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## Preface

All radiological departments aspire to a high quality of radiological services at the lowest possible risk to the patient. Unfortunately services may not always achieve these goals and errors and mishaps occur even in the best run organisations. It is therefore important that radiology departments address in advance their potential areas of weakness and also try to reduce as far as possible the sources of error. This requires the proactive approach of risk management, which is a structured way of reducing risk to patients and staff to the lowest achievable level. The key to risk management is a willingness to evaluate all actions with transparency and openness and to try to remedy obvious failures and alter working practices where appropriate. This document produced by the Professional Organisation Committee of the EAR in conjunction with the Radiological Section of Union of European Medical Specialists (UEMS), attempts to guide radiologists through this process indicating where structural changes to practice may reduce the risks to patients.

Although the level of medical litigation varies throughout Europe, the cost is still high and the stress of errors to both the radiologists and patients may be considerable. It is therefore in our own interest and those of our patients to try to reduce risk as much as possible recognising that medical care is often a balance of risk and benefit. If both radiologists and patients are fully aware of these risks, the resulting expectations will be realistic.

The EAR Executive hope that this advisory document will be of value to all national and subspecialty radiological societies in guiding departments to reduce risk.

### Executive Bureau of the European Association of Radiology, November 2004

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# 1. Introduction

Risk is defined as a chance or possibility of danger or incurring loss or injury. It is recognised that harm may befall a patient even in the best hospitals and departments delivering the highest possible standards of care and the practice of medicine is often a process of balancing a risk against the efficacy of a diagnostic or therapeutic procedure. Risk management is a proactive approach involving the systematic identification, quantification and assessment of risks, the appraisal of options to eliminate or reduce them and the recognition by all concerned of the implications of the remaining risks. This process involves all those who are responsible for the delivery of health care, not just the individual clinician who is caring for the patient. The managers of the health care facility have a particular responsibility to provide the necessary facilities, staff, equipment and financial support for the front-line clinicians in order for them to practice at standards which are considered satisfactory by their peers and which keep the risk of harm to the patient at the lowest practicable level. This is particularly the case in radiology departments where the quality of equipment and staffing numbers can have a major effect on the accuracy of the diagnostic report or the success of an image-guided intervention. The radiologist or radiographer cannot be held responsible for errors that are a consequence of under-investment by the management and the implications of inadequate resources. In terms of patient risk, it should be clearly identified, if a proper risk management evaluation is undertaken.

The main aim, therefore, of risk management in radiology is to reduce and, where possible, eliminate harm to the patient by

- recognising the limits of radiological diagnosis;
- identifying and where possible reducing or eliminating complications of radiological examinations through the establishment of robust protocols and appropriate safety systems;
- ensuring the highest quality of radiological accuracy;
- learning from mistakes and monitoring significant or critical clinical incidents and near misses;
- sharing knowledge;
- investing appropriately in equipment and properly trained staff.

Lapses in the standards of care may be present in a variety of different ways:

- A completely unexpected error which results in harm to the patient.
- A service performing sub-optimally over a long period of time producing unsatisfactory outcomes.
- An individual practitioner whose performance is impaired due to inadequate knowledge or skills or dysfunction of health or behavioural problems.
- Inappropriate conduct.

Risk management helps to safeguard the patient, the radiologist and the organisation in which the radiologist works in terms of finance, reputation and potential loss of morale from possible errors. The overall goal is the improvement in the quality of care for the patient.

There is nothing revolutionary about risk management as the analysis of the benefit and risk of any procedure is an integral part of every radiologist's working day. All health care establishments should work to minimise harm to the patient. However, the process of risk management encourages radiologists to address potential problems in advance, so that the appropriate protocols and procedures may be put in place to minimise risks.

Whilst the reduction of litigation and its costs is an obvious objective of risk management, avoidance of problems that may lead to litigation will benefit patients as much as radiologists. Management of risk is a responsibility of all involved in the radiology department and the understanding and ownership of the process is essential.

