establish whether there were any patient safety concerns, to provide reassurance that radiographs and scans had been read correctly, to ensure that patients had been managed appropriately and that no harm had occurred to any patient. It involved reviewing 1,697 x-rays and 435 ultrasound scans. This was not a formal review of the professional competence of any individual consultant radiologist.

2.2 **Radiology Service in Oban**

Lorn and Islands District General Hospital (LIDGH) in Oban is one of the designated Rural General Hospitals within NHS Highland, servicing a population of approximately 40,000 in north and mid-Argyll. The x-ray Department is fully equipped and provides facilities in x-ray screening, general x-ray, ultrasound, CT and barium examinations. Day to day activity is managed by the Superintendent Radiographer supported by a team of qualified radiographers.

For a period in excess of five years up to late 2007 the radiology service was provided by a part-time, single handed consultant radiologist. This consultant was contracted to work three days per week performing plain film reporting, barium examinations and ultrasound scanning. The Oban based service also reported plain films for the Community Hospitals in Lochgilphead and Mull.

CT scanning was performed at LIDGH but reported by radiologists at the Royal Alexandria Hospital, Paisley under the terms of a Service Level Agreement with NHS Greater Glasgow and Clyde. MRI and all invasive radiology procedures were performed and reported for all Argyll and Bute patients in NHS Greater Glasgow and Clyde.

Radiology services for all other hospitals within the Argyll and Bute Community Health Partnership (CHP) (Cowal, Rothesay and Campbeltown) were provided directly by hospitals in NHS Greater Glasgow and Clyde under a separate Service Level Agreement whilst a further agreement was in place to cater for the radiology needs of residents of Helensburgh.
The professional link for the consultant radiologist at Lorn & Islands District General Hospital was through the Clinical Head of Services at the Royal Alexandra Hospital, Paisley. Professional links and supervision for radiographers in hospitals throughout Argyll and Bute CHP were with Superintendent Radiographers in NHS Greater Glasgow and Clyde, again under Service Level Agreements.

In November 2007, the CHP began a strategic review of radiology service provision throughout all of its hospitals. This action was taken because

a) The substantive consultant radiologist was known to be going to retire at some time in 2008 (although at that time no date had been intimated).

b) The existing Service Level Agreements with NHS Greater Glasgow and Clyde had been examined and it had been decided that an in-depth consideration of financial and clinical considerations would be appropriate, and

c) PACS, a system enabling x-ray scans and reports to be electronically transmitted between hospitals and health boards, was planned to be commissioned during 2008. This would offer a new level of flexibility in x-ray reporting in future.

In addition to these factors, Argyll and Bute CHP was being closely assimilated within NHS Highland and it was considered that closer clinical ties between both the radiologist and radiographers in Argyll and Bute and colleagues in Raigmore Hospital in particular may be worthy of consideration.

2.3 Background to this Review

In October 2007 the substantive consultant radiologist at LIDGH took sickness leave. His locum was arranged in the normal way through the medical staffing HR department in accordance with NHS Highland Locum Policies. The appointment of the locum consultant radiologist was approved by the Locality Acute Clinical Director, having discussed his CV with professional colleagues and the Locality Management Team. The locum had been appointed with the correct registration, qualifications and references from previous employers in Glasgow and Ireland that did not report any regulatory or competence issues.

The locum commenced the locum Consultant Radiologist position on 16th October 2007 and remained in place until the substantive consultant’s return from sick leave on 10th January 2008.
In early 2008 the substantive consultant confirmed his intention to retire in March 2008, although with annual leave due, his final working day was agreed as 19th February 2008. The radiology service review was incomplete at that time, so that it was agreed to offer the resulting locum consultant position to the same locum, after discussion with the substantive consultant and LIDGH consultants.

In mid-March 2008 an Incident (IR1) Form relating to two x-ray reports completed on behalf of the locum consultant was received by the Locality Manager in LIDGH. This had been raised by a Lochgilphead GP on 3 December 2007, but a failure in processing this incident timeously was evident, resulting in a significant delay. It had been passed between various offices before eventually arriving in Lorn and Islands District General Hospital. The Locality Manager immediately passed this to the Superintendent Radiographer, to identify the specific patients and to commence an investigation.

In early April 2008 the Lochgilphead GP raised the Incident Report issue in passing with the CHP General Manager. It was subsequently decided, in conjunction with the Locality Acute Clinical Director, and the CHP Clinical Director to request a consultant radiologist in Paisley to review these initial sentinel case x-rays and reports and another case, which had subsequently been raised by the same GP.

On further reflection and in the knowledge that an investigation was taking place, the Lochgilphead GPs then raised reporting concerns relating to a further nine radiological reports. These were added to the Initial Case Review.

The Radiology Clinical Director in Paisley decided that the service in NHS Greater Glasgow & Clyde would not be able to undertake this review. This resulted in an initial delay of four weeks.

Simultaneous to this decision, on Sunday 18th May 2008, the Locality Manager noted an article in the Mail on Sunday which identified the locum consultant radiologist in Oban as being under investigation in two hospitals in Ireland, where he was alleged to have misdiagnosed up to four cancer cases when employed at hospitals there previously.

He immediately drew this to the attention of the CHP General Manager, who escalated the incident to the NHS Highland Board Medical Director.

On Monday 19th May 2008, the locum consultant radiologist contacted the Locality Manager and submitted his resignation with immediate effect.

The original concerns raised by GPs in Lochgilphead in December 2007 related to two patients and were regarded as the sentinel cases. Over the subsequent three months further concerns were raised relating to the radiological reports of nine more patients. Concerns had been raised regarding the reporting accuracy of the locum consultant radiologist. The Initial Critical Case Review of all of the eleven original
Lochgilphead radiology cases were reviewed independently by the Head of Service of Radiology at Raigmore Hospital, Inverness. Missed pathology was confirmed in several of these cases.

Those x-rays which fell within the parameters of the Substantive Critical Incident Review (i.e. chest x-rays, barium examinations, ultrasound examinations and under x-rays in patients under 12 years old undertaken between 16 October 2007 and 15 May 2008) were considered within the Look Back Critical Incident Review process. For others falling outwith the review parameters, the reviewed reports were returned to the referring clinicians for further consideration. Full details of these initial critical cases is attached.

The decision of the Board Medical Director was that due to the potential seriousness of the allegations in Ireland combined with the nature of the concerns raised locally, a formal Critical Incident Review should be undertaken. A Critical Incident Review Team was established. The Critical Incident Review team met for the first time on 4 June 2008.
3. Risk Assessment and Methodology

The concern was that one or more patients may have been adversely affected because of a discrepancy in x-ray reporting in the LIDGH radiology service.

As a result of the events arising in Ireland, it was perceived that the locum consultant radiologist may have misreported or under reported in a manner similar to the allegations raised against him in Ireland. A telephone conversation between the Locality Manager at LIDGH and his counterpart at Our Lady’s Hospital, Navan, County Meath confirmed that the investigation in Ireland related to over 4000 x-ray reports. The result of this review was anticipated by the end June 2008 (but actually became available in early November 2008). This did not affect either the process or the outcome of this Critical Incident Review in LIDGH. It should be noted that both Consultant Radiologists involved in the scope of this Look Back Radiological Review were no longer working in the radiological department in Lorn & Islands District General Hospital Oban or in any other location.

