

# Review of Chest X-Rays and CT Scans

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reported by a Locum Consultant Radiologist  
at Louth Meath Hospitals from August 2006 to August 2007

HSE North East Radiology Look-Back Review Steering Group  
October 2008



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## 1. Foreword

In May 2008 a major review of chest x-rays (radiographs) and CT scans reported by an individual consultant locum radiologist commenced at Louth/Meath Hospitals. The review was prompted by concerns that a small number of patients in two Louth/Meath Hospitals during 2006/7 had their diagnosis delayed, due to an abnormality on their chest x-ray not being identified on initial reporting.

The review was carried out to identify any possible significant ongoing patient safety issues and to provide reassurance to those patients whose chest x-rays and CT scans were assessed by this consultant that they had been correctly diagnosed and treated.

This report sets out the background, methodology, outcomes and learning from this review.

The distress and worry caused to patients and families by a review of this nature are highly regrettable. However, where patient safety concerns exist, the HSE and the health service have a responsibility to act - to tell patients what has happened, to identify any possible harm, to ensure any remedial action required is taken and to minimise any recurrence of similar events. It is essential that the lessons to be learned from reviews of this kind are disseminated and implemented, in order to allow constant improvements in patient safety standards

The HSE is placing clinical governance at the heart of its new structure, and historic changes are underway in the establishment of the Cancer Control Programme in this country. The findings of this review will be taken on board at the highest level within the Irish health service, and will inform and enhance our work to control and minimise risk of error in the services we deliver to our patients.

The Steering Group is grateful to everyone who assisted with this review, including the medical, nursing, radiology and clerical staff of Louth Meath Hospitals.

At the core of these events are the patients involved and their families. The HSE wishes to apologise to the families of the patients who were harmed by these delayed diagnoses, and to all patients included in the review. While the events cannot be reversed, this organisation is unequivocally committed to providing an honest record of what happened, and to doing what it can to avoid a recurrence of similar events.

**Stephen Mulvany**

*Chair, Radiology Look-Back Review Steering Group*

*HSE North East Hospitals Network Manager*



# 2.

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## Executive Summary

## 2. Executive Summary

### 2.1 Introduction

From May to October 2008, a major review of chest radiographs (x-rays) and CT scans reported by an individual consultant locum radiologist was undertaken at Louth Meath Hospitals. The review was prompted by a missed diagnosis in a small number of patients who later died from lung cancer.

The review re-assessed all of the chest x-rays and CT scans reported by the locum consultant radiologist while he worked at Drogheda and Navan Hospitals from August 2006 to August 2007. The review was carried out to establish whether any ongoing patient safety concerns were in existence, and to provide reassurance to these patients and to the hospital that their radiographs and scans had been read correctly. It involved reviewing 5,835 chest x-rays and 67 CT scans from a total of 4,936 patients.

### 2.2 Methodology

Patient safety considerations greatly determined the precise methodology protocols adopted for this review. The methodology for this review was developed to identify any ongoing harm or disadvantage to patients, and allow for any additional care or treatment required to be delivered. The review had 2 steps, the first of which was an initial review where the x-rays and CT scans were re-examined and reported by reviewing radiologists.

This was followed by a consensus review designed to verify the initial review and to ensure consistency, particularly with reference to on-going patient safety issues.

**Following verification of any patient safety issues identified, their ongoing significance for the patient was assessed by one or more of the following processes:**

- Further review of all imaging available, including examinations from other hospitals
- Detailed clinical information from the patient's chart or GP, facilitated by the nurse case managers
- Further imaging by chest x-rays and/or CT scans
- Assessment of patient records and charts by an external chest physician and supporting clinicians, to establish if there was any evidence of any actual harm or disadvantage to the patient

### 2.3 Outcomes of the Review

- The main finding of the look back review was that 9 people in the care of Louth Meath Hospitals had their diagnosis of cancer delayed by some months as a result of radiological missed diagnoses. The HSE and Louth Meath Hospitals have apologised to these patients and/or their relatives, and will continue to offer whatever support and ongoing information as is possible
- The delayed diagnoses had varying impacts on these patient's care and treatment options, but included lost opportunities in relation to cure prospects, additional life-span and earlier palliative care
- The delay in diagnosis led to worry uncertainty and distress for families and greatly reduced the time available to them to come to terms with the serious diagnosis and the impending death of their family member. In some cases this period of uncertainty prevented advance planning for and adjusting to the inevitable terminal phase of cancer
- In the cases where a small chance of cure had been denied, by delayed diagnosis, the families concerned would have the added burden of trying to deal with that very difficult issue. This included the tragic impact on a family whose relative lost a major chance of cure for her cancer.



- All of the patients whose diagnosis was delayed had already been diagnosed with cancer before the look-back review began. The look-back review did not find any undiagnosed cases of lung cancer
- Two new cases of tiny probable lung tumours were discovered in patients scanned for other reasons arising from the review. These were not visible even in retrospect on the radiographic examinations under review; therefore their participation in this review was responsible for their cancer being diagnosed.

## 2.4 Results of the Review

The review examined 5835 chest x-rays and 67 CT scans. The total number of patients whose examinations were reviewed was 4,936.

**Final results were grouped into three categories:**

4628 (93.76%) patients were in Group A, requiring no further action, and the patients and their GPs were accordingly reassured by letter.

270 (5.47%) patients were in Group B, with an unreported finding unlikely to have any clinical significance, but one that should be recorded, such as evidence of old healed tuberculosis. A supplementary report was issued to the original referring physician or the patient's GP. The patients were advised by telephone call and letter.

9 (0.18%) patients were in Group C, with an unreported potentially significant ongoing safety issue for the patient: in all these cases this was a delayed diagnosis of lung cancer. This figure includes the original three confirmed cases which prompted the review. 8 of these patients have now passed away. Details of all 9 cases were sent for external clinical review to assess the impact of the delay in diagnosis on the patients' care and outcomes (see Section 6).

29 (0.59%) patients' examinations could not be retrieved for this review and were the subject of separate follow up (see Section 5).

## 2.5 Assessing Other Categories of Radiological Examination

In September 2008, 2 additional categories of radiological examination were included in the review process and reviewed using the same methodology.

### Review of Skeletal Surveys

A skeletal survey is an x-ray of the bones used to detect a range of conditions including cancers. 11 patients had skeletal surveys reported by the locum consultant radiologist between August 2006 and August 2007. All these patients were contacted and notified in advance of their examinations being reviewed. Following full review according to the methodology outlined, all 11 cases were in Group A, ie. no further action required.

### Review of Barium Studies

A barium study enables a physician to examine the digestive tract for the presence of ulcers, tumours and other abnormalities. 23 patients who had barium studies have had their tests reviewed as part of the overall Radiology look back review. The rationale for undertaking the review was a concern relating to the overall technical quality of the tests rather than any suspicion of missed diagnoses. The Radiologist produces the images and therefore is responsible for both the technical quality as well as the interpretation of the barium study.

Of the 23 studies reviewed, 4 were deemed "incomplete studies" by our expert reviewing Radiologists. Guidance was then sought from an external Consultant Gastroenterologist. He advised that these 4 patients be referred for further examination as a precautionary measure.

This work is on-going and in order not to delay the publication of the report, will be the subject of a follow-up addendum publication as soon as it is complete.

#### **Other Examinations**

The locum radiologist reported approximately 17,000 other examinations while working at Louth Meath Hospitals. No concerns have been raised either by patients or clinicians about this group of examinations and these studies were mainly done for conditions other than possible cancer. The type of examination, e.g. fractures in the Emergency Department, is such that it is thought extremely unlikely that a serious condition could have been misdiagnosed during the time period in question and not have surfaced in the interim period, therefore review of this group of examinations is not deemed to be required.

## **2.6 Clinical Significance of Delayed Diagnoses**

The results of the look-back review showed that nine patients had a diagnosis of lung cancer delayed. This figure includes the initial three confirmed cases which prompted this review. Eight of these patients have now passed away.

An expert review of all of these cases was commissioned in order to assess the clinical significance of the delayed diagnoses of lung cancer. Professor MX FitzGerald, former Dean of the Faculty of Medicine UCD and former Consultant Respiratory and General Physician at St. Vincent's University Hospital carried out these reviews, supported by relevant additional clinicians from the multi-disciplinary Lung Cancer Team at St. James's Hospital, Dublin.

In each case, an assessment of the significance of the delay in diagnosis of lung cancer was carried out and detailed individual reports and an individual personal letter were written directly to the families concerned.

Subsequently, Professor FitzGerald met privately and confidentially with each of the nine families where a confirmed missed diagnosis had occurred. The feedback from the families as relayed to Professor FitzGerald was passed on to the HSE in a written report. The HSE is following up such issues with each family.

## **2.7 Actions and Learning**

### **Action 1 - Improving Quality and Patient Safety in North East Hospitals**

Clinical governance within healthcare systems reduces the likelihood of errors occurring and increases the likelihood of detecting those errors which do occur. In response to the matters described in this report, HSE North East Hospital Network has added to its existing patient safety measures by beginning an additional project to enhance Clinical Governance in the Radiology Service in the Hospital Group.

This will cover its 5 constituent hospitals; Our Lady of Lourdes Hospital, Drogheda, Louth County Hospital, Dundalk, Our Lady's Hospital, Navan, Cavan General Hospital and Monaghan General Hospital; and will produce an agreed programme to improve clinical governance, and therefore patient safety and quality of care.

The HSE North East Hospitals are fully committed to driving change and, in partnership with its clinical staff, doing all it can to enhance patient safety at all levels. This clinical governance project was initiated in September 2008 and represents an important step in fulfilling that commitment.

**Action 2 - Referral to Professional Regulatory Bodies**

Reviews of this kind will always be subject to a degree of hindsight bias and outcome bias, and as outlined in the main report, chest x-ray interpretation for lung tumours is subject to significant published variation rates. This review was designed to identify patients who may need additional care, not to assign blame or culpability to a particular individual. However, given the degree and nature of discrepancies observed in this review between the original reports and the review reports, the Steering Group will forward a copy of this report and refer the radiologist to the Medical Council of Ireland and the General Medical Council in the UK.

**Action 3 - Recruitment of Locum Consultants**

The use of appropriate qualified and skilled Temporary and Locum Consultants to cover annual and maternity leave or illness is a core element in ensuring the continued delivery of health services. Louth Meath Hospitals Radiology Department over recent years has had no more than one or two locum consultant radiologists employed at any one time, out of a complement of ten consultant radiologists.

In the case of the locum consultant radiologist involved in this review, all normal recruitment procedures were followed. Following an interview, registration with the Medical Council was confirmed and a reference was received from previous employers. Therefore, it is not considered that there was a specific issue with this consultant's recruitment or appointment.

However, given the overall requirement to provide assurance on the level of and recruitment of locums in medical practice, in May 2008 the HSE issued national guidance which requires hospitals and facilities to only accept locum doctors from Medical Recruitment agencies that meet a series of stringent requirements relating to doctors they are referring to the employer. Standards in recruitment and in levels of use of locum clinicians will continue to be reviewed and monitored by the HSE.

