Errors and discrepancies in radiology: frequency, causes, prevention and management.
Nov 2009

A. Background:

(1) Expectations of perfection:

Radiology involves decision-making under conditions of uncertainty [Fitzgerald 2001], and therefore cannot always produce infallible interpretations or reports. There is an inevitable element of patient exposure in medicine to problems arising from human error, and this is increasingly the subject of bad publicity, often skewed towards an assumption that perfection is achievable, and that any error or discrepancy in reporting results of investigations represents a wrong that must be punished (RCR 2001).

(2) Definition of errors:

With respect to radiological investigations, the use of the term **"error"** is often unsuitable; it is better to concentrate on **"discrepancies"** between a report and a retrospective review of a film or outcome (RCR 2001).

Professional body guidelines recommend that all imaging procedures should include an expert opinion from a radiologist, given by means of a written report or comment (RCR 2006). **"Opinion"** may be defined as "a conclusion arrived at after some weighing of evidence, but open to debate or suggestion", and thus an expert's opinion should not be expected to be incontrovertible [Robinson 1997].

Error implies a mistake (an incorrect interpretation of an imaging study, in this context). In order for a report to be erroneous, it follows that a correct report must also be possible. Because of the subjectivity of image interpretation, the definition of error depends on "expert opinion". An observer makes an error if he or she fails to reach the same conclusion that would be reached by a group of expert observers. Errors can only arise in cases where the correct interpretation is not in dispute. Somewhere between the clear-cut error and the inevitable difference of opinion in interpretation is an arbitrary division defining the limit of professional acceptability (Robinson 1997).

(3) Frequency of errors/discrepancies:

Unlike physical examination of patients, or findings at surgery or endoscopy, evidence of a radiologic examination remains available for subsequent scrutiny, and can be used for study of observer variation. A 20-year literature review in 2001 suggested the level of error for clinically significant or major error in

radiology is in the range 2-20% and varies depending on the radiological investigation (Goddard 2001).

The issue of error in radiology has been recognised for many years. Studies in the 1940s found that CXRs of patients with suspected tuberculosis were read differently by different observers in 10-20% of cases. In the 1970s, it was found that 71% of lung cancers detected on screening radiographs were visible in retrospect on previous films [Robinson 1997, Berlin 1995]. The "average" observer has been found to miss 30% of visible lesions on barium enemas. [Robinson 1997]. A 1999 study found that 19% of lung cancers presenting as a nodular lesion on chest x-rays were missed [Quekel]. Another study identified major disagreement between 2 observers in interpreting x-rays of patients in an emergency department in 5-9% of cases, with an estimated incidence of errors per observer of 3-6% [Robinson 1999]. A 1997 study using experienced radiologists reporting a collection of normal and abnormal x-rays found an overall 23% error rate when no clinical information was supplied, falling to 20% when clinical details were available (Tudor 1997). A recent report suggests a significant major discrepancy (13%) between specialist neuroradiology second opinion and primary general radiology opinion (Briggs 2008).

A recent review found a "real-time" error rate among radiologists in their day-to-day practices averages 3-5%, but also quoted previous research showing that in patients subsequently diagnosed with lung or breast cancer with previous "normal" relevant radiologic studies, retrospective review of the chest radiographs (in the case of lung cancer) or mammogram (in breast cancer cases) identified the lung cancer in as many as 90% and the breast cancer in as many as 75% of cases [Berlin 2007].

Common experience in radiology suggests that many errors are of little or no significance to the patient, and some significant errors remain undiscovered. Prolonged attention to a specific area on a radiograph ("visual dwell") increases both false negative and false positive errors. Reducing the viewing time for CXRs to less than 4 seconds also increases the miss rate [Robinson 1997].

Comparative studies of other medical non-radiologic fields have found a similar prevalence of inaccuracy in clinical assessment and examination. A Mayo Clinic study of autopsies published in 2000, which compared clinical diagnoses with post-mortem diagnoses, found that in 26% of cases, a major diagnosis was missed clinically [Berlin 2007].