This paper addresses the risks inherent in direct patient care, but organisational risks such as inadequate facilities or health and safety issues also have a direct impact.

## 2. Direct Patient Care

### 2.1. Radiology Reporting

The accuracy and timeliness of the radiological report is a key component of the patient's overall care in a radiology department. High reporting accuracy requires an optimum environment for detecting and reporting abnormalities which is the responsibility of the management of the health care facility. This is achieved by the adherence to high standards of practice within the department and an insistence on technically satisfactory images.

However, in terms of risk management it must be recognised that variation between experienced radiologists in the interpretation of plain radiographs has been consistently demonstrated in comparative studies. In a comparative study of casualty plain radiographs significant disagreement varied between 5 to 9 % with an average incidence for all observer pairs of 5.6 %. The presence of an abnormality rather than its significance was more likely to give rise to observer variation (1).

#### 2.1.1. Errors of Reporting

Such errors can be defined as perceptual or cognitive (2). Perceptual errors occur when image features though recorded were not appreciated. A cognitive error occurs when image features though appreciated lead to wrong conclusions as a result of response bias or flawed diagnostic logic. Reporting errors may also be classified as either false positive or false negative. A false positive study can be subdivided into either an interpretation of a feature as pathological which is in fact normal or normal variant, or the recognition of an abnormality but with misclassification where the finding is attributed to the wrong cause. A false-negative or under-reading may be a finding that is present but is missed or one where the lesion was not present on the image due to inadequacy of the examination.

False-negative errors are five times more common than false-positive errors (3). Similarly perceptual errors are four times more frequent than cognitive errors (2). It has also been shown that more lesions are perceived retrospectively (4).

##### 2.1.1.1 False Positive Errors

The reasons for false positive examinations or cognitive errors are more likely to be related to a lack of radiological skills and knowledge rather than external factors. However, they may also be partly due to incomplete clinical data (5) and the unavailability of old examinations (3).

Over-reading may be due to

- misinterpretation of normal variants;
- inadequate knowledge of normal anatomy;
- misinterpretation of signal changes on MR and radio-isotope studies, or echoes on sonography;
- variants in development and growth.

Over-reading is a particular problem with respect to trauma as treatment may be instigated on the basis of the report and complications of treatment or financial and social problems may ensue. False-positive lesions are a particular potential source of error in paediatrics.

##### 2.1.1.2. Incorrect Diagnosis

Lesions that are perceived but incorrectly diagnosed or inappropriately interpreted may include such issues as:

- misinterpreting scarring and tumour recurrence,
- lymph node enlargement interpreted as tumour invasion when it is due to inflammation,
- misinterpreting changes as tumour instead of infection, vascular disease or benign tumour (6).

These types of lesions can be classified as those where a lesser or a more severe disorder has been diagnosed. In particular, subtle findings may be overlooked, if overt abnormalities are present. The presence of a small tumour recurrence masked by post-irradiation fibrosis may be an example of such a situation.



Risk management issues in this field may, if in doubt, involve repeated examinations to assess change and examinations of opposite side in cases of paediatric trauma. Confirmation of a normality or resolving interpretative problems may be achieved by additional examinations.

There are a number of factors that may lead to false negative and false positive evaluation of a radiographic examination.

These may include the following:

#### 2.1.1.3 Poor Quality of Examination

The management of the health care facility and the department of radiology have the responsibility of ensuring that the radiographic staff are properly trained to recognise national or European standards and that sufficient such staff are employed to allow optimal standards to be maintained. If staff are inadequately trained or too busy, there is an increased likelihood of poor-quality examinations due to:

- incorrect exposure,
- inadequate coning areas of the film,
- abnormalities outside the area of the primary examination,
- inappropriate views,
- type of imaging modality chosen,
- inappropriate imaging protocols,
- inadequate imaging technique e.g. sonography.