**Additional Learnings from this review****Communications**

As has arisen in earlier reviews and incidents in the Irish health service, communication with patients was a hugely important feature of this review, and in this instance, was subject to significant challenges. Following initial errors in relation to patient communication in this review, the hospital group took on the task of issuing all patient communication directly from the hospital, and where possible, this approach should be echoed in any future circumstance.

**Guidance, Decision Making and Timeframes**

Following challenges in sourcing protocols, guidance and expert personnel to assist with such a large scale review, two processes have been initiated to address these barriers in any future circumstance. The Faculty of Radiology in the RCSI has engaged with the HSE's National Hospitals Office and the Department of Health and Children to develop an agreed protocol and guidance around complaints of error in radiology. It is believed that this process will allow future clarity and confidence in decision-making around reports and reviews of this nature.

To avoid the personnel barriers experienced, the HSE has formally engaged with the Forum of Postgraduate Training Bodies to set up rapid-response mechanisms to incidents of this kind. This should ensure that an appropriate mix of national and international expertise would be available to advise on the design and implementation of look-back protocols and reviews. In this way, a swift co-ordinated multi-disciplinary response could be triggered that would ensure effective and efficient reviews that would report in a comprehensive and timely manner.

## 2.8 Comments from the Consultant Radiologist

In the interest of fairness and due process, a final draft of this report was shared with the consultant radiologist whose work was reviewed in this look-back. (See page 38 of this report).

### Acknowledgements

Louth Meath Hospitals and the Health Service Executive would like to express their deepest regret and sincere apologies to all of the patients involved in this review, to the patients whose diagnosis was delayed, and to their family members.

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## Introduction and Background

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From May to October 2008, a major review of chest x-rays (radiographs) and CT scans reported by an individual locum consultant radiologist was undertaken at Louth Meath Hospitals. The review was prompted by a missed diagnosis in a small number of patients who later died from lung cancer. These patients had chest x-rays that were examined by a locum consultant radiologist, on which abnormalities that could have led to an earlier diagnosis were not reported.

The review re-assessed all of the chest x-rays and CT scans that were reported by the locum consultant radiologist while he worked at Drogheda and Navan Hospitals from August 2006 to August 2007. It was carried out to establish whether any ongoing patient safety concerns were in existence, and to provide reassurance to these patients and to the hospitals that their x-rays and scans had been read correctly. It involved reviewing 5,835 chest x-rays and 67 CT scans from a total of 4,936 patients.

The consultant whose work was reviewed worked at Louth Meath Hospitals for a period of one year, and had come to the hospital group following interview and with the correct registration, qualifications and reference from previous employers. There is no record of the consultant having previously worked in any other Irish public hospital, and the consultant no longer works within the Irish healthcare system.

The distress and worry caused to patients and families by a review of this nature are highly regrettable. However, where patient safety concerns exist, the HSE and the health service have a responsibility to act - to tell patients what has happened, to identify any possible harm, to ensure any remedial action required is taken and to minimise any recurrence of similar events.

#### 3.1 Radiology in Louth Meath Hospitals Group

Louth Meath Hospitals Group consists of Our Lady of Lourdes Hospital Drogheda, Louth County Hospital Dundalk and Our Lady's Hospital Navan. Louth County Hospital in Dundalk is not part of this review.

Our Lady of Lourdes Hospital Drogheda is the regional referral centre for the north-east of Ireland, with 310 beds and 1360 staff. All acute orthopaedic trauma cases in the north-east are referred to Drogheda, and other major departments include paediatric medicine and surgery, breast radiology and surgery, obstetrics, gynaecology, neonatology, respiratory medicine, geriatrics, cardiology, gastrointestinal and general surgery.

Teaching hospital status was granted to the hospital in January 2005. Specialist registrars in internal medicine, paediatrics, anaesthetics and surgery rotate through the hospital and the Royal College of Surgeons (RCSI) Medical School sends medical students to the Departments of Medicine, Surgery, Obstetrics and Paediatrics. Approximately thirty new consultants, across all disciplines, have been appointed to Drogheda over the past 4 years.

Our Lady's Hospital Navan is a busy, small general 157 bed hospital with 512 staff, providing a general acute hospital service to the catchment area of Meath and an elective orthopaedic service to the region as a whole. There are also 10 day beds at Our Lady's Hospital. It has seven orthopaedic attending surgeons, three physicians and three general surgeons.

A joint Department of Radiology provides a comprehensive radiology service to the patients of Louth Meath Hospitals. The joint department across the three sites at Drogheda, Navan and Dundalk has a complement of ten full time consultant radiologists and a range of support staff. All the consultant radiologists have joint appointments to two of the three hospitals and radiological interpretation at Louth Meath Hospitals is exclusively consultant delivered – so all reports on radiological examinations are reported by consultant radiologists, not by junior doctors.

Over 200,000 radiological examinations are performed each year in the three Louth Meath hospitals, on about 140,000 patients. An extensive tele-radiology system is in place, allowing CT scans to be sent to between the three hospitals, to all the radiologists' homes, to the National Neuro-surgical Centre in Beaumont Hospital, Dublin, and to the Children's University Hospital at Temple Street, Dublin.

The radiology equipment used in the three hospitals is well maintained, up-to-date, and produces very high quality radiographic images. All equipment is regularly inspected and approved by the Department of Bio-Engineering and Medical Physics at St. James's Hospital and the Radiological Protection Institute of Ireland. A 1.5 T MR scanner was installed in Drogheda in April 2005, and a new 64-slice CT scanner was provided in 2007. Two state-of-the-art dual-detector digital (DR) general x-ray rooms are in operation. There are two additional radiology rooms utilising computerised radiography processing (CR) and a digital C-arm for GI radiology and interventional radiology. All examinations are currently printed out full-size on laser film.

The radiology department at Navan has three general radiography rooms, one with dual-detector (DR) digital equipment; a digital fluoroscopy room and a separate dental room. Computerised processing has been operational for three years and a Siemens Emotion 6 CT scanner was installed in 2006.

### 3.2 Interpretative Variation and Error 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. The key health professionals involved are radiographers and radiologists. Diagnostic radiographers use sophisticated equipment to produce high quality images of the internal human body. Radiologists are highly trained specialist doctors who interpret and report on the images generated by radiographers, 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.

Chest radiographs or x-rays are performed as overview survey examinations for patients presenting with numerous conditions such as chest infections, bronchitis, asthma, accidents, injuries, chest pain, and heart failure. Published studies on variation or error rates in interpreting chest radiographs, particularly in respect of detecting lung tumours, show remarkable variability. This reflects the well-recognised complexity of chest x-ray reporting, where a multiplicity of normal and non-specific shadows compete for the radiologist's attention and challenge his interpretive judgement.

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. While methodologies for reviews are carefully designed to reproduce the original reporting circumstances, the fact that reviewers are aware of the review process creates an unavoidable higher level of sensitivity. This increases the likelihood of 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. This review's methodology put in place safeguards to minimise these phenomena and elicit a fair and appropriate re-reporting of each examination looked at.

### 3.3 General Information on the diagnosis and detection of lung cancer

The initial journey to a diagnosis of lung cancer begins with the performance of a chest x-ray ordered by a doctor, often because of cardio-respiratory symptoms such as a cough, blood-streaked sputum, breathlessness or new chest pain.

A radiologist will look for cancerous and non-cancerous abnormalities or 'shadows' on a plain chest radiograph in order to assist the clinician in investigating such symptoms. Such abnormalities can be very subtle or very obvious, some shadows are very suspicious for cancer, while others may equally represent a cancerous or non-cancerous diagnosis.

Where a radiologist identifies a shadow that is probably or possibly abnormal, and might represent cancer, this is identified in a written radiologic report and usually followed by more detailed investigations. These may include CT scans of the chest and, where appropriate, internal examinations of the lungs (bronchoscopy), and the performance of a tissue biopsy.

A missed diagnosis by a radiologist of what later turns out to be a lung cancer may sometimes unfortunately occur. In a relatively recent UK analysis the miss-rate was 19%<sup>1</sup>. In this study, put simply, one in five lung cancers were not recognised on a previous x-ray, where the shadow had gone undetected. An identical miss-rate of 19% was also reported in a Dutch study<sup>2</sup>.

Other studies have shown both lower and higher miss-rates. The analysis of how such errors occur indicates that the majority result from the radiologist not seeing the shadow. In a minority of cases the error is due to mistakenly attributing the observed shadow to a non-cancerous condition.

Research has shown that missed diagnoses particularly occur when the shadow on the lung is small, is peripheral in distribution, is located at the apex of the lung or involves the glands in the mediastinum.

Only a few reports have assessed the impact to the patient of missed diagnoses of lung cancer. Not surprisingly, what evidence there is points to

- (a) significant delay in subsequent diagnosis and
- (b) decreased survival time due to the extension or spread of cancer

#### The prognosis of lung cancer

In order to gauge the impact of missed radiologic diagnosis of lung cancer it is necessary to understand the contemporary position with regard to:

- (a) how advanced the lung cancer is when it is correctly diagnosed using current conventional methods
- (b) what treatments are available and how effective they are
- (c) what is the prognosis when it is eventually discovered

#### The key facts relating to these questions are as follows:

- (1) A majority of lung cancers when detected have already spread locally, to lymph glands or to areas outside of the lung, resulting in extremely low one-year and five-year survival rates
- (2) Only a minority of diagnosed lung cancer patients are suitable for potentially curative surgical treatment at initial diagnosis (about 15% of Non-Small Cell Cancers – NSCC and barely 1% of Small Cell Cancers – SCC)

1 Misinterpretation of the chest x-ray as a factor in delayed diagnosis of lung cancer. Turkington PM et al, Postgraduate Medical Journal, 2002,78,158-160

2 Miss-rate of lung cancer on the chest x-ray in clinical practice. Quekel, L et al :Chest,1999,115,720-724



- (3) The majority of lung cancer patients who require therapy receive either chemotherapy, radiotherapy or both, even though many tumours eventually prove resistant to such therapy. The predominant aim is to attempt to slow down or contain the growth of the tumour. However, in a small minority of early-diagnosis cases, cure can be achieved.
- (4) A substantial minority receive either no specific cancer treatment or have local palliative radiotherapy for pain or pressure symptoms.
- (5) In recent years palliative care programs have made a huge difference to making end-of-life care more effective and particularly in providing patient comfort and family support.

#### **Other factors**

Lung cancer occurs generally in older patients with a history of heavy smoking and associated smoking-induced lung or heart conditions like Chronic Obstructive Pulmonary Disease (COPD) or Coronary Heart Disease (CHD). This often restricts therapy options by virtue of the risk of surgery or the adverse side-effects of intensive chemo- or radiotherapy. These diseases, in their own right, also involve a significant reduction in life expectancy prior to any lung cancer diagnosis.