Errors are inevitable, and the concept of necessary fallibility must be accepted. Equally a threshold of competency is required of all professionals involved in the delivery of radiology services.

(4) Impact of Volume and Complexity:

The volume and complexity of information being provided to radiologists for reporting has increased enormously in recent years. Given the complexity of newer imaging modalities, particularly CT and MR, it is now commonplace for the interpretation of clinical images to take longer than the process of acquiring them [Robinson 1997]. Workload can be a factor in increasing the likelihood of errors in radiology reporting [Fitzgerald 2001]. A variety of studies have shown that most abnormal findings on plain radiographs are found during the first few seconds of searching the image, with the number of true-positive findings decreasing abruptly after a short time. However, a radiologist interpreting a radiograph in a few seconds is gambling that a large proportion of the radiograph shows normal findings [Berlin Liability 2000]. In at least one instance, a radiologist in the United States has been sued for punitive damages in a medical malpractice lawsuit arising from a case of breast cancer missed on a mammogram, because "the defendant radiologist read too many x-ray examinations on the day in question, demonstrating a wanton disregard of patient well-being by sacrificing quality patient care for volume in order to maximize revenue" [Berlin Liability 2000]. The case was settled out of court without a formal finding.

(5) Negligence:

The courts occasionally treat false negative errors as if they were errors of negligence. It is frequently alleged after retrospective review that lesions should have been noted prospectively. However, application of theories of perceptual thresholds shows that it makes sense that more lesions will be perceived retrospectively [Renfrew].

The legal basis for negligence involves a breach of the standard of care, which is usually defined as being the use of the same degree of knowledge, skill and ability as an ordinary careful physician would exercise under similar circumstances. Many legal judgements in the US and other jurisdictions have clearly established that doctors cannot be required to be perfect, and cannot be expected to guarantee a good result to patients. Negligence occurs not when there is merely an error, but when the degree of error exceeds an acceptable norm [Berlin 2007].

An appellate court in Wisconsin gave a ruling in 1998 that said: "radiologists simply cannot detect all abnormalities on all x-rays….Errors in perception by radiologists viewing x-rays occur in the absence of negligence". Hindsight bias is the tendency for people with knowledge of the actual outcome of an event to believe falsely that they would have predicted the outcome. Hindsight bias is an extremely compelling influence; people try to make sense of what they know has happened rather than analyzing the available data independently. The exact mechanism by which hindsight bias influences judgement called "creeping determinism" - a process in which outcome information is immediately and automatically integrated into a person's knowledge about the events preceding the

outcome. Hindsight bias is not supposed to influence the determination of medical negligence, but it ensures that some reasonably-acting defendants will be unfairly subjected to adverse liability judgements when after-injury evaluation has taken place [Berlin 2000].

It has been suggested that, in malpractice cases relating to radiology, judges should instruct juries that

"there is an absolutely unavoidable 'human factor' at work in the review of films; some abnormalities may be missed, even the obvious ones; the mere fact that a radiologist misses an abnormality on a radiograph does not mean that he or she has committed malpractice; and not all radiographic misses are excusable. Therefore, the focus of attention should be on issues such as proof of competence, habits of practice, and use of proper techniques" [Caldwell, quoted in Berlin 2007].

B. <u>Generic factors contributing to underperformance/discrepancies/errors</u>:

(1) Radiologist specific causes of error.

Renfrew reviewed 182 cases presented at a problem case conference between August 1986 and Oct 1990. Causes of error identified were classified:

(a) Complacency – the finding was appreciated but attributed to the wrong cause

(b) Faulty reasoning – the finding was appreciated and interpreted as abnormal, but attributed to the wrong cause

(c) Lack of knowledge on the part of the viewer

(d) Under reading – finding missed

(e) Poor communication – lesion identified and interpreted correctly, but the message fails to reach clinician

(f) Miscellaneous – lesion not present on the images, even in retrospect. This may be due to limitations of the examination or an inadequate examination

(g) Complications – most frequently during invasive procedures [Renfrew]

Another individual cause for error is "satisfaction of search", the phenomenon whereby detection of one abnormality on a radiographic study results in a premature termination of the search, allowing for the possibility of missing other, related or unrelated abnormalities [Renfrew, Fitzgerald 2001]

Perceptual errors continue to constitute the bulk of errors made by radiologists – false negative errors are the most frequently committed perceptual mistakes [Renfrew].