3.1 Aims and Objectives of the Review

The scope of the Look-Back Review was to ensure that there had been no missed pathology in the radiological reporting undertaken in Oban between 16th October 2007 and 15th May 2008.

Patient safety considerations greatly determined the precise methods adopted for this review. The methodology for this review was developed specifically to identify any ongoing harm or disadvantage to patients, ensuring appropriate management had taken place and in addition to identify that any additional care or treatment required was delivered.

3.2 Interpretative variation in Radiology

Diagnostic radiology is a multi-step process where high-tech imaging equipment is used to assist health professionals in the diagnosis of a range of conditions. Sophisticated equipment is used to produce high quality images of the internal human body. Radiologists interpret and report on the images generated in order to diagnose or treat diseases and conditions. A critical step in diagnostic radiology is the radiologist’s interpretation and evaluation of these images, in the light of given clinical circumstances. This evaluation and interpretation, by its very nature, contains a significant element of human perception and judgement.

International studies suggest that the incidence of discrepancies and errors in general radiology practice lies between 2% and 20%. This range of errors is a worldwide phenomenon and includes all radiology departments, from academic departments to smaller district units. The number varies according to many factors, including the volume and complexity of the radiological images, the skill of the radiologist, and the reporting environment, including the age and condition of the radiology equipment. Published studies
on variation or error rates in interpreting chest radiographs, particularly in respect of detecting lung tumours, show remarkable variability.

In reviews of this kind, which involve a re-examination of radiological examinations, a phenomenon known as hindsight bias is internationally accepted as impacting to some degree on the results. The fact that reviewers are aware of the review process creates an unavoidable higher level of sensitivity and diagnostic reporting. This increases the likelihood of diagnosing pathology as opposed to spotting results that may reasonably have not been previously observed or reported. An extension of this is known as outcome bias, where when one knows that a condition has later been diagnosed, it becomes ‘easier’ to appreciate on review of an examination.

3.3 Review Process

Advice was taken from the Royal College of Radiologists (UK), the Scottish Standing Committee of RCR, the Head of Service of Radiology at Raigmore Hospital, Inverness, Public Health and other experts in the field who had completed radiological reviews previously. It was decided that a review should be undertaken. Sourcing appropriate radiologists was explored and various options considered. These options included the use of consultant radiologists within NHS Highland, the use of consultant radiologists in other Scottish Health Boards and the use of private sector providers. A number of factors were considered in reaching this decision. One was the speed with which the review could be commenced, given the sensitivity of the subject and the desire to identify any ongoing morbidity as quickly as possible. Another was consideration of the workload capacity of the selected provider. A third was whether the provider could undertake the review in Oban. It was important to limit as far as possible the need to transfer x-rays and reports to other centres.

Having considered all of these factors it was decided that it would be impractical and less appropriate for the review to be undertaken by consultant radiologists within NHS Highland or NHS Greater Glasgow and Clyde. Two potential independent sector providers were then identified who could meet the terms of the review, one of which, Medica, was able to commence the review very quickly. A contract was therefore placed with Medica, who arranged for a consultant with a substantive contract with another Scottish health board to undertake the review.

The Critical Incident Review Group had decided early in its deliberations that the purpose of the review was to identify whether any pathology had been missed in a range of key radiological examinations. For this reason the time period to be covered was determined as being from the date of commencement of the locum consultant radiologist to the date of his resignation i.e. 16 October 2007 to 16 May 2008. It was noted that this period incorporated a period of several weeks when the radiologist reporting service was provided by the substantive consultant. This was judged to be entirely consistent with the approach that
the purpose of the review was not an audit of the professional performance of an individual consultant, rather a means of identifying any missed pathology over a period of time.

The Critical Incident Review Group, following consultation with the Royal College of Radiologists, determined that a targeted Look Back approach should be carried out and that the appropriate examinations to be reviewed should comprise of all chest x-rays, all Barium examinations and all x-rays involving children under the age of 12. These examinations were selected due to their particular clinical sensitivity or seriousness and subsequent amenability to treatment. It was judged that any missed pathology in these examinations could have potentially more serious consequences for patients than other types of examination e.g. trauma, where any errors were more likely to have been identified by other means of diagnosis or where complications would have been resolved with the passage of time between the examination and the start of the review.

It was also deemed appropriate that all ultrasound examinations undertaken within the review period should be reconsidered. Ultrasound is a dynamic examination however and with the report being compiled from a moving image, there would be no accurate film or image which could be re-reported or compared. Consequently it was decided that initial referring clinicians should be asked to review their own clinical cases and determine in which patients it would be appropriate to invite for a repeat examination. (See 3.3.2)

The patients whose x-rays were to be re-examined came mainly from Argyll, with the majority from the Oban and Lochgilphead localities. Original x-rays had been undertaken in the Rural General Hospital in Oban, the Community Hospitals in Lochgilphead and Campbeltown and at the Dumaros Unit on Mull but all reporting had been carried out in Oban.

It was quickly recognised that a review of this scale would represent a significant administrative challenge. Consequently staff from various departments were drafted into the x-ray department to assist with the pulling, debagging, rebagging, filing and recording of the exercise. The x-rays and reports of x-rays undertaken in Oban were held in hard copy in the x-ray department so considerable preparation was required to enable the consultant radiologist to perform his review. X-rays performed elsewhere were stored electronically, so the radiologist needed to access these scans and reports from the recording system himself.

3.3.1 Chest x-rays, Under 12 x-rays, and Barium examinations

The examinations within the Critical Incident Review Look Back were reported by the reviewing independent consultant radiologist. He had access to the original x-ray request forms identifying the type of examination requested and clinical details, the original x-rays and reports (as well as previous x-rays where relevant). At the commencement of the exercise the radiologist was advised on the scoring system
and the primacy of patient safety in the review process. Following review, each report was then compared to the original report by the reviewing radiologist who was then able to categorise it according to the agreed scoring system. In every case the new report was digitally recorded prior to being typed up by secretarial staff. The completed radiological report was then verified by the radiologist as his final assessment.

The scoring system used was a modified version of the one developed by the Royal College of Radiologists and the Department of Health in the UK. Their 5 point scoring system was originally designed primarily for identifying radiological reporting discrepancies within a review of individual clinical performance and competence. This scoring system was therefore modified by the Critical Incident Review Group to reflect the focus on patient safety and potential adverse clinical outcomes, rather than identifying radiological discrepancies or scoring performance. The scoring system developed for this review categorised each report on a scale of 1, 2 or 3:

- **Category 1** - no discrepancy with the original report
- **Category 2** - a discrepancy in reporting which is unlikely to have any clinical significance or implication for patient outcome (e.g. old rib fracture)
- **Category 3** - a discrepancy in reporting which may have clinical significance with possible implications for patient outcome (e.g. a lung tumour)

### 3.3.2 Ultrasound Scans

It was decided that patients who had undergone ultrasound investigations should have their cases reviewed by their referring clinicians.

Ultrasound is a dynamic examination in which part of the investigative process is actually carrying out the technique and viewing images as the investigation proceeds. It was therefore determined that it was not appropriate simply to review the original report. All ultrasound patients whose examination had been undertaken by a consultant radiologist from the review period were therefore referred back to the referring clinicians, who were asked to reassess their patient’s case and determine whether they should now have a repeat ultrasound examination. This decision would be informed by the clinicians’ current knowledge of the patient, any change in their clinical condition since the first investigation and any other tests carried out and subsequent treatment. It would be necessary to arrange additional ultrasound clinics to perform the examinations generated within this exercise and it was decided that the best method of completing these clinics expeditiously would be for them to be performed either by some of the NHS Highland Consultant Radiologists from Raigmore Hospital, Inverness or by the Ultrasonographer based in Oban.