In summary, lung cancer often has a poor prognosis because, at diagnosis, it may have spread significantly. Only a minority of individuals have the prospect of a cure, through surgery. Despite radiotherapy and chemotherapy in selected cases the one year and five year survival rates remain depressingly low.

However, despite the overall poor prognosis of lung cancer compared to other cancers, it is self-evident that the earlier a diagnosis can be made, the better the outlook in terms of possible cure, survival time and control of symptoms.



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## Planning and Methodology

## 4. Planning and Methodology

### 4.1 Establishing the need for a Look-Back Review

Look-back reviews are carried out when a hospital or health service makes a decision to review the care or treatment provided to a specific group of people using a service.

This re-examination is usually done when it is considered that the results delivered by either a service or an individual may not have been up to the standard which would be expected when benchmarked against available international norms.

Louth Meath Hospital Management were informed in mid-September 2007 by a consultant physician at Drogheda that two patients may have had their diagnosis of lung cancer delayed due to an abnormality on a chest x-ray not being identified. The original chest x-rays were reported by a locum consultant radiologist, who worked only in Drogheda and Navan Hospitals between August 2006 and August 2007.

As is routine with a report of this nature, Louth Meath Hospitals responded by promptly examining the cases as reported, and taking an early decision that a sampling audit of the work of the clinician concerned should be carried out to establish the nature of the problem and whether any other patient safety concerns existed.

An audit of this nature had never been undertaken in these hospitals, and immediate questions arose in relation to identifying an appropriate approach. At the time, there was an absence of protocols or guidance on the threshold for investigating a radiologist and a lack of clarity in international published standards for acceptable levels of reporting error. The hospital was therefore unable to access guidance or protocols on the format required for an audit of this kind, which would satisfy patient safety requirements and feature a robust and appropriate methodology. Logistical requirements for any review of patient records and x-rays would be considerable.

In October and November 2007, a proposal was formulated that a 20% sample of the consultant's work would be reviewed. The hospital sought to confirm that this approach was appropriate by seeking advice from relevant external bodies in December 2007 and January 2008 - the Faculty of Radiology in the UK; Specialists in Public Health Medicine from the HSE; the National Hospitals Office's Assistant National Director for Quality, Risk and Consumer Care. The diverse responses received agreed that a review was advisable but there was no consensus in relation to the methodology. The hospital also sought advice from the Health Information and Quality Authority (HIQA).

In early 2008, a further report was received by Louth Meath Hospitals of two possible additional missed diagnoses of lung cancer.

Following this, in February 2008, a further letter from the hospital to HIQA prompted a meeting between the Hospital Group, the National Hospitals Office of the HSE, HIQA and Department of Health and Children. UK radiology experts were then sourced to carry out a risk assessment and make final recommendations on the nature of review required. At the end of March 2008 it was agreed that a full look-back review of all chest x-rays reported by the locum consultant radiologist would be carried out, to identify any possible ongoing patient safety concerns.

During the review planning stages, the four cases reported were re-examined by a panel of radiologists. The first 2 reported cases, and one of the later reported cases, were all confirmed as missed diagnoses, the other later case was carefully examined by the panel of radiologists, who agreed it did not represent a missed diagnosis. There were now three cases of concern going into the review.

A more detailed general chronology of these events and decisions is set out in Appendix C.

## 4.2 Planning for the Look-Back Review

From the 9th April, 2008, a Steering Group undertook detailed preparatory work, including:

- Defining in detail the methodology for the review
- Developing the process and resources for the review across two radiology departments
- Sourcing Radiologists to undertake the review
- Establishing the communication needs around the review and putting arrangements in place to meet these
- Agreeing indemnity with participants

With the decision to review all chest x-rays reported by the locum consultant came the certainty that the logistical requirements for this review would be extensive. The review would have to re-assess up to 6,000 radiological examinations, which could represent six months' interpretative work for one consultant. Added to the initial x-ray review time was the need to then carry out wider clinical and chart reviews to assess patient safety issues and patient outcomes. Dedicated and secure space would be required to store and process the x-rays, CT scans and patient records being examined. The review would create an enormous additional demand on the clinical, support, clerical and information technology resources of an already very busy hospital system.

Securing consultant radiologists within Ireland that would undertake the review in association with the Louth Meath radiologists was a major difficulty. Although significant efforts were made to source such consultants in Ireland, this was not solved despite consultation with the Faculty of Radiology of the Royal College of Surgeons in Ireland. The option of sourcing external consultant radiologists to undertake the review was then examined. Three quotations were received from private UK companies but these suppliers would undertake the review of the x-rays only, and would not be in a position to carry out the detailed patient chart reviews that would follow. In addition, registering external radiologists with the Irish Medical Council is a process that can take approximately 6-8 weeks. The Faculty of Radiology of the Royal College of Surgeons in Ireland had at that stage communicated with radiologists in other hospitals, seeking assistance with the review, and a group of radiologists working in Northern Ireland, all of whom were registered with the Irish Medical Council, offered to participate.

Following a review of the options available to the Steering Group, it was decided that proceeding with a mixed internal/external panel of radiologists from Louth Meath Hospitals and Northern Ireland would allow the review to begin without additional delay. As the review progressed, 25 other consultant radiologists from a range of Irish hospitals also gave of their time to participate in the review on a sessional basis.

## 4.3 Identifying the group of patients to be reviewed

To identify and quantify the patients involved, the review team extracted the relevant records from the hospital group's radiology information systems. These information systems are designed to process patients who are undergoing radiological examinations, and record only limited patient information, including names and addresses. The data extracted amounted to a total of 5835 chest x-rays and 67 CT scans, from a total of 4936 individual patients, some of whom had had more than one examination performed.

The hospital established a database of patient names and addresses and endeavoured to validate the database, in particular to identify all deceased patients. While these patients' record would be reviewed as normal, it was not intended that their families would be informed in advance or unnecessarily intruded upon until any result was known. Several hundred records of known deceased patients were identified, but the possibility remained that some patients who had passed away would be retained in the database. Every effort was made to reduce this eventuality, but certainty on this issue was not possible due to the fact that deaths are not automatically registered at the time of death, and in some cases may not be registered by the family for many months afterwards. In addition the considerable time required to check each record would have represented an unacceptable delay in communicating with patients.

#### 4.4 Communication with Patients and the Public

Communication with the patients concerned was a very important part of the planning and the undertaking of this review. New procedures for communicating with patients in reviews of this kind were adopted by the HSE in consultation with the Department of Health and Children in 2007/8. These make it clear that patients whose cases are being reviewed must be informed about the review before it commences, and before any other group such as media or public representatives. In the planning stage, a detailed communications plan was agreed, which set out timelines for meeting patient information needs once the review was ready to commence.

The objective in all reviews of this kind is to inform patients directly, and to inform the entire groups of patients simultaneously, in so far as is possible. Because of the very large number of patients concerned, phone calls were not practical, so it was decided to send a letter to each person involved, along with a question and answer sheet. The hospital group arranged for the HSE information line to provide a back-up service, with the letters inviting people with further queries to phone a lo-call information line.

Once it was confirmed that radiology personnel were available to commence the review at the beginning of May 2008, the hospital initiated the communication of the prepared information for patients and families, and subsequent announcement of the review.

Given the requirement to notify patients of their inclusion in the review, and the logistical challenge of ensuring many thousands of letters be printed and posted in one day, a mailing company was engaged to carry out this task. This is common practice in the health and wider public service, and is done with clear requirements to safeguard patient privacy and in compliance with data protection principles. The company engaged had a long and excellent reputation in managing mailings of this kind.

While it was understood that receipt of these letters would cause concern for patients and their families, it was of paramount importance that patients were informed of the situation, of what the hospital was doing to respond and that while the nature of the review was serious, for most patients it was precautionary.

Detailed letters were posted on 14th May 2008 from the hospitals to all of the patients involved, advising them that their chest x-ray or CT scan was being reviewed as part of this review. The letters explained the reason for the review, and confirmed that each patient would be sent the result of their chest x-ray or CT scan review as soon as it was completed, over the subsequent eight weeks. The HSE also wrote to GPs and hospital consultants in the region to advise them of the review.

Patients involved in the review were invited to contact the HSE information line at 1850 24 1850, 10am to 6pm, should they have any further queries about the review. In total, between 15th May and 14th August 2008, the information line received 669 calls in relation to this review, and the hospitals concerned also received high volumes of direct phone enquiries in relation to the review.

All patients were informed in the initial letters that they would be contacted again by letter as soon as their chest x-ray or CT had been reviewed. The HSE also gave a commitment to contact every patient and their doctor immediately if any issue that could affect that patient's care was identified. A copy of the letters sent to patients and the question and answer sheet is provided in Appendix D.

### **Public Announcement of the Review**

On 15th May 2008, a full statement on the commencement of the review was made in the Dáil by the Minister for Health and Children. The HSE then issued a media statement, and sent information briefings to local and national public representatives and patient advocacy groups. Hospital staff had been briefed on the review earlier that day.

### **Misaddressed Letters**

Following calls to the HSE information line on 16th May 2008, it became evident that a small number of patients involved in the review had received both their own letters and letters addressed to other patients enclosed in error.

It was established that a number of letters had been misaddressed by the company who undertook this work. The HSE acted immediately in response to this breach of its patients' data protection rights and arranged for the correct information to be re-sent to all patients that afternoon, with a cover note from the mailing company explaining the error and apologising to all recipients. The HSE notified the Office of the Data Protection Commissioner and Louth Meath Hospitals' staff also personally collected and retrieved information that was misaddressed.

Given the issues at hand for the people concerned with this review, this error was particularly serious and the HSE expressed then and repeats now its sincere apologies to everyone concerned.

### **Letters to deceased patients**

Despite much work having been put into planning the patient communications requirements around this review, it was a significant challenge to ensure that the data used to write to such a large group of patients was completely accurate. Lack of integrated patient record information systems within these and other hospitals creates a challenge in carrying out communications of this kind.

Checking data against the Death Registration Records in particular created a difficulty, in that records are not automatically updated as a death occurs, and deaths are commonly registered some months after taking place.

In a number of cases, the initial patient database that was used to generate the patient letters failed to completely exclude patients that had passed away. In all, 179 letters of the total of 4936 were addressed and posted to patients who had died, which caused understandable distress to their relatives. Again, the HSE apologised to all these people and immediately worked to overhaul the patient database used, to ensure that these errors did not recur as the review progressed.

### **Review Phase Communications**

After the review had begun, a clear policy was followed that it would be unfair to patients to engage in rolling media updates as the review progressed. For this reason, no additional information about the review was released into the public domain as the review progressed. The hospitals focused on communicating solely with patients and their families, and it was stated that when the review was complete, a detailed report would be published.

As the review progressed, some patients were asked to attend for new x-rays or CT scans, and in these cases, patients were communicated with by phone and in writing and each individual case was managed by dedicated review team staff.