Radiologists should not attempt to make a diagnosis from poor-quality examinations unless it is imperative and the risks have been assessed. A proper risk assessment should also be undertaken to clarify the cause for the poor quality of the examinations and rectified where possible.

#### 2.1.1.4. Failure to Consult Previous Radiological Studies or Reports

This may be due to

- previous images having been lost or destroyed,
- radiologists being too busy to go through previous images,
- insufficient administrative assistance to find old images or inappropriate digital retrieval,
- an urgent report being required before previous studies can be retrieved.

It is the responsibility of the management of the health care facility and the radiology service to define the length of time of storage of old examinations which is often a balance between the cost, practicality of storage and retrieval of old films and the risk of a lesion being missed or misinterpreted when old films are not available. Management should also ensure that there are adequate clerical staff and systems to ensure that old examinations are available when and where they are required.

Previous examinations may however not demonstrate a lesion due to the fact that the equipment used was of an older generation and/or had inferior technical characteristics. For example the detection of a lung nodule has improved with increasing development of equipment and the size of a discernable lesion has decreased (7).

#### 2.1.1.5. Clinical Information

Lesions may be missed related to a misdirected search secondary to inaccurate or incomplete clinical history/details (5). Errors can arise, because the abnormality is outside the area of primary examination or because the imaging protocol used e.g. in CT/MRI, while adequate for the clinical indication given is suboptimal for other pathology (8, 9, 10).

#### 2.1.1.6. Multiple Lesions

A lesion may be missed in circumstances where the radiologist recognises one abnormality, but fails to see a second lesion. Failure to report multiple lesions has been noted in several studies (3, 11, 12).

2.1.1.7. Poor Viewing Conditions	Poor viewing conditions may lead to errors, particularly for chest x-rays. Management should ensure that up-to-date viewing boxes or digital viewing equipment are provided and that the ambient lighting is appropriate for optimal viewing of examinations.
2.1.1.8. Repeated Interruptions	Repeated distractions and interruptions will cause a loss of concentration and may lead to errors. Efforts should be made to decrease interruptions as far as possible during the reporting session by ensuring that there is an adequate number of radiologists so that queries can be dealt with in a planned and non-disruptive manner.
2.1.1.9. Fatigue	<p>Fatigue has been cited as a potential source of false-negative examinations. The effect of overwork on radiological accuracy and potential medico-legal implications has been highlighted (8, 13, 14, 15, 16). Management and radiologists must evaluate the level of risk in each area that may result from overwork and tiredness and seek to alleviate this wherever possible.</p> <p>The risk assessment and resolution of this is the responsibility of the departmental or health care facilities managers in discussion with the radiologists.</p>
<b>2.1.2. Training</b>	<p>Radiology is becoming more complex and the range of investigations and techniques is extensive. Considerable subspecialty training may be required in certain areas and it is important that radiologists do not work beyond their competence. Defining special interests is now a prerequisite for many radiologists and in large departments each radiologist may effectively pursue a subspecialty interest. In small departments, however, and in private practice, radiologists may be required to undertake a wide spectrum of procedures. During holiday periods and on-call there is a greater likelihood of radiologists being placed in the position of having to undertake examinations for which they do not feel properly trained, or have not maintained their expertise.</p> <p>It is therefore important that a risk assessment is performed to ensure that radiologists delivering any part of the service are properly trained. Hospitals may need to define what services they are able to provide on a day-time basis and a 24 hour basis in order to ensure that the radiologists undertaking the investigations or therapy are competent to undertake them. In holiday periods some services may need to be temporarily withdrawn or special cover arrangements may need to be made with other health care facilities.</p> <p>It is essential that radiologists undertaking new tasks or using new investigative equipment should undertake proper training prior to providing a patient service. This will clearly be an integral part of their continuing professional development and each radiologist should have a programme of development that is related to the specific requirements of their clinical task that they perform or are likely to perform.</p>
<b>2.1.3. Risk Management Recommendations</b>	<ul style="list-style-type: none"> <li>· The hospital and departmental management should ensure that the viewing facilities where the reporting is undertaken are of high quality. If digital equipment is used, this should be of a standard which is internationally acceptable. Quality assurance of viewing facilities should be in place and deficiencies brought to the attention of the management.</li> <li>· Disturbances whilst reporting should be kept to a minimum, although clearly clinical consultation and feedback should not be discouraged as it is a vital part of the audit cycle.</li> <li>· The management of the hospital or health care facility should ensure that the complement of radiologists is sufficient to undertake the workload without resulting in either fatigue or radiologists being forced to undertake investigations for which they are not appropriately trained. Radiologists should define which areas they are capable of undertaking, specifying procedures, and managers should ensure that alternative</li> </ul>