The CHP Clinical Director wrote to the referring clinicians of all relevant ultrasound patients (435 in total), inviting them to review the patients’ records and clinical status and to advise which patients should
be invited back for a further repeat ultrasound examination. This review was duly performed for every patient, after which the radiological department in Oban wrote to the identified patients for recall inviting them to telephone the x-ray department to make an appointment or to confirm that they did not wish to attend. Contact was made with every one of these patients and arrangements made for all who wished to have their examinations repeated to be given a clinic appointment. The majority of these appointments were made in July and August 2008 in Oban although a number of patients were examined at their request in September and October.

Because of the nature of the examination (as has been specified earlier) it is impossible to provide a direct comparison of the original reports to the repeated ultrasound reports. The examinations were undertaken by different clinicians using different equipment. In addition, up to a year had elapsed between the date of the two examinations for some patients with a minimum of three months for any individual patient. Following each ultrasound examination, the validated report was sent to the referring clinician, who would then be responsible for undertaking any further appropriate management, treatment or referral.

3.4 Communication with Patients and Professionals

At the beginning of the review process, a communication strategy was adopted to positively manage communications around the incident. (See Section 5)

A number of press releases were issued. Members of the public who had concerns about the incident were encouraged to contact a helpline which was established via NHS24.

Throughout the Critical Incident Review process, regular meetings were held involving senior clinicians and managers to monitor the progress of the review and to ensure that the correct priorities and processes were being adopted at all times.
4. Results and Actions

4.1 Review Findings

The review examined 1697 x-rays and 435 ultrasound scans – a total of 2132 procedures.

Table 1 shows the numbers of procedures involved, by type.

Table 1

<table>
<thead>
<tr>
<th>Radiological Investigation</th>
<th>Number</th>
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<tbody>
<tr>
<td>Chest x-ray</td>
<td>1445</td>
</tr>
<tr>
<td>Barium examination</td>
<td>127</td>
</tr>
<tr>
<td>x-ray in under 12s</td>
<td>125</td>
</tr>
<tr>
<td><strong>Sub-total</strong></td>
<td><strong>1697</strong></td>
</tr>
<tr>
<td>Ultrasound</td>
<td>435</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2132</strong></td>
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</tbody>
</table>

Review report categories for all the x rays are shown in Table 2

Table 2

<table>
<thead>
<tr>
<th>No comparison</th>
<th>Category 1</th>
<th>Category 2</th>
<th>Category 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest x-ray</td>
<td>5 (0.3%)</td>
<td>1192 (82.6%)</td>
<td>206 (14.3%)</td>
</tr>
<tr>
<td>Barium Examinations</td>
<td>2 (1.6%)</td>
<td>86 (67.7%)</td>
<td>37 (29.1%)</td>
</tr>
<tr>
<td>Under 12 x-rays</td>
<td>4 (3.2%)</td>
<td>118 (94.5%)</td>
<td>2 (1.5%)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>11 (0.6%)</strong></td>
<td><strong>1396 (82.3%)</strong></td>
<td><strong>245 (14.4%)</strong></td>
</tr>
</tbody>
</table>

4.1.1 No Comparison

During the review it was identified that 11 images had previously been taken, but for which there was no report available, hence no comparison could be made. Several of these related to x-rays which had been given to patients who were moving away so they could be presented to their local healthcare provider for ongoing management. The external consultant radiologist reported all of these x-rays and none of these reports identified any pathology. These reports were sent to the referring clinician.

4.1.2 Category 1 Reports

Category 1 reports - were returned to referring clinicians for information and reassurance indicating that no further action had been taken or was anticipated.

4.1.3 Category 2 Reports

All Category 2 reports – these were returned to referring clinicians to determine what, if any, further investigation may be appropriate in the light of the opinion of the reviewing radiologist. In each case the clinician was requested to forward details of the outcome to the CHP Clinical Director.
4.1.4 Category 3 Reports
All Category 3 reports were then reviewed by either the Locality Acute Clinical Director or the CHP Clinical Director, or both, in conjunction where appropriate with the referring clinician. They assessed the clinical significance of the different findings within the clinical context, and assessed whether there was any detrimental effect to the patient concerned. It was further decided what, if any, further investigation was appropriate. In all cases, all subsequent examinations and ensuing treatment were completed as a matter of urgency, in conjunction with the referring clinician.

After the collation of all the Category 3 Patient data, each patient’s case was reviewed individually by a panel consisting of the locality Acute Clinical Director, the CHP Clinical Director and the Board Medical Director. The aim of this review was to ensure that any appropriate ongoing clinical care or management had taken place and to make an assessment as to the clinical significance resulting in any radiological mis-reporting.

4.1.5 Category 3 Barium Enema Reports
There were two patients who had a Barium enema in Category 3. One barium examination was reported as being inadequate and the clinicians correctly interpreted this in the clinical context of the patient and appropriate further management was given subsequently. One barium enema was reported as not outlining the caecum and this was repeated and was subsequently reported as normal.

4.1.6 Category 3 X-ray Images in Patients Under 12 Years of Age
There was one Category 3 x-ray taken of the hand of a child where a metacarpal fracture was not reported. The reviewing consultant radiologists reported that no further action was required in respect of the child’s x-ray or subsequent clinical management.

4.1.7 Category 3 Chest X-rays
The majority of the Category 3 discrepancies arose in chest x-rays and these were discussed jointly by the reviewing consultant radiologist and the local Consultant Respiratory Physician, who also fulfils the role of Clinical Director in LIDGH. In the case of chest x-rays where there was a Category 3 discrepancy originating from requests by LIDGH clinicians then the referring clinician was contacted. In some of these cases the clinician concerned referred the patient to the chest physician for ongoing care. In all other cases the referring clinician followed the patient up personally. Several of the patients remain under the care of hospital clinicians. In no case was the discrepant report responsible for any harm.

In the case of referrals from General Practitioners the relevant General Practitioner was contacted mainly with a view to repeating the chest radiograph if clinically indicated.
4.2 Category 3 Chest X-Rays: Outcomes

The outcomes of all those who had a CXR are identified in the following flowchart:

4.2.1 Analysis of Category 3 Chest X-Ray Discrepancies

Of the 45 radiological examinations that were designated Category 3, 42 of these were chest x-rays.

There were two cases of lung cancer identified as follows:

(i) The first was in an elderly female patient. On review of all her radiography she had had a very slow growing tumour for years, was hemiplegic and wheelchair bound. A clinical decision was made on the basis of her presenting pulmonary disease and significant co-morbidities to observe the lesion and to offer palliative therapy as and when the need arose. The patient remains in a clinically stable condition. The situation was fully discussed with the patient and her daughter.

(ii) The second patient was an elderly lady with a lung cancer that was identified during the Look Back process. Further investigation, particularly on CT scan appearance, suggested her diagnosis of carcinoma of the lung. The situation was discussed fully with the patient and her daughter and further investigation or management was declined. The management plan was to include follow-up and only for investigation and/or intervention should there be tumour-
related symptoms. She died in May 2008 from infected leg ulcers. The consultant has confirmed that the lung tumour was not a contributory factor in the patient’s death.