## 4.5 Review Methodology

This review was carried out in order to provide reassurance to those patients whose chest x-rays and CT scans were assessed by this consultant that their care had been provided correctly. The methodology for this review was developed to identify any ongoing harm or disadvantage to patients, and allow for any additional care or treatment that may be required.

### Clinical Team

The initial radiological assessment phase of the review was primarily carried out by consultant radiologists from Louth Meath Hospitals and from the Erne Hospital, Enniskillen, assisted by a senior consultant radiologist from the UK and by 25 consultant radiologists from other hospitals in Ireland and Northern Ireland. The participation of the 25 additional clinicians was facilitated by the Dean and the Board of the Faculty of Radiologists of the Royal College of Surgeons in Ireland.

Two senior nurses were assigned to the review in the later stages to act as case managers for patients who were involved in the review. They facilitated clinical decision-making by undertaking chart assessments and reviews and made arrangements for any follow-up radiology examinations and clinical reviews required.

### Review Process

All the x-rays and CT scans to be reviewed were retrieved from the hospital radiology departments and from storage in an off-site facility. An individual file pack was prepared for each patient, including all of that patient's x-rays and the original reports of those x-rays. These files were distributed to the reviewing radiologists using a secure courier. The examinations under question were read and scored by the reviewing consultant radiologist.

The scoring system used was a modified version of one developed by the Royal College of Radiologists and the Department of Health in the UK. The scoring system was originally designed primarily for identifying discrepancies. This was modified by the steering group's consultant radiologists to enable evaluation and scoring of patient safety issues. The scoring system developed for this review measured image quality, the language used in the report and the clinical interpretation, each on a scale of 1 to 5, with 1 being of concern and 5 showing agreement with the original report.

Each reporting radiologist was given advice on the scoring system and the primacy of patient safety in their review process. The radiologists had access to the original x-rays, the original reports, and all available x-rays taken both before and after the examination in question. As a quality control measure and to ensure consistency and accuracy of the review process, 10% of the examinations scored as showing no concern were double-read and re-scored by a second radiologist who was unaware that these examinations were being audited.

Any examinations which showed concern following the initial overall review were then re-assessed by a consensus panel of three consultant radiologists: two external from the Erne Hospital, Enniskillen and Great Western Hospital, Swindon, UK and one internal from Louth-Meath Hospitals. The role of the consensus panel was to verify issues identified by the initial review and to ensure consistency, particularly with reference to on-going patient safety issues.



Following verification of the patient safety issues by the consensus panel, their ongoing significance was further assessed by one or more of the following processes:

- Further review of all imaging available, including examinations from other hospitals
- Detailed clinical information from the patients chart or GP, facilitated by nurse case managers
- Further imaging by chest x-rays and/or CT scans
- Assessment of patient records and charts by an external chest physician and supporting clinicians, to establish if there was any evidence of any actual harm or disadvantage to the patient

#### Review Support Team

The review process was managed by Louth Meath Hospitals' Group Risk Advisor, and was supported by a team that included:

- Review Operational Co-ordinator
- Senior Nursing, Administrative and ICT personnel from HSE North East
- Radiology Services Managers and Medical Records Officers from Drogheda and Navan Hospitals
- Clerical Officers from Drogheda and Navan Hospitals Radiology Departments
- HSE North East Consumer Affairs Department

Dedicated offices were set up within Our Lady of Lourdes Hospital Drogheda to manage the retrieval of radiology files and charts and the storage and processing of individual patient records through the review process.

#### Look-Back Review Information Technology System

As outlined earlier, the initial communication to patients unfortunately allowed letters to be sent to deceased patients in error. The Review Steering Group responded to this by internally commissioning a dedicated computer database system to record all patient information and all outcomes of the review, and to oversee and quality assure all data. As the review involved such a large number of people, a good data management system was critical to ensure all the people involved were from this point communicated with correctly and also that their review outcomes were recorded accurately.

The system, which was developed by the HSE North East, aligned with and supported the review methodology, and incorporated a process for communicating results to patients, thereby eliminating the earlier dependence on an external company for communicating with patients. It is likely that, should it be required, this system can be replicated for any similarly complex patient safety look-back reviews in this country in the future.

The review Steering Group met each week to monitor the review process and to respond to any issues that arose.



# 5.

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## Results of the Review

## 5. Results of the Review

The review examined 5835 x-rays and 67 CT scans.

The total number of patients whose examinations were reviewed was 4,936.

Issues identified by the initial reviewing radiologist were grouped into three categories:

- A. Agreement with original report or minor abnormality of no ongoing clinical significance (e.g. old healed rib fracture) (Scores 4,5)
- B. An unreported finding unlikely to have any clinical significance, but one that should be recorded (e.g. evidence of old healed tuberculosis (TB) (Score 3)
- C. An unreported potential or definite significant ongoing patient safety issue (e.g. a lung tumour) (Scores 1,2)

### Initial Review

Following initial review, 4289 patients were in Group A. Therefore, the majority of examinations (86.9%) required no further action, and the patients and their GPs were accordingly reassured by letter as the review proceeded.

As an audit measure, 553 (10.7%) of these 4289 examinations were double-read and re-scored by a second radiologist who was unaware that these examinations were being audited. No significant issues were identified in the audit.

Following initial review, 618 patients (12.5%) were in Groups B and C, and were then assessed by a consensus panel of three consultant radiologists: two external from the Erne Hospital, Enniskillen and Great Western Hospital, Swindon, UK and one internal from Louth-Meath Hospitals.

### Consensus Panel and Patient Safety Review

The role of the consensus panel was to verify issues identified by the initial review and to ensure consistency, particularly with reference to on-going patient safety issues.

Following verification of any patient safety issues identified, their ongoing significance for the patient was assessed by one or more of the following:

- Further review of all imaging available, including examinations from other hospitals
- Detailed clinical information from the patient's chart or General Practitioner (GP), facilitated by the nurse case managers
- Further imaging by chest x-rays and/or CT scans
- Assessment of patient records and charts by an external chest physician and supporting clinicians, to establish if there was any evidence of any actual harm or disadvantage to the patient

Following final review by the consensus panel, the 618 patients had final results in the three categories:

339 patients were added to Group A, requiring no further action, and the patients and their GPs were accordingly reassured by letter. This brought the total number of reviewed patients in Group A to 4,628.

270 patients were in Group B, with an unreported finding unlikely to have any clinical significance, but one that should be recorded, such as evidence of old healed TB. A supplementary report was issued by the radiology consensus panel to the original referring physician and/or the patient's GP. The patients were advised by telephone call and letter.

9 patients were in Group C, with an unreported potentially significant ongoing safety issue for the patient: in all these cases this was a delayed diagnosis of lung cancer. This figure includes the original three confirmed cases which prompted the review. 8 of these patients have now passed away. Details of all 9 cases were sent for external clinical review to assess the impact of the delay in diagnosis on the patients' care and outcomes. More detail on these clinical reviews is provided in Section 6 of this report.

### Final Results

Group A	Agreement with original report or minor abnormality of no ongoing clinical significance (e.g. old healed rib fracture)	4,628 (93.76%)
Group B	An unreported finding unlikely to have any clinical significance, but one that should be recorded (e.g. evidence of old healed TB)	270 (5.47%)
Group C	An unreported potential or definite significant ongoing patient safety issue( e.g. a lung tumour)	9 (0.18%)
	Missing Examinations – these patients were followed up but not included in the overall results, since the examinations reported by the locum consultant could not be examined	29  (0.59%)

### Delayed Diagnoses

All 9 patients whose lung cancers were originally unrecognised by the locum radiologist had been identified and diagnosed prior to March 2008. These included three of the four cases initially reported in September 2007 and in early 2008. The review did not therefore find any previously undiagnosed lung cancers.

### Major mis-reports without clinical harm

A number of significant errors in reporting (scores 1, 2) that were sent for clinical chart review were judged not to have caused any clinical harm. Detailed clinical analysis of the patient records in all cases indicated that harm was averted as a result of the alertness of clinicians, other clinical information or tests, or other factors such as timely intervention with appropriate treatment. International patient safety standards regard the recording and understanding of these so-called potential 'near-misses' as enormously valuable in developing safer care delivery systems.

### Review of CT Scans

The 67 CT scans included in this review did not lead to any Group C results. It was felt that this was because compared to chest x-ray, CT is a more technically specific examination, the interpretation of which routinely involves additional clinical input from other specialties.

### Unrelated Diagnoses

Two new cases of tiny probable lung tumours were discovered incidentally in patients who had new CT scans during the review. These tumours had not been present or visible, even in retrospect, on the radiographic examinations reported by the locum radiologist; therefore their participation in the review was responsible for these tumours being detected.

### Additional Radiology Performed

In all, the review recalled 92 patients for additional x-rays or CT scans. This was required in some cases where the original examinations were missing, or when the detailed chart reviews and existing radiology records did not offer a full picture of the person's outcome. Of the 92 patients recalled, 60 attended Drogheda Hospital, 16 attended Navan Hospital and 16 declined the offer of an additional examination.

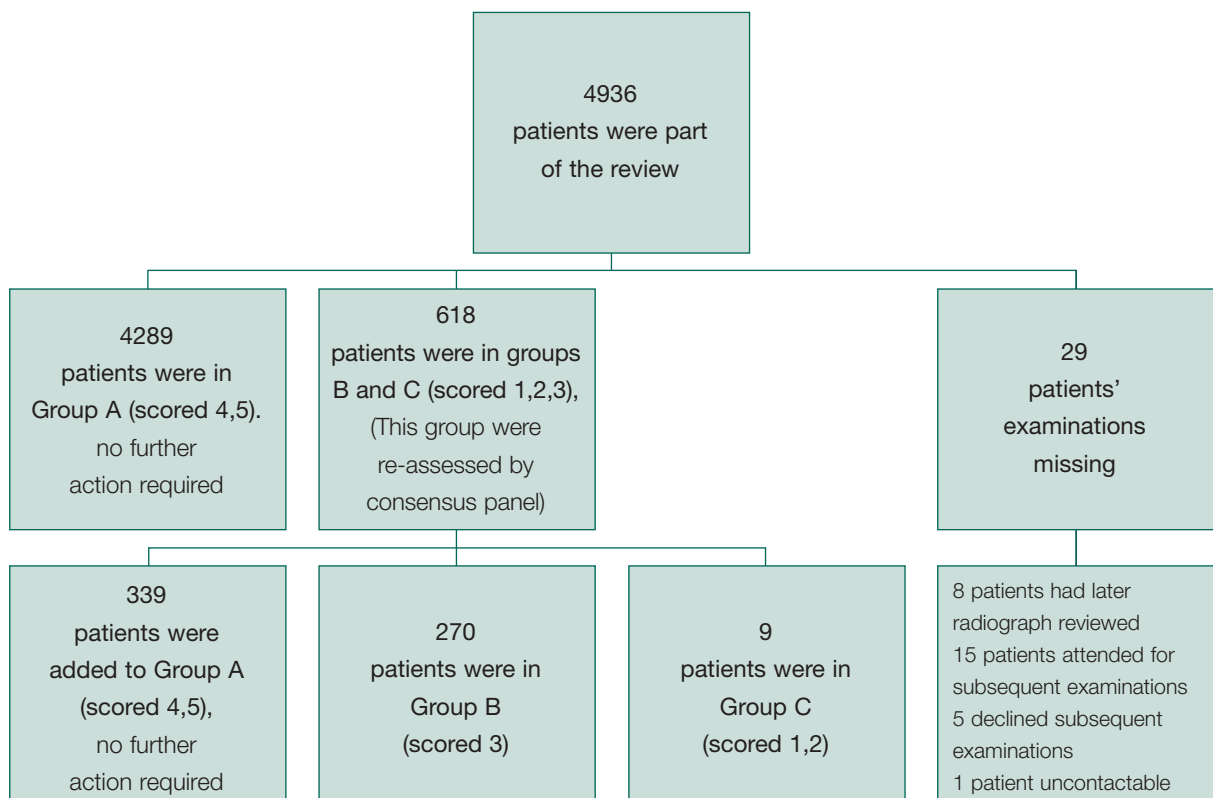
### Missing examinations

Missing x-rays are a feature of hospitals internationally and despite extensive searches, a small number of patient examinations (29 patients' examinations) could not be retrieved for this review. In some cases the specific examination under question was missing, in others all the patient's radiology files were missing. These patients were followed up but not included in the overall results, since the examinations reported by the locum consultant could not be examined.