(2) System issues contributing to errors.

System contributors to discrepancies and errors include the following:

(a) Staff shortages

(b) Excess workload – studies have demonstrated degradation of lung cancer detection with decreased viewing time, and increased error rates in abdominal CT reporting when the radiologist reports more than 20 studies per day [Fitzgerald 2001].

(c) Inexperience of staff

(d) Inadequate equipment [Fitzgerald 2001]

(e) Inadequacy of clinical information available to the reporting radiologist – the clinical diagnosis has been shown to change in 50% of cases following communication between clinician and radiologist, with a change of treatment in 60% of cases discussed [Dalla Palma]. This is one of the many strong arguments against the use of remote teleradiology reporting for radiologic studies. Knowledge of pertinent clinical history has been shown to increase the accuracy of CXR interpretations from 16 to 72% for trainees, and from 38 to 84% for consultant-grade radiologists [Berlin 1995].

(f) Inappropriate expectations of the capability of a particular radiologic technique, which might not be suitable for the question being asked of it.

(g) Unavailability of previous studies or reports for comparison [Robinson 1997].

(h) Over reliance on locum radiologist within a department.

C. Generic factors mitigating underperformance/discrepancies/error

The factors outlined below are at different stages of development/underdevelopment within the Irish Healthcare system and individual radiology departments. Some of the factors are therefore, of necessity, aspirational, and their implementation will require significant planning and resources.

(1) Trained/accredited Radiologist

The evolving role of competence assurance, including continuous professional development, under the auspices of the Medical Council will play a significant role in the validation of skill maintenance.

(2) Trained and Certified Radiographers and Physicists.

(3) An integrated quality assurance/improvement programme.

There are many components to an integrated quality assurance programme.

(a) **Audit** - self-directed, randomised or peer audit. Audits of structure, process and outcome.

(b) **Imaging Protocols.**

(c) **Communication Protocols.**
Many errors in Radiology may be attributed to poor communication at some stage in the imaging/reporting process. Structure and process audits may identify such deficiencies.

(d) **Equipment Maintenance:**
A regular programme of equipment maintenance within a radiology department is an importance element of quality assurance. A rolling capital programme for equipment replacement is also desirable.

(e) **Discrepancy meetings:**
These are advocated as a learning process not as a method of competence assessment. (Appendix 1)

(f) **Double reading:**
There is ample evidence that double reading improves accuracy. The only area where a hundred percent double reading is the norm in Ireland is in the Breast Screening Programme. It has also been

used in the United Kingdom for Breast screening and for the outsourced Independent Sector MRI contract, where 10 percent of studies were audited/double read. Double reading is one of the best ways to safeguard the quality of service and the introduction of routine double reading on an agreed percentage (e.g. 2-5%) of work would have a significant impact on the maintenance of quality. There is however a significant manpower issue related to double reading.

(g) **Multidisciplinary Conferences:**
Multidisciplinary conferences have been advocated particularly in the context of cancer care. One of the key elements in multidisciplinary conferences is the double reading of images within the context of the appropriate clinical scenario. This is now seen to be an essential component of cancer care.

(4) Appropriate Work Load:

The increasing number and complexity of imaging studies requires a matching increase in radiology manpower

D. <u>Identifying Underperformance</u>

(1) Means of assessing error.