The remaining 40 Category 3 chest x-ray examinations are categorised as follows:

(iii) There were eight cases where x-ray shadowing had been missed, and where repeat examination showed no change indicating that serious pathology was unlikely.

(iv) There were nine cases in which an x-ray abnormality had been missed, but where a repeat examination had shown the abnormality to have disappeared and resolution had taken place.

(v) There were eighteen instances including two x-rays from each of two patients in which chest x-ray abnormalities had either been missed, underreported or misreported in the opinion of the Look Back Radiological Reviewer, but in whom the subsequent management of the patient had been unchanged. This was a heterogeneous group, varying from patients in whom incidental pathology was “missed” in the last days of life and in whom this had no effect on clinical management or outcome, to patients who were already being followed-up for the pathology correctly identified by the Look Back Reviewer. The common feature in this group of patients was that their management was at no time affected by the original radiological report. Many of these patients remain under clinical care with no evidence of alteration of their outcome as a result of the radiological reporting discrepancy.

(vi) In one case both the original Radiologist and reviewing Radiologist diagnosed pulmonary oedema. The reviewing radiologist also identified some extra shadowing in the left upper zone. The patient was treated for a clinical respiratory infection with good response and full resolution of the x-ray changes.

(vii) In one case a significant pneumonia was missed on the radiological report on 3 February 2008. The film dated 3 February 2008 was grossly abnormal, but a previous chest x-ray of the same patient dated 3 January 2008 was and had been reported as normal. It is suggested, because of the gross radiological abnormality present, that in fact the wrong radiological film was probably debagged and therefore the wrong radiological film was reported. Subsequent to the Look Back, the radiological images have been reported and the copies sent to either the referring clinician or the patient’s resident GP.

(viii) There were two cases in which the chest x-ray was completely correctly reported as showing pneumonia, both by the initial reporter and the review reporter but the review report was classified as a Category 3 because no recommendation was made to repeat the x-ray. In some professional quarters, it is regarded as good clinical practice, that the reporting radiologist
should advise on further investigation. Both these cases occurred in visitors from out with the area and in both cases the clinicians who had dealt with the patients had made specific recommendations to the General Practitioner on discharge letters that the x-ray be repeated. The outcome of both of these cases was reported as satisfactory.

(ix) There was one x-ray film involving a teenage girl. The original report was correct and it was noted in the report that the Radiologist had discussed the case with the General Practitioner. The Reviewer had recommended a lateral x-ray to make a diagnosis of pectus excavatum (funnel chest). This is a clinical diagnosis and it is completely unnecessary to take an x-ray. The General Practitioner was advised by the hospital chest physician that no further radiology was necessary, however on receipt of the official letter from the CHP, the General Practitioner felt obliged to do the repeat film that was requested. This was clinically unnecessary and did not influence our management or change the outcome.

4.2.2 Summary of Category 3 Reports

In summary, the review of these results confirmed that there were no cases where any pathology missed in the original radiological report, had a significant and detrimental effect on patient care, management or safety. Two cases of carcinoma of the lung were missed on initial radiological reporting. A total of fourteen patients have died either prior to or during the course of the Look Back review. In the case of deceased patients the notes have been reviewed and in no case was the radiology discrepancy seen to contribute to the patient’s death.
4.3 Ultrasound Examinations

In the Lorn & Islands District General Hospital 435 ultrasound examinations had been undertaken within the review period. These fell into the following ultrasound categories by anatomical site:

<table>
<thead>
<tr>
<th>Examination Type</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdomen</td>
<td>8</td>
</tr>
<tr>
<td>Abdomen &amp; Pelvis</td>
<td>18</td>
</tr>
<tr>
<td>Abdominal Aorta</td>
<td>7</td>
</tr>
<tr>
<td>Anterior Abdominal</td>
<td>1</td>
</tr>
<tr>
<td>Achilles Tendon</td>
<td>1</td>
</tr>
<tr>
<td>Breast Lt</td>
<td>1</td>
</tr>
<tr>
<td>Breast Rt</td>
<td>3</td>
</tr>
<tr>
<td>Chest/Pleural Cavity</td>
<td>2</td>
</tr>
<tr>
<td>Extremity</td>
<td>4</td>
</tr>
<tr>
<td>Groin Rt</td>
<td>1</td>
</tr>
<tr>
<td>Groin/Inguinal Region</td>
<td>2</td>
</tr>
<tr>
<td>Knee Lt</td>
<td>2</td>
</tr>
<tr>
<td>Knee Rt</td>
<td>1</td>
</tr>
<tr>
<td>Lower Abdomen</td>
<td>1</td>
</tr>
<tr>
<td>Neck</td>
<td>2</td>
</tr>
<tr>
<td>Pelvis (Transabdominal)</td>
<td>21</td>
</tr>
<tr>
<td>Salivary Glands (Paratid)</td>
<td>2</td>
</tr>
<tr>
<td>Salivary Glands (Submandibul)</td>
<td>2</td>
</tr>
<tr>
<td>Testes</td>
<td>57</td>
</tr>
<tr>
<td>Thyroid &amp; Parathyroid</td>
<td>3</td>
</tr>
<tr>
<td>Upper abdomen</td>
<td>199</td>
</tr>
<tr>
<td>Urinary Tract</td>
<td>97</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>435</strong></td>
</tr>
</tbody>
</table>

At the request of the Review Team, the referring clinician in each case was asked to undertake a case note review and clinical re-assessment to determine whether or not the initial ultrasound examination should be repeated. The referring clinician had obviously been made aware of the context of this request in that the initial ultrasound scan radiology report may have been questionable. This resulted in a request that 92 ultrasound examinations should be repeated.
Contact was made with all 92 patients, 29 of whom declined the opportunity of a repeat examination, despite a full explanation. 63 repeat ultrasound examinations (15% of total ultrasounds examinations undertaken in this review period) were therefore requested and all of these examinations have now been undertaken and the radiological report results communicated to the initial referring clinician.

The 63 repeat ultrasound examinations were allocated into the following broad categories by anatomical site or system:

**Table 3. Ultrasound Examination by Type**

<table>
<thead>
<tr>
<th>Type of Ultrasound</th>
<th>No of Examinations</th>
<th>No of Examinations where a difference was noted between the initial and subsequent report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper abdomen</td>
<td>26</td>
<td>16</td>
</tr>
<tr>
<td>Urinary tract</td>
<td>17</td>
<td>3</td>
</tr>
<tr>
<td>Testes</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Pelvis</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Neck (T/PT)</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Abdominal Aorta</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Knee</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>63</strong></td>
<td><strong>29</strong></td>
</tr>
</tbody>
</table>

It was noted at the beginning of the review that ultrasound is a dynamic examination. For this reason and also because the repeat examinations were performed by different sonographers, using different equipment during a period which could have been up to 10 months after the original examination, it would not be possible to reliably compare the original report with that provided by the Critical Incident Review. This therefore is not a comparative analysis.