Where the x-rays were missing, 8 patients who had a later similar radiograph were reassured that on review the later radiograph showed no abnormality. 20 patients with no subsequent imaging were offered a new examination following discussion with the patient and their GPs. Of these, 15 had new examinations and 5 refused.

The review was unable to contact one patient who was part of the overall group reviewed. The person was not an Irish resident and despite every effort, the contact details held by the hospital did not permit them to be traced.

Fig 5.2 Diagram of Patient Review Results



### Patient Initially Declined Further Diagnostic Examinations

One patient who was reviewed, initially declined further diagnostic examinations. This case is part of the final Group B results. The family of this patient contacted Louth Meath Hospitals after the main review process was complete and have requested a full review of this case. This request is being followed up by Louth Meath Hospitals. Any change in the final result of this case will if necessary be documented after this review has been completed. Communication with this family is ongoing.

### Deceased Patients

All chest x-rays and CT scans reported by the locum radiologist were reviewed, and this included examinations from patients who were now deceased. Where no issue of concern was raised by the review of a deceased patient's examination (Group A), a decision was made that it would be unnecessarily intrusive to communicate with their family members. Where any unreported abnormalities were discovered (Group B and C), the significance of these was established by detailed chart review. Where there were Group B results, the GPs of deceased patients were notified by letter of the outcome of the review to facilitate complete medical records being kept.

### Quality of Imaging

Image quality was remarked on by external radiologists as being generally excellent from both hospitals. This was attributed to the excellent standard of radiography and the hospitals' investment in high quality direct digital and computed radiography systems.

#### Image Quality Results:

Score	1	2	3	4	5	Total
Examinations	1	16	152	735	4959	5863*

NOTE: These results measure individual x-rays and CTs, not patients. Some patients had more than one examination. Scores range from 1 to 5 where 5 represents excellent image quality

\* 39 missing examinations (relating to 29 patients).

### Quality of Language

The language used in the original reports was reviewed and scored, and no significant issues were found with the language used.

#### Language Quality Results:

Score	1	2	3	4	5	Total
Examinations	6	22	71	429	5335	5863*

NOTE: These results measure individual x-rays and CTs, not patients. Some patients had more than one examination. Scores range from 1 to 5 where 5 represents appropriate use of language.

\*39 missing examinations (relating to 29 patients).

### **Assessing Other Categories of Radiological Examination**

The original risk assessment which provided the basis and methodology for this review stated that it was necessary to re-examine chest x-rays, since this was the category of examination where concern had been raised. Secondary to that was the nature of conditions that are assessed via chest x-rays, which included lung cancer. Since there was an outside possibility, given the timeframe that had elapsed since the consultant's tenure at the hospital, that there could be patients who required ongoing follow up or care, the review of chest x-rays was deemed appropriate. Since the consultant had limited experience with CT, these were also included at the outset.

During the review process, concerns were expressed to the Steering Group about the quality of reporting of a small number of barium examinations and skeletal surveys by the same locum radiologist. Following a risk assessment of these, it was agreed that these should be reviewed using the same methodology.

### **Review of Skeletal Surveys**

A skeletal survey is an x-ray of the bones used to detect a range of conditions including cancers. 11 patients had skeletal surveys reported by the locum consultant radiologist between August 2006 and August 2007. All these patients were contacted and notified in advance of their examinations being reviewed. Following full review according to the methodology outlined, all 11 cases were in Group A, ie. no further action required.

### **Review of Barium Studies**

A barium study enables a physician to examine the digestive tract for the presence of ulcers, tumours and other abnormalities. 23 patients who had barium studies have had their tests reviewed as part of the overall Radiology look back review. The rationale for undertaking the review was a concern relating to the overall technical quality of the tests rather than any suspicion of missed diagnoses. The Radiologist produces the images and therefore is responsible for both the technical quality as well as the interpretation of the barium study.

Of the 23 studies reviewed, 4 were deemed "incomplete studies" by our expert reviewing Radiologists. Guidance was then sought from an external Consultant Gastroenterologist. He advised that these 4 patients be referred for further examination as a precautionary measure.

This work is on-going and in order not to delay the publication of the report, will be the subject of a follow-up addendum publication as soon as it is complete.

### **Other Examinations**

The locum radiologist reported approximately 17,000 other examinations while working at Louth Meath Hospitals. No concerns have been raised either by patients or clinicians about this group of examinations and these studies were mainly done for conditions other than possible cancer. The type of examination concerned, e.g. fractures in the Emergency Department, is such that it is thought extremely unlikely that a serious condition could have been misdiagnosed during the time period in question and not have surfaced in the interim period, therefore review of this group of examinations is not deemed to be required.

### **Variation and Error in Radiological Interpretation**

As referred to in Section 3, reviews of this kind are always subject to a degree of hindsight bias and outcome bias, and as also referred to earlier, chest x-ray interpretation for lung tumours is subject to extremely diverse published variation rates. In the practice of general radiology, variation rates of up to 20% are internationally recorded. Any review of any set of patient files will show variance and in some cases error, and while this is regrettable and certainly not to be discounted, it is to a limited extent a feature of all health services which are delivered by potentially fallible human beings.



The challenge in carrying out this review was to ensure a thorough examination of patient safety issues, and where it was found, an examination of harm to patients. It is important to emphasise that the results of or outcomes of this report do not imply that the harm done was exclusively attributable to the radiologist under investigation, nor was it designed to assign degrees of culpability, depending on the magnitude or impact of each reporting error.



# 6.

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## Clinical Significance of Delayed Diagnoses

## 6. Clinical Significance of Delayed Diagnoses

The results of the look-back review showed that nine patients had a diagnosis of lung cancer delayed. This figure includes the initial three confirmed cases which prompted this review. Eight of these patients have now passed away.

An expert review of all of these cases was commissioned in order to assess the clinical significance of the delayed diagnoses of lung cancer. The HSE approached the Royal College of Physicians of Ireland (through its Chief Executive, Mr. Leo Kearns) to source an appropriate expert to carry out the clinical review of these and any subsequently discovered cases.

As a result, Professor MX FitzGerald, former Dean of the Faculty of Medicine UCD and former Consultant Respiratory and General Physician at St. Vincent's University Hospital agreed to participate in the review. Later, Professor FitzGerald and Mr. Kearns approached Professor Ken O'Byrne, Consultant Medical Oncologist, and Dr. Finbar O'Connell, Consultant Respiratory Physician both of St. James's Hospital's multi-disciplinary Lung Cancer Team, who also agreed to participate in analysing all the data and producing a consensus report.

In each case, an assessment of the significance of the delay in diagnosis of lung cancer was carried out and detailed individual reports and an individual personal letter were written directly to the families concerned. These reports comprehensively outlined the findings in the case of their family member and offered a personal meeting to go through the reports and explain any outstanding queries.

The reports consisted of a detailed records-based evaluation of each case. They adjudicated on the significance of the delay in the diagnosis of lung cancer.

**Essentially a judgement was made in every case on the following four features:**

- (1) the negative impact on cure prospects
- (2) the negative impact on length of survival and any slowing in the progression of the cancer (if cure could not be achieved)
- (3) the negative impact on control of cancer symptoms and patient comfort and
- (4) the negative impact on family members

These detailed reports and family letters were the culmination of an agreed, comprehensive consensus judgement involving Prof. FitzGerald, Prof. O'Byrne and Dr. O'Connell.

Subsequently, Professor FitzGerald met privately and confidentially with each of the nine families where a confirmed missed diagnosis had occurred. The feedback from the families as relayed to Professor FitzGerald was passed on to the HSE in a written report. The HSE is following up such issues with each family.

The reports contain detailed personal information about the medical history and conditions of these patients, and therefore it is not possible to include the full reports within this public document without breaching the privacy of the patients and their families. A summary of the outcomes of the reports and a table outlining the impacts on the nine patients and their families is provided in the pages that follow.

**Clinical Significance Reports - Summary by Professor MX FitzGerald**

Details of findings – 9 patients (age range 61-84: 6 men, 3 women):

1. **Delay in diagnosis of lung cancer:**  
In the nine cases, the delay in diagnosis was due to the failure to recognise a lung nodule or mass on chest x-ray. Diagnosis of cancer was delayed by periods ranging from five weeks to 14 months. The nature and degree of each mis-report were detailed by the consensus panel of radiologists in their written report on each case
2. **Consequences of delay:**
  - In 3 cases lung cancer had widely disseminated throughout the body
  - In 5 cases major expansion of cancer within the chest had occurred
  - In 1 case there was a slight increase in size of a very small tumour
3. **Cause of death:**
  - In 7 cases, directly due to the cancer
  - In 1 case, respiratory failure due to pre-existing advanced emphysema and chronic obstructive pulmonary disease (COPD), with some acceleration due to localised chest-wall cancer and its consequences
  - The remaining patient is receiving ongoing care
4. **Significant pre-existing non-cancerous co-morbid conditions:**
  - In 8 cases, major cardiac or respiratory conditions, or both, with major implications for suitability for surgery, radical radiotherapy or intensive chemotherapy
  - In 1 case, no major cardio-respiratory disease
5. **Interval between diagnosis and death:**
  - In 8 cases this interval ranged from one month to twelve months
  - 1 individual is still living

**Negative impact on cancer outcome:****A. Cure prospects:**

- In 2 cases, there was no impact on cure because this was not a realistic prospect at any stage
- In 5 cases, the original small chance of cure was lessened by the delayed diagnosis
- Tragically in 1 case, a major (60%) chance of cure by surgery was denied to that patient
- 1 individual is receiving ongoing care

**B. The original expected length of survival (if cure was not possible):**

- In 6 cases, this was definitely reduced by a valuable number of months due to delay in diagnosis and the subsequent delay in initiating treatment, especially radiotherapy.
- One of the above 6 cases also had severe advanced non-cancerous lung disease, there was a separate risk of imminent life-threatening end-stage respiratory failure, independent of the lung cancer
- 1 individual was deprived of a substantial prolongation of life
- 1 individual, who is still undergoing care, had only a marginally small reduction in life expectancy.
- In 1 individual there was minimal impact on length of survival.