Human error can be viewed in either a person-centred or system-centred way, or both. A person-centred approach focuses on the individual who commits the error, and adopts counter-measures aimed at that individual, including disciplinary measures: 'naming, shaming and blaming' (Fitzgerald 2001). The NHS has concluded that the person centred approach, though attractive from a managerial and legal perspective, is 'ill-suited to the health care domain'. (Fitzgerald 2001, NHS). The system-based approach accepts that humans are fallible and errors inevitable, and seeks to address contributing system causes for these errors. What matters less is who made the error, and more how and why defences failed, and what factors helped create the conditions in which the error occurred (Fitzgerald 2001). The concept of Root Cause Analysis has been used as a method to learn from mistakes and reduce hazards in the future. This process is based on the principle of answering 3 questions:

1. What happened?
2. Why did it happen?
3. What can be done to prevent it happening again? [Murphy 2008]

As stated in the NHS Chief Medical Officer's report on this issue : '*It is of course right, in health care as in any other field, that individuals must sometimes be held to account for their actions – in particular if there is*

evidence of gross negligence or recklessness, or of criminal behaviour. Yet in the great majority of cases the cause of serious failures stretch far beyond the actions of individuals immediately involved''. (NHS)

(2) Allegation of incompetence.

One of the initial actions should be due consideration of the nature and source of the allegation, and the means by which the allegation is made. The allegation may come from a patient, a relative of a patient, a clinician, management personnel, or a Radiology colleague. Complaints from a referring clinician are particularly significant.

Possible approaches would include all or some elements of the following sequence of escalation:

(3) Is there a problem?

(a) The views of the Clinical Director, Institutional Risk Management Director, Medical Director and CEO may be sought.

(b) Risk Assessment Template. This 3 part process , based on the HSE Risk Assessment Tool (HSE June 2008) uses a scoring methodology to assess the impact of a particular discrepancy episode and estimate the likelihood of a wider problem. This may assist in guaging the scale and nature of any intervention. The initial assessment should be carried out by the Clinical Director.

STEP 1: Evaluate level of Discrepancy / Error.
Score should reflect the magnitude of the error and the clinical impact.

Score	Impact	
1	Negligible	No ill effects
2	Minor	Minimal ill effects
3	Moderate	Error resulting in short term ill effects
4	Major	Error resulting in long term ill effects
5	Extreme	Error resulting in severe long term or fatal ill effects

STEP 2:Evaluate proof of competence, habits of practise and and use of proper techniques.

System Related Issues

System Factor	Score
Clinical team working environment	5
Audit	5
Case conferences	5
Appropriate Workload	5
PACS/ Available clinical information	5
Discrepancy Meetings	5
Modern Equipment	5
Trained Radiographic Staff	5

Professional Factors

Professional Factors	Score
Experienced	8
Working in a radiology team	8
Isolated incident	8
CPD	8
No health/stress issues	8

Calculate score: 80- total, express as percentage and round to nearest 20%, ie score of 60/80, 80-60= 20, 20/80 =25% score 1**Risk Matrix**

Risk Matrix	Negligible	Minor	Moderate	Major	Extreme
5	5	10	15	20	25
4	4	8	12	16	20
3	3	6	9	12	18
2	2	4	6	8	10
1	1	2	3	4	5

(4) Acting on the results of the risk assessment process.

STEP 3: Application of Risk Matrix Outcome.

BAND 1: Local resolution desirable. Error should be fed back by the Lead Radiologist to the imaging professional concerned and subsequrntly discussed and recorded at the departmental discrepancy meeting. Relevent clinicians should be informed. Any remedial actions required can be directed from the discrepancy meeting platform.

BAND 2: Local resolution possible. Error should be fed back to imaging professional concerned and discussed at departmental discrepancy meeting. Relevent clinicians should be informed. The case can be reviewd by the Lead Radiologist with the input of Institutional Risk Management. Consideration can be given to an internal audit comprising a review of a random sample of cases. The radiologist should be informed that an audit is taking place. If there is persitant concern after internal audit, than an external review can be considered.