Nevertheless the 63 repeated ultrasound reports were reviewed by the Head of Service of Radiology at Raigmore Hospital with the previous ultrasound examination reports available for context. The ultrasound examination report was sent to the referring clinician in each case. The reviewing Radiologist confirmed that no further action was required in regard to 62 of these ultrasound reports as they were full and comprehensive. The reviewing Radiologist
also recommended to the GP of one patient, that a follow up MRI examination of the thyroid and neck would be appropriate. This investigation has been undertaken and no intervention or management was required and the patient has been discharged from follow up by the endocrine surgeon.

Subsequently the Board Medical Director reviewed the outcome of the 29 of the 63 repeated ultrasound reports, where a difference was noted between the original ultrasound examination report and the subsequent repeat examination report. However, it must be stressed that this was not a comparative analysis but to identify the possibility of continuing morbidity.

Out of the 63 repeat ultrasound scans only 2 ultrasound scans identified ongoing morbidity, which was likely to have been present at the initial investigation and where there had been an effect on clinical management and outcome. These cases were:

4.3.1 There was a probable misdiagnosis of gallstones resulting in an 8-9 month period of ongoing mild pain or discomfort. The rationale for this decision was that the size of the gallstones at the review ultrasound examination, were of a size that it was likely these gallstones were present, and missed, at the initial ultrasound examination.

4.3.2 There was a probable misdiagnosis of a small renal calculi in the calyx of a kidney and this resulted in a 5-6 month delay in surgical ablation which was successfully carried out with the resolution of loin pain symptomatology. Given the aetiology of the development of renal calculi it is probable that this renal calculus was evident 5-6 months earlier.

4.3.3 Out of the 63 repeated ultrasound scans in addition to the 2 cases identified in 4.3.1 and 4.3.2, it was noted that in 2 cases a potential time delay in ultrasound diagnosis may have been evident in the following:

4.3.4 A potential delay of 4 months in the diagnosis of a small thyroid cyst that required no clinical management subsequently.

4.3.5 A possible 3 month delay in the diagnosis of gallstones after the initial ultrasound examination. However, this patient was placed on a weight reduction programme after the initial ultrasound report and, due to obesity, would not have been considered for cholecystectomy until weight reduction had been gained.
4.4 **Action Following Initial Completion of Case Reviews**

Of the x-rays reviewed by the external radiologist:

4.4.1 All Category 1 reports (1381 in total) have been returned to the referring clinicians with no action undertaken by the Review Team.

4.4.2 All Category 2 reports (245 in total), have been returned to referring clinicians with a request to advise the CHP Clinical Director what follow up investigations or treatment have been arranged. The following table gives a brief analysis of the outcome of the review of Category 2 patients. The overwhelming majority of Category 2 reports related to incidental discrepancies. 218 of these resulted in no other further action. Feedback from referring clinicians has identified no further significant clinical findings. Several patients will be kept under review, however the clinicians have advised that this is not as a consequence of this Look Back Review.

<table>
<thead>
<tr>
<th>No further action</th>
<th>Further consultation</th>
<th>Further radiological examination</th>
<th>Patient deceased</th>
<th>Temporary resident/Left practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>218</td>
<td>10</td>
<td>3</td>
<td>12</td>
<td>2</td>
</tr>
</tbody>
</table>

4.4.3 All Category 3 reports (45 in total) have been reviewed by the Locality Acute Clinical Director, the CHP Clinical Director and the referring clinicians. Appropriate follow-up investigations were arranged immediately and appropriate clinical review treatment and management have been implemented.

4.4.4 All repeat ultrasound examinations (63) requested have been undertaken and the results sent to the referring clinician.

4.5 **Incident Reporting Timeline**

Incident Report Forms for the initial patients over whom Lochgilphead GPs expressed their concern were completed on 3 December 2007. These were appropriately countersigned, but there was a delay of two weeks in them being received into the office of the CHP Clinical Governance office on 17 December 2007.

It then took until 18 January 2008 for the reports to be logged and they were then included in that weeks weekly clinical incident circular on 22 January and the locality Clinical Services
Manager (MAKI) was asked to identify whether further action was to be undertaken. At the same time concern was expressed by the NHSH Head of Clinical Governance and Risk Management, as a result of which, the Clinical Service Manager was asked to fully investigate the incidents.

A reminder was sent to the Clinical Service Manager on 29 January 2008 and there were further discussions involving the Clinical Governance Manager, the CSM and the Locality Manager, MAKI, but it took until 14 March 2008 for the Locality Manager (MAKI) to pass the incident to his counterpart in Oban, Lorn and Isles for investigation.

Upon receipt in the Locality Manager’s (OLI) office on 18 March 2008 the reports were passed immediately to the Superintendent Radiographer for investigation. Two weeks later the specific patient details were identified as these are not recorded on the IR1 form. On 2nd April 2008 the Locality Manager received a letter from one of the Lochgilphead GPs concerning the original incidents at which point the incidents were escalated to the CHP Clinical Director.

The CHP Clinical Governance Manager investigated the management of these incidents in May 2008 and identified a series of learning points/actions arising out of this sequence of events, as follows:

4.5.1 Learning Points / Actions from the Incident Reporting Process

**Learning Point 1:** It is recognised that the Adverse Event Administrator should not be solely responsible for flagging up issues of concern. It is recognised that when there is a backlog of forms to be inputted to Datix a number of weeks may have passed before all incident form received are read by the CG Manager and the Risk/Health & Safety Advisor.  
**Action:** All IR1s will be read within 5 working days of receipt by either the CG Manager or the Risk/Health & Safety Advisor. All incidents where there are concerns about the appropriateness/completeness of actions will be followed up at the time they are identified, rather than waiting until the Weekly Memo is issued.  
**Timescale:** Immediate, already implemented.

**Learning Point 2:** IR1s are reported to the CSM in the first instance and they should initiate action/ investigation / request additional information.  
**Action:** CSMs will be reminded of their responsibilities and the process for escalation of incidents
**Timescale:** The CHP CG Manager sent an e-mail to Senior Managers 30/04/08 to reiterate the process for SUIs. Another e-mail was be sent on 26/05/08 regarding actions and responsibilities for all reported incidents.

**Learning Point 3:** The Clinical Governance and Health & Safety Team are responsible for ensuring that requests for follow up / investigations of incidents are actively monitored and a timely response obtained. In this case there was a delay in following up an outstanding request for an investigation.

**Action:** In addition to the weekly memo, a table with outstanding incident requests has been circulated. Responses received and outstanding requests will be reviewed by the CG Manager and the Risk/Health/Safety Advisor on a weekly basis.

**Timescale:** Implemented.
5. Communication

It was recognised at the outset of the review that it would be important to ensure that effective communications be established with the members of the medical community, community representatives, the clinicians concerned, the media, concerned patients and relatives and others. This issue was co-ordinated by the Head of External Communications for NHS Highland.

5.1 Patients

A helpline was established for patients at the outset of the review and also when patients were offered and recalled for Ultrasound scans. Despite widespread media coverage in both local and national press, broadcast and online there were 11 calls received from patients before the lines were closed. NHS 24 faxed the details of calls who had called into the Head of External Communications and the Medical Director and these were forwarded to Argyll and Bute CHP.

For patients whose x-ray reports were categorised as 1 or 2, the majority of communication was within their referring doctor, but for those whose report fell into Category 3, there was a significant amount of direct communication between their consultant and themselves as well as with their referring doctor. In many instances patients had been undergoing treatment either before or after their original x-rays, but in many instances their case management was discussed with them afresh following completion of the review of their x-rays.