### C. Control of symptoms and patient comfort:

In 8 cases there were distressing symptoms of, for example, pain or breathlessness which could have been more effectively controlled by palliative care at an earlier stage and which would have significantly contributed to greater comfort and quality of life.

### D. Effect on families:

The delay in diagnosis often led to worry, uncertainty and distress for families and greatly reduced the valuable time they had to come to terms with the serious diagnosis and the impending death of their family member. In some cases this period of uncertainty prevented advance planning for and adjusting to the inevitable terminal phase of cancer.

An improved quality of life for their family member in the final phase of illness would have been of greater comfort to the family, not only during the period leading up to death, but also in the subsequent difficult period of bereavement and loss. In the cases where a small chance of cure had been denied, by delayed diagnosis, the families concerned would have the added burden of trying to deal with that very difficult issue. This included the impact on the family whose mother lost a major chance of cure for her cancer.

### Overall commentary:

Clearly, the most significant finding of these reviews was that in one case a very substantial chance of cure was lost. In five other individuals, a small chance of cure was denied, as well as a reduction in their life-expectancy by a valuable number of months. Only in two individuals out of the total of nine was there no prospect of cure at the time of the original mis-report. One other patient is still alive with a significant prospect of cure as a result of ongoing treatment

The degree of harm or disadvantage that accrued to individuals involved was considerable and the human cost was clearly very significant. However, it is important to emphasise that if these same radiologic errors in reporting had occurred in individuals whose cardiac and/or respiratory status would have permitted curative surgery, or more intensive radical radiotherapy, the cost would have been far higher. It is also important to emphasise that the results of or outcomes of the reviews carried out do not imply that the harm done was exclusively attributable to the radiologist under investigation, nor was it designed to assign degrees of culpability, depending on the magnitude or impact of each reporting error. This issue was addressed, where relevant, in the reports given to families, or discussed during individual confidential family meetings.

In eight individuals it was deemed that the period of uncertainty in diagnosis had led to a delay in the institution of timely palliative care. This delay resulted in varying degrees of unnecessarily prolonged distress, pain or discomfort.

Finally, a delayed cancer diagnosis had varying adverse effects on families. The uncertainty caused by lack of a diagnosis for different periods of time resulted in distress and worry for families and to varying degrees impaired their support plans and aggravated the grieving process. Subsequently, there was the added stress for some families of learning that a prospect of cure, no matter how small, had been lost and that the possibility of longer survival with the cancer, no matter how modest, was also sacrificed.

This cumulative negative impact indicates the overall gravity of the consequences of delayed diagnosis in cancer, and there are major implications, particularly in respect of ensuring safe systems of quality-assured audited radiologic reporting.

	Negative Impact on Cure Prospects (5 year survival)	Negative Impact on Slowing Cancer Progression (if cure not achieved)	Negative Impact on Symptom Control and Patient Comfort	Negative Impact on Family Members
Case 1 Delay: 2-3 months  Deceased	None, negligible	Prospects of survival time reduced by a number of months	Yes – significant – as outlined in 2 written reports to the family	Yes – significant – as per family reports and meetings
Case 2 Delay: 5-6 months  Deceased	Original small chance of cure was greatly lessened	Prospects of survival time reduced by a number of months	Yes – significant – as outlined in 2 written reports to the family	Yes – significant – as as per family reports and meetings
Case 3 Delay: 6-7 months  Deceased	Original small chance of cure was greatly lessened	Prospects of survival time reduced by a number of months	Yes – significant – as outlined in 2 written reports to the family	Yes – significant – as as per family reports and meetings
Case 4 Delay: 8 months  Deceased	Original small chance of cure was greatly lessened	Prospects of survival time reduced by a number of months	Yes – significant – as outlined in 2 written reports to the family	Yes – significant – as as per family reports and meetings
Case 5 Delay: 14 months  Deceased	Major, substantial prospect of cure (60%) was fully lost and denied to patient	Prospects of survival time substantially reduced by many months or even years	Yes – significant – as outlined in 2 written reports to the family	Yes – significant – as as per family reports and meetings
Case 6 Delay: 5 weeks  Deceased	None	Minimal	Yes – significant – as outlined in 2 written reports to the family	Yes – significant – as as per family reports and meetings
Case 7 Delay: 7 months  Deceased	Original small chance of cure lessened	Prospects of survival time reduced by a number of months	Yes – significant – as outlined in 2 written reports to the family	Yes – significant – as as per family reports and meetings
Case 8 Delay: 5 months  Alive	Chance of cure only marginally lessened	Yet to be determined	None, negligible	Yes – significant – as as per family reports and meetings
Case 9 Delay: 11 months  Deceased	Original small chance of cure greatly lessened	Prospects of survival time reduced by a number of months	Yes – significant – as outlined in 2 written reports to the family	Yes – significant – as as per family reports and meetings

**Feed-back from interviews with families:**

All the families were clearly deeply troubled by the detailed analysis contained in the reports on the impact that the radiologic missed diagnoses had on their family member. Particularly upsetting for all the families were the lost opportunities in relation to cure prospects, additional life-span and earlier palliative care (including radiotherapy). They had understandable reactions of frustration and sometimes anger at what they saw as a failure of the system to deliver safe care. They also spoke of the personal impact that these events and many of the details contained in the report had caused them in their grieving process.

Thus, all were determined in their view that the tragic lessons learnt from this series of events should be immediately applied within the health system in order to ensure that there was the minimum chance of such events occurring again. In particular, many families expressed the view that there is a need to urgently introduce systematic safe systems in respect of radiologic diagnosis throughout the healthcare system.

**Several families specifically urged the following measures:**

- systems to ensure the professional competence of radiologists throughout their working lifetime and
- regular systematic audit of all x-rays and radiologic reports in every hospital in Ireland, and, where necessary, systems of 'double reporting'.

Care or diagnosis issues that were outside the terms of reference of this investigation were recorded and, with the families' permission, were relayed to the HSE for further evaluation and, where necessary, action.

*Prof. MX FitzGerald, October 2008*

Louth Meath Hospitals would like to thank Professor FitzGerald for the professionalism, care and sensitivity with which he undertook these meetings and this was echoed by the families with whom he met.

The HSE and Louth Meath Hospitals has offered and repeats here its sincere apologies to the families of all the patients concerned. The hospital group has offered and continues to make available all it can in terms of information, counselling and support to the families of these patients.

**Comments from Consultant Radiologist**

In the interest of fairness and due process, a final draft of this Report was shared with the Consultant Radiologist whose work was reviewed in this look-back. The Consultant has not accepted all the points raised in the Report.

Some of the comments made by the Consultant Radiologist have already been considered in this Report. Other comments include the following:-

The Consultant Radiologist offered his sincere condolences to all the families and wished to convey his apology for the sorrow and anguish that has been caused as a result of these missed diagnoses.

The Consultant made reference to the fact that all radiologists are faced with the same challenges around diagnosis, whether or not they are locums.

The Consultant pointed to the significance of outcome and hindsight bias which he felt should be acknowledged explicitly in this review.



The Consultant also submitted that a number of extenuating factors can be taken into account. These included his comments on reporting errors, overall work load, communication, his work environment and in particular the radiological case-mix that he was assigned.

The Consultant also advised, in regard to the recruitment of locum consultants, that he complied with all the requirements as set out by the HSE.

The Consultant stated that that welfare of patients has been his primary concern throughout his career and he profoundly regrets any missed diagnosis.

He said that he had been personally devastated by the findings of the Review and will never be able to put it from his mind. He will always remember the distress that has been caused to patients and their families.



# 7.

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Outcomes, Actions  
and Learning

## 7. Outcomes, Actions and Learning

Every hospital and health facility strives to provide the highest possible quality and safest possible services to the people in their care. They also work to manage and minimise adverse incidents, and critically, to learn from them. This report has outlined the events that occurred in this case, and the work that was involved in carrying out this extensive review.

- The main finding of the look back review was that 9 people in the care of Louth Meath Hospitals had their diagnosis of cancer delayed by some months as a result of radiological missed diagnoses. The HSE and Louth Meath Hospitals have apologised to these patients and/or their relatives, and will continue to offer whatever support and ongoing information as is possible.
- The delayed diagnoses had varying impacts on these patient's care and treatment options, but included lost opportunities in relation to cure prospects, additional life-span and earlier palliative care, including radiotherapy
- The delay in diagnosis led to worry, uncertainty and distress for families and greatly reduced the time available to them to come to terms with the serious diagnosis and the impending death of their family member. In some cases this period of uncertainty prevented advance planning for and adjusting to the inevitable terminal phase of cancer
- In the cases where a small chance of cure had been denied by delayed diagnosis, the families concerned would have the added burden of trying to deal with that very difficult issue. Included in this was the tragic impact on the family whose mother lost a major chance of cure for her cancer.
- All of the patients whose diagnosis was delayed had already been diagnosed with cancer before the look-back review began, therefore the look-back review did not find any undiagnosed cases of lung cancer
- Two new cases of tiny probable lung tumours were discovered in patients scanned for other reasons arising from the review. These were not visible even in retrospect on the radiographic examinations under review, therefore their participation in this review was responsible for their cancer being diagnosed.

### Action 1 - Improving Quality and Patient Safety in Louth Meath Hospitals

Louth Meath Hospitals will enhance patient safety in Radiology and in the wider hospital system, commencing with a Radiological Clinical Governance Project

Look-back exercises of this kind are usually triggered by individual or systems failures, which on examination, can be preventable. Setting up robust quality assurance systems, or clinical governance systems, within hospitals, health facilities and the system in general, helps to prevent such failures, and to encourage the highest service standards for patients. A good system of clinical governance reduces the likelihood of errors occurring and increases the likelihood of detecting those errors which do occur.

In Louth Meath Hospitals, all radiology services are entirely consultant-delivered. There are no junior doctors in Radiology, so the level of professional expertise in Radiology within the hospitals is high. An important element in clinical oversight is represented by regular meetings between clinicians, to provide review and oversight of the work of the hospital.

Radiologists at all three Louth Meath Hospitals hold separate weekly clinical radiology meetings, in medicine, surgery and breast radiology. They also participate in weekly Hospital Grand Rounds in Drogheda and Navan, where a large group of clinicians from a range of specialties meet to present, discuss and comment on cases, providing a forum for learning and clinical development. These meetings involve the review of interesting or difficult cases as well as demonstration of teaching cases. Attendance at all these meetings is excellent and electronic conferencing is fully operational in Navan and is being developed in Drogheda.