BAND 3: Error should be fed back to imaging professional concerned and discussed at departmental discrepancy meeting. Institutional Risk Management and and relevent clnicians should be informed.. Consideration given to an external review comprising an ad hoc group of representing Faculty, the HSE hospitals office and HIQA. Any review should involve other departmental radiologists with their consent. Ths would allow internal control for varying departmental factors and conform to a system based approach.. At least three radiologists should be chosen [Jolly 2001]. The reviewing radiologists should reflect whether Radiologist under review is a general or subspecialist radiologist i.e. the same reporting conditions, as afar as possible , should apply. Following consultaton, the HSE Srious Incident Policy may be activated.

(5) Medical Council.

Persistent concern after external review may require evaluation and declaration of competency by the Medical Council. Any determination made by the medical council may have grave consequences for the individual under investigation and due care must be taken to ensure the process used is fair and judicious.

(6) What is the Impact of a Confirmed Problem?

Once a problem is confirmed after an external review, a 'look back' may be instigated to assess the impact of the problem; this should be targeted (e.g. mammograms only), graduated (e.g. initially over most recent 3-6 months period) and risk based (e.g. plain films not reviewed by another doctor). This should probably be performed in the public domain as a problem has now been confirmed (as opposed to a suspicion), and there is a duty to inform the public where a problem exists. All patient whose studies are being reviewed should be informed prior to the commencement of the process.

E. Other Issues Agreed:

(1) The role of the Faculty of Radiologists vis-a-vis other organisations.

The Faculty of Radiologists sees its role as being to help employing authorities, quality agencies, and the DOHC to consider how best to review the work of Radiologists. If the Faculty were to play a role in this regard however, a protocol would need to be evolved to define the roles and responsibilities of both the employing authorities, the Medical Council, HIQA and the Faculty of Radiologists, including the issue of indemnity. While the Medical Council has employed the expertise of the Faculty for guidance in some areas, currently the Faculty has no statutory role with respect to accreditation, CPD, quality assurance or remediation.

(2) Organisation of an Integrated Quality Assurance/ Improvement Programme.

Ad-hoc audit is performed in many Radiology departments throughout the country. An integrated structured quality assurance/improvement programme is not a feature of most departments. Significant facilitation from the HSE would be necessary to organise a nationwide role out of such a programme. The question of integration of smaller hospital departments within such a programme would also need to be considered. The new consultant contract (2008) may help facilitate quality assurance by including this activity as part of the additional hours under the new contract. The CME Committee of the Faculty, taking account of the Competence Assurance structures of the Medical Council and the Forum for Post Graduate Medical Training Bodies, can arrive at precise definition of the elements of a quality assurance programme.

(3) Teleradiology.

Issues relating to accreditation, competence assurance, communication, and multidisciplinary care are critical in the evaluation of the appropriateness of Teleradiology service. (See Faculty Document on Teleradiology). The

development of quality assurance within the public system must be matched with similar transparent standards in the private sector, and in teleradiology (public or private). The Faculty of Radiologists will be involved in setting quality assurance standards, to apply to all patients in the state having radiological investigations or procedures.

(4) Appointment of Locum Tenens.

The recent Health Information of Quality Authority (HIQA) report on the investigation into the provision of symptomatic breast services at University Hospital Galway has made specific recommendations with respect to the use and appointment of temporary or locum Consultant staff. This equally applies to Radiology. The position of the Faculty of Radiologists is that all locum radiologists should be on, or eligible to be on, the Specialist Register. However, it must be recognised that these recommendations will lead to significant practical difficulties in smaller radiology departments. The percentage of radiology consultant positions occupied by locums at any one time and the impact on service quality of reliance on locums need discussion.

(5) Cross Jurisdictional Cases.

The issue of underperforming individuals moving from one jurisdiction to another will need to be addressed at a regulatory level, most likely under the guidance of the Medical Council.

(6) Remediation.

When under performance is identified remediation should be offered to the Radiologist. It should be tailored to address specific deficits. Some situations can be corrected with education, skill development or supported learning. Upon completion of necessary training, a period of monitored supervision may testify to the success or otherwise of the intervention. The Medical Council will obviously play a key role in this area and it is unclear whether the Faculty of Radiologists will have a role in such remediation.

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