A total of 92 patients who had previously had an ultrasound examination were contacted directly to ask if they wished to follow the advice of their referring doctor and undergo a further examination. Responses were received from every patient, 63 of whom accepted this invitation.

5.2 Referring doctors

At the commencement of the review, all consultants and GP’s were written to and advised that a significant Look Back exercise was to be undertaken.

For patients whose plain x-rays were reviewed, i.e. chest x-rays, barium examinations and under-12 x-rays, referring clinicians were written to after the review and advised on the outcome in every case. For those patients whose report fell into Category 2, the referring
doctor was asked to review the outcome in the light of other clinical history and was offered the opportunity of follow up action with any patients about whom they remained concerned.

For patients whose report was categorised as Category 3, the consultant in charge of the case performed a comprehensive case review. Where appropriate this involved detailed discussions with the referring doctor and any other clinicians who had been involved in the diagnosis or treatment of the patient. Again, the conclusions of each patient review were shared with the referring clinicians where this was appropriate. Subsequently, every Category 3 case was reviewed by the locality Acute Clinical Director and the CHP Clinical Director and when necessary, further reference back to the referring doctor was made.

For patients who had undergone an ultrasound examination within the review period, each referring doctor was written to by the CHP Clinical Director, requesting that they review the patient history and consider whether, in their clinical opinion, a further ultrasound may be beneficial. Out of 435 patients who had been examined previously, referring doctors requested that a total of 92 be offered a repeat examination, although in the event, only 63 patients wished to avail themselves of the opportunity.

5.3 Community Representatives

Letters were sent to MSPs at the outset of the Review from the Medical Director. In addition local managers have commented on the Review at public meetings including the Board of NHS Highland, the CHP Committee and at local Public Partnership Forums.

5.4 Scottish Government

Regular updates have been requested and were sent to the Scottish Government Health Department. These initially came through the communications department as deadlines were extremely short. Subsequently more substantial briefings were provided by the Medical Director.

5.5 Consultant Radiologists

The Medical Director has spoken to both of the consultant radiologists concerned within this review to inform them of the Critical Incident Review process that was to take place. Following completion of the review, both have been contacted again and the outcome explained to them.
5.6 Media

Full media releases have been issued and supplemented by statements on other occasions. Copies of media releases and letters sent out are attached at Appendix 5.
6. **Summary and Recommendations**

A number of observations and recommendations can be made from the findings of the report:

6.1 There were two cases where the diagnosis of lung cancer was delayed. However, in the opinion of the authors of this report, this did not impact significantly on their clinical care or outcome.

6.2 In the remaining 43 Category 3 cases, the reported radiological discrepancies did not impact on patient management, care or outcome.

6.3 The Look Back confirmed that two ultrasound scans identified ongoing morbidity which was likely to have been present at the initial investigation where there had been an effect on clinical management and outcome. In both cases this led to prolonged discomfort of the patients but did not affect their eventual recovery. (See Section 4.)

6.4 **Recommendation 1:** This Critical Incident Review report should be reported through the CHP and NHS Highland Clinical Governance and Risk Management structure ensuring that dissemination is across NHS Highland. This will reassure all stakeholders that no significant harm has accrued from any potential radiological reporting discrepancy. It should be stressed that the radiological diagnosis is only one significant element in the assessment, care and management of patients. Despite radiological misreporting, the significant majority of care was appropriate.

**Action** - Clinical Governance Manager.

6.5 **Recommendation 2:** This Critical Incident Review should be shared with, and discussed with, the General Medical Council and the two Consultant Radiologists involved and distributed widely throughout NHS Highland for educational purposes.

**Action** - Medical Director.

6.6 The Incident Reporting Procedure was inadequate and failed in this instance. An Incident Reporting Form (IR1) was raised by a Lochgilphead GP in December 2007 and this was not reviewed or actioned by the locality manager until mid March 2008. The Lochgilphead GP also mentioned this issue informally to management in April 2008. This was an unacceptable delay and adherence to the adverse incident reporting timetable were not adhered to.
**Action** – Clinical Governance Manager

**6.7 Recommendation 3:** The Incident Reporting process within Argyll & Bute CHP should be reviewed to ensure that appropriate managers are able to investigate incidents in a timely fashion adhering to the Clinical Governance and Risk Management protocol and standards.

**Action** – Clinical Governance Manager.

**6.8 Recommendation 4:** Direct communication between clinicians should be encouraged where an Incident has occurred and an Incident Report Form has been generated.

**Action** – Clinical Governance Manager

6.9 The Report identified a small number of patients in which the clinical diagnosis differed from the radiological report. The patients were medically assessed by the clinician who reviewed the radiological image in making a clinical diagnosis with an appropriate treatment plan. It is normal practice in Lorn & Islands District General Hospital that every radiological image is reviewed by a consultant radiologist at a later stage and a report is generated. There were a number of cases where the working clinical diagnosis was correct and appropriate treatment was given but the radiological report showed a discrepancy of diagnosis. It is evident that when a discrepancy occurs, there is no reporting mechanism utilised to identify this issue.

**6.10 Recommendation 5:** The suggested review of the Incident Reporting Process (IR1) should consider developing a process to report where there is a disparity between the clinical diagnosis and the subsequently received radiological report. This should be integrated into Clinical Governance and Risk management.

**Action** - Clinical Governance Manager

6.11 During the review it was identified that 11 images had previously been taken, but for which there was no report available, hence no comparison could be made. Several of these related to x-rays which had been given to patients who were moving away so they could be presented to their local healthcare provider for ongoing management. The external consultant radiologist reported all of these x-rays and none of these reports identified any pathology. These reports were sent to the referring clinician.
6.12 **Recommendation 6**: Under Clinical Governance & Risk Management an audit process should be developed to ensure that every Radiological image reported has a written report.

*Action* - Clinical Director of Argyll & Bute CHP

6.13 It should be noted that the Lochgilphead GP’s raised initial concerns about a number of X-rays prior to the Critical Incident Review Look Back. A number of these cases fell outwith the scope of this review methodology and all of these cases were reviewed by the head of Radiology Services Raigmore Hospital in a separate exercise. Comprehensive feedback was given to the referring clinicians on this small group of patients outwith the Critical Incident Review Look Back process. It has been reported that appropriate management and care has been given.

6.14 Reviews of this kind will always be subject to a degree of hindsight bias and outcome bias, and chest x-ray interpretation for lung tumours is subject to significant published variation rates. This review was designed to identify patients who may need ongoing and additional care, and was not an individual professional review.

6.15 The Royal College of Radiologists (UK) previously regarded an ‘error rate’ in reporting of 4 – 5% as acknowledged. Whilst this measure is no longer quoted officially, the performance of radiologists in Oban within the review period may be considered to be within acknowledged limits, as the Category 3 reports represented 2.6% of the total images reported and reviewed.

6.16 The use of appropriate qualified Locum Consultants to cover annual, maternity leave or illness is a core element in ensuring the continued delivery of health services especially in remote and rural locations. In the case of the locum consultant radiologist involved in this review, all normal recruitment procedures were followed. Registration with the General Medical Council was confirmed and satisfactory references were received from previous employers.

6.17 **Recommendation 7**: Arrangements should be put in place to introduce regular external peer review and quality assurance of the practice of radiologists in Argyll & Bute, especially radiologists working in isolation or locum appointments.