In response to the matters described in this report, Louth Meath Hospitals has now begun an additional process to enhance Clinical Governance in the Radiology Service in the Hospital Group. A project has begun to provide a specific action plan to enhance the system and ethos of effective clinical governance in radiology services in the North East.

This will cover its 5 constituent hospitals; Our Lady of Lourdes Hospital, Drogheda, Louth County Hospital, Dundalk, Our Lady's Hospital, Navan, Cavan General Hospital and Monaghan General Hospital.

**This project will:**

- Develop an agreed programme to improve clinical governance, and therefore patient safety and quality of care
- Optimise the use and deployment of current resources and thereby improve service capacity to better manage both the clinical demand and patient safety
- Improve service integration across the five sites as part of a fully functioning joint department, enhancing professional relationships and organisation

While every hospital system aspires to the highest standards of patient safety, clinical audit and governance, these objectives will always exist within the context of a finite staff and financial resource. Louth Meath Hospitals are fully committed to driving change and, in partnership with its clinical staff, doing all it can to enhance patient safety at all levels. This clinical governance project was initiated in September 2008 and represents an important step in fulfilling that commitment.

**National Clinical Governance Developments**

In the wider health system, clinical audit and clinical governance is now recognised as a significant requirement for the delivery of safer patient services. The recent report of the Commission on Patient Safety and Quality Assurance has made strong recommendations on the need for formal clinical audit and governance in our health system, including a system of credentialing for clinicians.

Many doctors already participate in lifelong learning to make sure that they are competent to practice and participate regularly in educational activities on a voluntary basis, but the Medical Practitioners Act 2007 as amended formally provides for programmes of Competence Assurance for medical practitioners. This provision is yet to be enacted or signed into law, but will require each medical practitioner to demonstrate that they are maintaining their skills in clinical practice,

The HSE is also making clinical governance a priority in the wider health system in Ireland, and is fundamentally altering its design and structure to demonstrate its importance to our services. A new National Director of Clinical Care and Quality is to be appointed in 2009, leading a directorate that will drive clinical governance, quality and risk, and define national clinical standards and protocols.

### **Action 2 - Referral to Professional Regulatory Bodies**

Reviews of this kind will always be subject to a degree of hindsight bias and outcome bias, and as referred to earlier, chest x-ray interpretation for lung tumours is subject to extremely variable published variation rates.

This review was designed to identify patients who may need additional care, not to assign blame or culpability to a particular physician. However, given the degree and nature of discrepancies between the original reports and the review reports during this look-back, the Steering Group will forward a copy of this report and refer the radiologist to the Medical Council of Ireland and the General Medical Council in the UK.

### **Action 3 - Recruitment of Locum Consultants**

Many hospitals in Ireland and internationally employ locum staff on a temporary basis to cover unexpected leave and absences of permanent staff. Locum consultant appointments are made when a consultant position is occupied in a non-permanent capacity for a period. The locum acts in place of the post holder.

The use of appropriate qualified and skilled Temporary and Locum Consultants is a core element in ensuring the continued delivery of health services. The July 2008 complement of 2,223 permanent Consultant posts in the Irish public healthcare system generates a requirement of approximately 16% of Temporary and Locum appointments.

Louth Meath Hospitals Radiology Department over recent years has had no more than one or two locum consultant radiologists employed at any one time, out of a complement of ten consultant radiologists. This is due to in part to the high degree of cross-cover provided among consultant colleagues in the hospital group.

Louth Meath Hospitals Human Resources Department has in place a procedure for the recruitment of permanent staff and this is also used for the recruitment of temporary and locum consultant staff. In the case of the locum consultant radiologist involved in this review, all normal recruitment procedures were followed. Following an interview, registration with the Medical Council was confirmed and a reference was received from previous employers. Therefore, it is not considered that there was a specific issue with this consultant's recruitment or appointment.

However, given the overall requirement to provide assurance on the level of and recruitment of locums in medical practice, in May 2008 the HSE issued national guidance which requires hospitals and facilities to only accept locum and doctors from Medical Recruitment agencies that meet a series of stringent requirements relating to doctors they are referring to the employer, including:

- ensuring that the doctor has full references,
- a full CV,
- membership of the relevant Medical Council register,
- full occupational health clearance
- police screening

Standards in recruitment and in levels of use of locum clinicians will continue to be reviewed and monitored by the HSE.

## Additional Learning from this Review

### Communications

As has arisen in earlier reviews and incidents in the Irish health service, communication with patients was a hugely important feature of this review, and in this instance, was subject to significant challenges. The issue of misaddressed letters was distressing for patients and disappointing for the hospital group given the degree of preparation that had preceded it. However, after detailed examination, this has been proved a matter of human error by a trusted contractor with an established national reputation and there is no reason to believe this will recur. Following the error, the hospital group took on the task of issuing all patient communication directly from the hospital, and where possible, this approach should be echoed in any future circumstance.

Letters being sent to deceased patients was again hugely regrettable and was a source of understandable upset for these patients' families and for hospital staff. Cross-referencing against death records will never be a failsafe option due to the frequent time-delay in families registering deaths, but if an exercise of this nature is required in the future, the HSE will do all it can to verify and revalidate its patient files to avoid similar events recurring. In the longer term, the development of integrated national patient record systems and unique patient identifiers would be of assistance in exercises of this kind.

### Guidance, Decision Making and Timeframes

Concerns were first raised about a possible radiological missed diagnosis in September 2007, and the decision to go ahead with this look-back review was taken after much consideration at the end of March 2008.

From the first concern being raised, there was consistent activity within the hospital to achieve a consensus as to how best to respond. However, despite this activity and the commitment of people within the Hospital Group to acting on the concerns raised, it was six months before a final decision and an agreed approach arrived at. Clear published data or literature of the type required to provide guidance on the extent of the issues faced, and the approach to an audit or a review, was not in existence.

Once the decision was taken at the end of March to commence the review, further delays were encountered around the logistical needs of such a significant piece of work - how to get people in place, registration of proposed external radiologists, assessing options around using internal clinicians or outsourcing.

**It is a challenge to source clinical experts to be involved with reviews of this kind, for reasons that include:**

- the huge time commitment involved in participating in any review of this kind
- the lack of any formal relationship with bodies outside of Ireland (e.g. UK Royal Colleges) which would provide access to a designated pool of experts readily available for such reviews

As a result of these issues, a process was initiated in mid 2008 to address these barriers. The Faculty of Radiology in the RCSI has engaged with the HSE's National Hospitals Office and the Department of Health and Children to develop an agreed protocol and guidance around complaints of error in radiology, and to identify the threshold and methodology for reviews of this kind. It is believed that this process will allow future clarity and confidence in decision-making around reports and reviews of this nature, and will be concluded during 2008.

To avoid the personnel barriers experienced, the HSE has formally engaged with Forum of Postgraduate Training Bodies to set up rapid-response mechanisms to incidents of this kind.

This should ensure that an appropriate mix of national and international expertise would be available to advise on the design of look-back protocols, support the logistics of such exercises and participate in carrying out essential reviews. In this way, a swift co-ordinated multi-disciplinary response could be triggered that would ensure effective and efficient reviews that would report in a comprehensive and timely manner.

#### **Acknowledgements**

Louth Meath Hospitals and the Health Service Executive would like to express their deepest regret and sincere apologies to all of the patients involved in this review, to the patients whose diagnosis was delayed, and to their family members.



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## Appendices

## Appendix A. Glossary of Terms

CT Scan	Computerised Tomography Scan
Chemotherapy	Treatment of disease using a standardised treatment regimen of chemicals that kill cancer and other types of cells
Diagnosis	Recognition of a disease or condition by its signs and symptoms
Delayed Diagnosis	A delay in the recognition of a disease or condition
Faculty of Radiology RCSI	Offers postgraduate training programmes and examinations in radiology, as well as education, radiation protection, EEC developments, and overseas training
GP	General Practitioner / Family Doctor
HSE	Health Service Executive
HIQA	Health Information and Quality Authority
Mediastinum	A group of structures in the chest, surrounded by loose connective tissue and containing the heart, heart vessels, oesophagus, trachea, phrenic nerve, cardiac nerve, thoracic duct, thymus, and lymph nodes of the central chest
Missed Diagnosis	A failure to diagnose a disease or a condition at a particular time
Misdiagnosis	An incorrect diagnosis of a disease or condition
Prognosis	A clinician's assessment of how a patient's disease will progress and whether there is a chance of recovery
Radiograph	Radiographs are commonly called 'x-rays', and are produced by exposing the patient to x-ray radiation. The image generated can be collected on photosensitive film, on a digital imaging plate, or on fluoroscopy
Radiographer	Radiographers employ a range of sophisticated equipment to produce high quality images to diagnose an injury or disease. Diagnostic radiographers are responsible for providing safe and accurate imaging examinations in a wide range of clinical environments
Radiologist	Radiologists are highly trained specialist doctors who interpret and report on the images generated by radiographers, in order to diagnose or treat diseases and conditions
Radiology	Radiology is the medical specialty directing medical imaging technologies to diagnose and treat diseases
Radiological Examinations	The range of radiographic images that can be examined and reported by a radiologist – including Radiographs (x-rays), CT, MR, PET, mammograms, ultrasound etc
Radiological report	A written report from a radiologist giving their interpretation of a radiological examination
Radiotherapy	Radiotherapy is the medical use of ionizing radiation to control malignant cells as part of cancer treatment
RCSI	The Royal College of Surgeons in Ireland
Tumour	Cancer is a collection of over 200 diseases in which cells of an organ or tissue in the body become abnormal, growing and multiplying out of control. When cells grow out of control, they usually form a mass, called a tumour
X-Ray	The radiation used to generate radiographic images, or a common name for a plain film radiograph

## Appendix B. Membership of Radiology Look-Back Review Steering Group

Stephen Mulvany, Chair	Network Manager, HSE North East Hospitals Group
Prof Muiris X FitzGerald	Consultant in Respiratory Medicine, nominee of the Royal College of Physicians in Ireland (from April 30th 2008)
Dr Padhraic Conneally	Lead Clinician Radiology, Western Health and Social Care Trust, Northern Ireland
Dr Mark Towers	Consultant Radiologist, Louth Meath Hospitals
Dr Alf Troughton	Consultant Radiologist and Medical Director, Great Western Hospital, Swindon
Dr James Hayes	Consultant in Respiratory and General Internal Medicine, Cavan General Hospital (from June 2008)
Dr. David Vaughan	Consultant Paediatrician, Chair of Medical Board, OLOL Drogheda (until August 2008)
Catherine Downes	A/Radiography Services Manager, OLOL, Drogheda
Des O'Flynn	Louth Meath Hospital Group General Manager
Irene O'Hanlon	Risk Advisor, Louth Meath Hospitals
Rosaleen Harlin	Area Communications Manager, HSE Dublin North East
Anne Carrigy	Director, HSE Serious Incident Management Team (replaced Jim Breslin, June 2008)
Gerry O'Neill	HSE Serious Incident Management Team
Fidelma Browne	HSE Serious Incident Management Team
Mary Culliton	Head of Consumer Affairs, HSE

## Appendix C. Chronology September 2007 – March 2008

### Establishing the need for a Look-Back Review

#### First Report – September 2007

A letter was sent on 12th September 2007 from a consultant respiratory physician in Our Lady of Lourdes Hospital, Drogheda to a consultant cardiologist at the hospital. The letter was copied to the hospital manager, a consultant radiologist and the hospital risk advisor. This letter referred to two patients who had presented with respiratory symptoms, recently diagnosed as lung cancer. The respiratory physician had noted that chest x-ray reports on these patients taken earlier in 2007 had not identified concerns. These x-rays had been reported by a locum consultant radiologist who was no longer working at the hospital. The consultant respiratory physician felt that the original reports had not been accurate, and that the cancers may have been missed on these earlier x-rays. These were the first concerns to be raised about this locum consultant.