*Action* - CHP Clinical Director
6.18 **Recommendation 8:** The overall requirement to provide assurance on the level of and recruitment of locum clinicians in medical practice will continue. This process requires to be reviewed and monitored by NHS Highland.

**Action** – Director of Human Resources, NHS Highland

6.19 The scale of the clinical review and administrative exercise was very considerable within the context of a Rural General Hospital and CHP. The resource implications especially within the review of Category 3 cases was more than anticipated.

6.20 **Recommendation 9:** In the event of any future Critical Incident Review being carried out within NHS Highland, the administrative and clinical resource implications of any review should be recognised at an early stage and appropriate support mobilised both locally and by the Health Board level.

**Action** - Medical Director, the Head of Clinical Governance and Risk Management and the Director of Public Health.

6.21 **Recommendation 10:** The various issues highlighted within this Critical Incident Review should help inform the Review of Radiology Services being undertaken across Argyll & Bute CHP.

**Action** - Clinical Director of Argyll & Bute CHP
7. Appendices
Appendix 1

Membership of the Critical Incident Review Team
<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Ian Bashford</td>
<td>Medical Director, NHS Highland</td>
</tr>
<tr>
<td>Ms Elaine Mead</td>
<td>Chief Operating Officer, NHS Highland</td>
</tr>
<tr>
<td>Dr Roger Gibbins</td>
<td>Chief Executive, NHS Highland</td>
</tr>
<tr>
<td>Dr Ken Proctor</td>
<td>Associate Medical Director, NHS Highland</td>
</tr>
<tr>
<td>Dr Ken Oates</td>
<td>Consultant in Public Health Medicine, NHS Highland</td>
</tr>
<tr>
<td>Dr Eric Baijal</td>
<td>Director of Public Health &amp; Health Policy, NHS Highland</td>
</tr>
<tr>
<td>Dr Lesley-Anne Smith</td>
<td>Head of Clinical Governance, NHS Highland</td>
</tr>
<tr>
<td>Mr Derek Leslie</td>
<td>General Manager, Argyll &amp; Bute CHP</td>
</tr>
<tr>
<td>Dr Mike Hall</td>
<td>Clinical Director, Argyll &amp; Bute CHP</td>
</tr>
<tr>
<td>Mr David Whiteoak</td>
<td>Locality Manager, Lorn &amp; Islands Hospital, Oban</td>
</tr>
<tr>
<td>Dr Allan Henderson</td>
<td>Clinical Director, Lorn &amp; Islands Hospital, Oban</td>
</tr>
<tr>
<td>Mrs Veronica Kennedy</td>
<td>Clinical Services Manager (Acute), Lorn &amp; Islands Hospital, Oban</td>
</tr>
<tr>
<td>Ms Caroline Reardon</td>
<td>Support Services Manager, Lorn &amp; Islands Hospital, Oban</td>
</tr>
<tr>
<td>Mrs Jayne Morton</td>
<td>Superintendent Radiographer, Lorn &amp; Islands Hospital, Oban</td>
</tr>
<tr>
<td>Mrs Susan Rose</td>
<td>Head of External Communications, NHS Highland</td>
</tr>
<tr>
<td>Dr George Aitken</td>
<td>Consultant Radiologist, Raigmore Hospital, Inverness</td>
</tr>
</tbody>
</table>
Appendix 2

Schedule of Initial Critical Cases Falling
Outwith the Review Parameters
# Schedule of Initial Critical Cases Falling Outwith the Review Parameters

<table>
<thead>
<tr>
<th>Patient</th>
<th>Type of X ray</th>
<th>Comment</th>
<th>Included in review</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cervical spine/Chest/Pelvis</td>
<td>Original reports corroborated by reviewer</td>
<td>Yes – chest, Cat 1</td>
<td>Spine &amp; pelvis - C</td>
</tr>
<tr>
<td>2</td>
<td>Foot</td>
<td>Original report corroborated by reviewer</td>
<td>No</td>
<td>C</td>
</tr>
<tr>
<td>3</td>
<td>Orthopantomogram</td>
<td>Reviewer reported evidence of fractures but poor quality images</td>
<td>No</td>
<td>C</td>
</tr>
<tr>
<td>4</td>
<td>Chest</td>
<td>Original report corroborated by reviewer</td>
<td>Yes – chest, Cat 1</td>
<td>N/A</td>
</tr>
<tr>
<td>5</td>
<td>Foot</td>
<td>Increase in soft tissue density noted by first reviewer.</td>
<td>Yes – U12, Cat 1</td>
<td>N/A</td>
</tr>
<tr>
<td>6</td>
<td>Ankle</td>
<td>Fracture noted after discussion with radiographer and reported. Report corroborated by reviewer</td>
<td>No</td>
<td>C</td>
</tr>
<tr>
<td>7</td>
<td>Abdominal Ultrasound</td>
<td>No comparison available. Second report showed possible gallstones.</td>
<td>Yes - U/S</td>
<td>N/A</td>
</tr>
<tr>
<td>8</td>
<td>Hip</td>
<td>Fracture not reported by original radiologist. Reviewer reported fracture, but regarded the appearances as subtle</td>
<td>No</td>
<td>C</td>
</tr>
<tr>
<td>9</td>
<td>Chest</td>
<td>Original report did not comment on enlarged left hilum, which was noted by reviewing radiologist.</td>
<td>No</td>
<td>D</td>
</tr>
<tr>
<td>10</td>
<td>Chest</td>
<td>Reviewer reported incidental discrepancy – no mention of previous pleural plaque.</td>
<td>Yes – chest, Cat 2</td>
<td>N/A</td>
</tr>
<tr>
<td>11</td>
<td>Abdominal ultrasound</td>
<td>No comparison possible. Initial ultrasound did not demonstrate gall stones or any abnormality, but a repeat ultrasound was recommended in a month.</td>
<td>No</td>
<td>D</td>
</tr>
</tbody>
</table>

## Key

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>Category excluded from review</td>
</tr>
<tr>
<td>D</td>
<td>Date outwith review period</td>
</tr>
</tbody>
</table>

In this Initial Critical Review, the following is noted:

1. 5 out of the 11 cases were included in the formal Critical Incident Review Look Back process.

2. 4 out of the 11 were trauma and orthopaedic cases in adults, and therefore out with the review inclusion criteria. All cases were appropriately clinically managed despite the reporting process.

3. 2 out of the 11 cases were out with the review process due to the timescale.

3.1 In 1 patient an ultrasound scan was requested for probable gallstones. The initial report suggested that the gallbladder was difficult to identify and suggested a repeat investigation if symptomatology persisted. A repeat ultrasound was undertaken 4 weeks later and, subsequent to CT scanning, a diagnosis was made and appropriate treatment initiated.

3.2 In one patient, the initial chest x-ray did not report a left hilar enlargement, which was reported by the reviewing radiologist.
Appendix 3

Media Releases
Media Release

USE: Immediate
ISSUE DATE: 10 June 2008
Contact: Susan Rose 01463 704781

Review of radiological investigations

Lorn and Isles Hospital, Oban

NHS Highland has convened a Critical Incident Team to review information gathered as part of the investigation into a small number of concerns about the interpretation of radiological investigations at Lorn and the Isles Hospital in Oban.

This group has agreed that we should proceed to a further review of clinically prioritised cases to make sure that no patient has ongoing, undiagnosed disease which should have been picked up at an earlier stage. NHS Highland has sought support from the Royal College of Radiologists to inform its review.