#### Hospital Responds by agreeing an Audit – October 2007

A meeting took place between a consultant radiologist and the hospital risk advisor to examine the cases. It was agreed following the meeting that an audit of the consultant's work should be undertaken to assess the significance of the matter and identify any possible ongoing patient safety concerns.

Consideration was given to making contact with the families of the patients concerned and hospital staff and management were in favour of this, but it was particularly noted that one of the patients had very recently passed away and the other was in advanced palliative care. In accordance with incident response standards, it was decided that until it was established that there had been any harm to the patients concerned, that families would not be contacted or intruded upon. Further meetings took place during October and November to discuss the options and the structure of the audit. The proposal from the hospital at this stage was that a 20% sample of the chest x-rays reported by the consultant be re-checked by the other consultant radiologists in Louth Meath Hospitals. This internal review would scope the scale of the problem and see if it was within the range of accepted international standards or a matter of greater concern. The hospital sought to confirm that this methodology was appropriate by approaching external bodies for advice

#### External Advice – December 2007 to January 2008

A range of groups and organisations were approached to advise on the most appropriate methodology for the review. The Royal College of Radiologists in the UK and the Faculty of Radiologists of the Royal College of Surgeons in Ireland have a role in education and training issues in radiology. While they replied to clarify that they did not conduct reviews of this nature, the UK College suggested that a sample scoping review might be the best initial approach. Advice was sought from a Public Health Specialist in HSE North East, and the hospital also consulted with the HSE National Hospitals Office's Assistant National Director for Quality, Risk and Consumer Care.

The advices received agreed that a sampling audit would seem appropriate and made diverse suggestions as to methodology. In December 2007, contact was made with the Medical Council and other hospital networks, stating that a review was being undertaken and that the consultant in question should not be offered any posts in the HSE until any outcomes of the review were available.

In January 2008, a letter was sent to HIQA, seeking their confirmation on the need for a review, and guidance on the proposed or appropriate approach. In relation to the two cases where it was believed a missed diagnosis had occurred, a decision was taken at this time to commission an external clinical review of these patients' records. This was to establish if the delay in diagnosis had had an impact on the individual patients' care or outcome. More detail on these external clinical reviews is provided in Section 5 of this report.

### **Additional Reports – January and February 2008**

On 30th January and 7th February 2008, a consultant radiologist at Our Lady of Lourdes Hospital Drogheda informed hospital management that two possible further cases of similar concern had been identified to him. Like the earlier cases, these patients were attending the hospital with respiratory symptoms and had been diagnosed with lung cancer. Both had had previous x-rays reported by the locum consultant radiologist in 2006/2007. It was considered that there may have been an opportunity to make a diagnosis on the earlier x-rays.

### **Finalising the Review - March 2008**

A further letter was sent to HIQA on 28th February 2008. Consequent to this, a meeting took place between the National Hospitals Office, the Chief Executive of HIQA, the Department of Health and Children, the Hospital Network Manager and senior management from the Louth Meath Hospitals Group. Following the meeting it was agreed that HIQA would provide contact details for independent radiology experts from the UK to advise on the need for and the methodology for a review. Louth Meath Hospitals then contacted these 2 experts and commissioned them to carry out a risk assessment and to advise on the review criteria.

This risk assessment was duly carried out by Dr. Alf Troughton, Consultant Radiologist and Medical Director, Great Western Hospital, Swindon and Dr. Patricia Woodhead, Consultant Radiologist and Medical Director, Weston Area Health NHS Trust. They recommended that all chest x-rays reported by the locum be reviewed, rather than a sample, in order to establish if there were any on-going patient safety issues that required active management.

On March 31st, 2008, the group above met again to consider this report. A decision was made to set aside earlier plans to review a 20% sample of the consultant's work, and instead commence planning for a full look-back review. This review would look at every chest x-ray reported by this consultant when they worked in Our Lady of Lourdes Hospital, Drogheda and Our Lady's Hospital Navan between August 2006 and August 2007, to identify any potential ongoing patient safety issues.

Individual radiologists have varied levels of experience with the various types of radiological examination, e.g. 'plain film' radiographs, mammography, ultrasound, CT, MRI etc. In assessing the volume of examinations the consultant had reported, it was noted that the consultant had also reported a relatively small number of CT scans (67). Due to the consultant's limited experience with this type of examination, these CT scans were also included in the review.

Planning for the review commenced on March 31st 2008 and a Steering Group was formed on the 9th April 2008 to oversee the look-back review.

## Appendix D. Letters to Patients & Questions and Answer Sheet

14th May 2008

Dear

I am writing to you to let you know of a look back exercise being undertaken at the Louth/Meath Hospital Group to review a number of routine chest x-rays and CT scans. The work of one individual temporary consultant radiologist who worked at Our Lady of Lourdes Hospital, Drogheda and Our Lady's Hospital, Navan between August 2006 and August 2007 is being reviewed.

Due to circumstances that have come to our attention, and as a precaution, we have decided to review all chest x-rays and CT scans read and reported by this temporary consultant radiologist. We have a record of you having a chest radiograph/CT scan taken as part of your care and this is one of the x-rays or scans that will be carefully re-examined by an expert team of radiologists who are carrying out this look back review.

I regret that your case has to be reviewed as part of this precautionary exercise, and would like to sincerely apologise on behalf of the hospital and the HSE for the concern this may cause. However, based upon expert medical advice it is our expectation that in the vast majority of cases there will be no cause for concern.

The review we are carrying out relates to re-checking of a large number of routine chest x-rays (approximately 6,000) and a small number of CT scans (approximately 65). Our clinical staff are working to ensure that all the x-rays/CT scans are reviewed carefully and in a short a timeframe as possible. It is expected that all reviews will be complete within the coming eight weeks. As each radiograph/CT scan is reviewed, we will write back to you to let you know the result of the recheck on your own scan or radiograph and seek to answer any questions you may have.

We have prepared a question and answer sheet which is enclosed with this letter, and is designed to answer what questions you may have. If you wish, you can also call the HSE Information Line on **1850 24 1850**, open from **10am to 6pm**. Our staff are fully aware of the issue and will be able to go through the question and answer sheet with you.

We have made every effort to ensure that our database of patients' names and addresses has been checked and validated, however if you are reading this letter and are not the addressee, we very much regret any distress this letter may cause you and your family.

I will be in touch with you by letter as soon as your radiograph/CT scan has been reviewed. Thank you in advance for your patience and do not hesitate to contact my colleagues on 1850 24 1850 if you have any further questions.

While I would like to stress again that this is a precautionary review, I also understand that these situations do cause concern, and regret any upset or anxiety this letter may cause you.

Yours Sincerely,

---

Stephen Mulvany  
*Hospital Network Manager*

## Questions and Answer Sheet

### Why is my radiograph/CT Scan being reviewed?

Due to circumstances that have recently come to our attention, we have decided to review a large number of chest x-rays (approximately 6,000) and small number of CT scans (approximately 65). We have a record of you having a chest radiograph/CT scan taken as part of your care. We are reviewing x-rays/CT scans which were read by an individual temporary consultant radiologist. This radiologist worked at Our Lady of Lourdes Hospital, Drogheda and Our Lady's Hospital Navan between August 06 and August 07

### Why are x-rays and scans read by this radiologist being reviewed?

This radiologist's work is being reviewed due a small number of errors that may have been made. The review is being done as a precaution, because the Louth /Meath Hospital Group wants to reassure you and itself that your radiograph or scan was read correctly.

### Are all x-rays/CT Scans taken during this period being reviewed?

No. We are just reviewing x-rays/CT scans which were read by an individual temporary consultant radiologist. This radiologist worked at Our Lady of Lourdes Hospital, Drogheda and Our Lady's Hospital Navan. Up to 11 other consultant radiologists have also worked in these hospitals, reporting on chest x-rays/CT scans and other examinations. The chest x-rays/CT scans under question are a small proportion of the very large total number of chest x-rays/CT Scans performed during this period. In total, approximately 6,000 x-rays and 65 CT scans will be reviewed.

### What will happen next?

Your chest radiograph/CT scan will be reviewed by an expert panel of Consultant radiologists. As soon as your radiograph/CT scan has been reviewed you will receive a further letter from us to inform you of the outcome.

### How soon will I hear back about my radiograph/CT scan review?

The expert panel are working to ensure that all the x-rays/CT scans are reviewed carefully and in as short a timeframe as possible, and so we expect that all reviews will be complete within the coming eight weeks. As each radiograph/CT scan is reviewed, we will write back to you to let you know the outcome and provide any further follow up required.

### Will I need a further radiograph/CT scan?

In the vast majority of cases there will be no need for a further radiograph/CT scan. If we think there is a need for any further checks, we will put together a defined care plan for you, with input from any staff required such as your Family Doctor/GP and Hospital Consultant.

### Why might I have needed a chest radiograph/CT scan?

Chest x-rays or CT scans are performed for many reasons. Most are done for respiratory tract infections, bronchitis, asthma, pneumonia, accidents, injuries, chest pain and heart failure. A small number would have been done for possible lung tumours.

### How can I be confident about the quality of this look back exercise?

An expert panel of Consultant radiologists will carry out the review.

### Has my GP been notified that my radiograph/CT scan is being reviewed?

We have made every effort to contact all GPs to advise them that radiograph/CT scans are being reviewed.

**Where can I get further information about this review?**

As mentioned in our letter, you can contact the HSE information line between 10am to 6pm. You can call this number to enquire about the review and to ask any questions you may have.

**Contact Details for the HSE Infoline**

HSE Information Line 1850 24 1850

Open from 10am to 6pm.

Our staff are fully aware of the issue and will be able to go through this question and answer sheet with you.

If English is not your first language we can make this letter available to you in different languages e.g. Irish, Polish, Russian, French, Portuguese.









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