Cases included in the review will be x-rays and barium enemas where the images were reported on at Lorn and Isles Hospital in Oban between October 2007 and May 2008. This includes investigations taken at other locations but reported on by radiologists based at Oban.

NHS Highland Medical Director Dr Ian Bashford said: “We are proceeding to a review because the information looked at so far is not enough to give us cause for concern or the necessary reassurance. We wish to stress that of the thousands of images read at Lorn and the Isles Hospital over the past several months we have only had concerns raised about very few. We are, however, taking these concerns seriously and are taking all necessary steps to provide reassurance.”

Any patient with concerns can see their own doctor or contact NHS Highland on 08000 2836.

Ends
MEDIA RELEASE

USE: Immediate
ISSUE DATE: 17 July 2008
Contact: Susan Rose 01463 704781

NHS Highland is reviewing radiology examinations which were reported on at Lorn and Isles Hospital in Oban between October of last year and May this year. The aim of this review is to check that no patient has any illness or injury which should have been identified earlier. The review was started in response to a small number of concerns being raised by some local GPs.

As part of this review we have identified approximately 400 patients who had an ultrasound examination at the hospital. We have asked the referring doctors to identify patients who would not benefit from having a scan repeated and have started sending letters to the remaining patients to invite them to have another scan. We are aiming to have all the letters out by the 1st of August. Special clinics have been set up to ensure this does not impact on other patients. Ultrasounds can only be reported at the time of the scan which is why they would have to be repeated.

Medical Director Dr. Ian Bashford is chair of the Critical Incident Review team. He said: “We understand that some patients may be anxious and we want to reassure them that we are taking the concerns which have been raised seriously. Although we had only a few concerns reported we are taking this very seriously to ensure no patient has undiagnosed disease, including offering to repeat scans. We have provided additional appointments with the support of our staff and are working to review all of these patients as quickly as possible. Obviously many patients’ conditions will have changed since their original scan and they may have been rescanned or treated for the original condition. Patients may feel it unnecessary but we would urge them to take this opportunity if they are in any doubt whatsoever.”

A contact number has been set up for any patient who has concerns it is 08000 282836. Patients can also discuss concerns with their own GP.
The review also includes approximately 1700 x-rays and some barium enemas. A consultant radiologist is making swift progress at reviewing these images. Any issues identified by this consultant will be referred to the patient's referring clinician whether a GP or hospital doctor so they can check that the patient is receiving the appropriate care.

Ends
Appendix 4

Correspondence
4th June 2008

**Reporting of radiological investigations at Lorn and Isles hospital, Oban.**

You may be aware that we have had concerns raised about interpreting of radiological investigations at Lorn and Isles Hospital, Oban.

We want to reassure you that we are taking these concerns seriously and are gathering information as a matter of urgency. The information will be reviewed by a critical incident team and NHS Highland will take the appropriate action to provide reassurance to clinicians and patients, including holding an extensive look back exercise if this is what is required. We will keep you informed of the progress of the investigation. In the meantime anyone with concerns about patients is asked to report them to the Argyll and Bute Community Health Partnership Clinical Director Dr Mike Hall or, in his absence, directly to Medical Director Dr Ian Bashford. Patients may of course raise concerns with their GP or hospital staff and we would be grateful if you would reassure them that action is being taken.

The issues raised relate a locum who worked for NHS Highland between September 2007 and May 2008.

Dr Ian Bashford
Medical Director
NHS Highland
6th June 2008

**Reporting of radiological investigations at Lorn and Isles hospital, Oban.**

NHS Highland has convened a formal Critical Incident Team to review information gathered as part of the investigation into concerns about the interpretation of a small number of radiological investigations at Lorn and the Isles Hospital in Oban.

It has been agreed that we should proceed to a retrospective, prioritised review of patients to make sure that no patient has ongoing, undiagnosed disease or injury which should have been picked up at an earlier stage. The details of how this will be carried out will be available in due course following discussion with the Royal College of Radiologists.

To provide some context we wish to stress that of the thousands of images read at Lorn and the Isles Hospital over the past several months only a few concerns have been raised. We are, however, taking these concerns seriously and are taking all necessary steps to be able to provide reassurance.

We reiterate that if you wish to highlight any concerns about the interpretation of radiological investigations at Lorn and Isles Hospital you can raise these with the CHP Clinical Director Dr Mike Hall and in his absence the Medical Director Dr Ian Bashford tel: 07825 522515

In the meantime, please continue to provide assurance to any patients who may be concerned that appropriate action is being taken.

Dr Ian Bashford
Medical Director
NHS Highland
Friday 6th June 2008
LETTER TO GPS OR CONSULTANT

Dear Dr

RE ULTRASOUND EXAMINATION

You will be aware of the current radiological “look back” exercise reviewing categories of x-rays and ultrasounds reported by Radiologists at Lorn & Isles Hospital over the period October 2007 to May 2008.

Unlike plain x-ray and barium examinations, ultrasound is a dynamic “real time” investigation and so it is not possible to review films retrospectively.

The Critical Incident Review Teams guidance is to offer a repeat ultrasound to any patient who previously had one reported by a Radiologist between October 2007 and May 2008, unless the clinician responsible for the patients care deems it to be no longer relevant or necessary to do so.

There are a number of reasons why repeating the ultrasound now might be no longer pertinent to the patients case.

I would ask you to consider the attached list of patients who had an ultrasound reported by a Radiologist at Lorn & Isles Hospital between October 2007 and May 2008.

Having reviewed each case, could you please indicate whether a repeat ultrasound examination is now relevant or not and return the completed list to me at the above address by Friday 11th July 2008.

If you believe that such a repeat is necessary, then we will contact your patient directly to make arrangements for the re-examination.

The report will be forwarded to you in the usual way and any further case management would naturally be your responsibility.

I am also enclosing a general briefing note which has been used to update Board members and the Scottish Government.

Thank you for your assistance with this.

Yours sincerely

Dr M Hall
Clinical Director
Argyll & Bute Community Health Partnership
Encl. – Ultrasound Examination return form.
Dear

Review of radiology reporting at Lorn and Isles Hospital in Oban

I am writing to update you on progress with our review of radiology reporting under taken on radiological examinations carried out between October of last year and May this year at Lorn and Isles Hospital in Oban.

The aim of this review is to check that patients do not have any illness or injury which should have been identified earlier.

The review was initiated in response to a small number of concerns being raised by some GPs in Lochgilphead.

As part of this review we have identified approximately 400 patients who had an ultrasound examination at the hospital. We have asked the referring doctors to identify those who would not benefit from a repeat scan.

Ultrasound images cannot be read and reported after the time of the examination so we are writing to the remaining patients offering them another scan. We have started sending letters out to patients this week and are aiming to have all the letters out by 1st of August. Special clinics have been set up to ensure this does not impact on other patients.

A contact number has been set up for any patient who has concerns, it is 08000 282836. Patients can also discuss concerns with their own GP.

The review also includes approximately 1700 x-rays and barium enemas. A consultant radiologist is making swift progress reviewing these images. Any issues identified by this consultant will be referred to the patient’s referring clinician whether a GP or hospital doctor so that they can ensure that the patient is receiving the appropriate care or whether any further management or treatment is required.

Yours sincerely

Dr. Ian Bashford
Medical Director