- arrangements are made when certain procedures are required and the necessary technical facilities or clinical expertise are not available.
- Radiologists should ensure that they obtain proper training in any new technique. Specialist centres are encouraged to provide training for established radiologists as well as trainees and that all radiologists, as part of the organisations risk management policy, should have adequate funding available for all necessary additional training.
  - Clinical data should be reviewed prior to evaluating or undertaking examinations. Patients may have a large number of previous investigations and careful assessment takes time. It is important that the radiologist's workload is not too high as a failure to undertake a proper review of previous examinations will also increase the risk of mistakes. Organisations are encouraged to develop integrated PACS systems to make previous examinations easily and rapidly available.
  - Regular clinico-radiology conferences enable feedback from clinical colleagues and the reviewing of examinations that have been undertaken in order to ensure that appropriate investigations are being performed, to identify any risk factors for individual patients, to bring potential errors to light and to assess continuing risk. A large direct practitioner referral programme for radiology may result in lower feedback and increased risk. Good communication with the referring general practitioners needs to be established to enable proper clinical feedback to take place.
  - Ideally all examinations should be reported by a qualified radiologist or trainee radiologist under specialist supervision. If, for reasons of inadequate radiologist staffing levels, clinicians are reporting examinations, it should be clear to them that they are doing so under appropriate protocols and to a standard that is equivalent of the experienced radiologist. This is usually only possible in highly selected areas or specific subspecialties such as orthopaedic surgeons reporting follow-up films of fractures and even in these circumstances they may not recognise additional conditions or complicating factors. The training of the clinician needs to be established in order for this activity to be undertaken appropriately, the clinicians are legally responsible for the interpretation.
  - If a radiological task is delegated by the radiologist, it is essential that the person to whom the task is delegated is competent and that the process of delegation is defined in a protocol agreed by the delegator, the person to whom the task is delegated and the relevant employer. The process and outcome of delegation should be monitored and the process should be modified, if necessary. The person to whom the task is delegated assumes responsibility for it, except that medical responsibility remains with the delegating medical professional.
  - If there is a likelihood that some imaging examinations may not be reported due to staffing difficulties, the radiologists and management will need to define these examinations from a risk management point of view and the process should be audited regularly. However, it must be emphasised that each radiation exposure must be justified and that a clinical evaluation of the outcome of each medical exposure should be recorded.(17)
  - A proper audit programme should be undertaken in order to regularly review the quality of the service provided. Audits should be properly structured and a clear standard should be set, which may be local or national, against which the service is audited (18). This is essential as the audit cycle is a risk management cycle.



It is important to review diagnostic procedures to avoid undertaking inadequate or outdated procedures or those procedures which have little value in patient management, unless there is a clear reason for such a course. Clinical radiologists should monitor their requests for investigations to reduce overall radiation exposure and maximise the risk benefit ratio of radiological examinations. This is an obligation under the Euratom directive which is being enacted into national laws throughout the EU (17).

## 2.2. Interventional Radiology

### 2.2.1. Complications

Complications are most frequently associated with interventional techniques and may involve a number of factors including haemorrhage, haematomas, post-arteriographic stenosis or vascular rupture.

Patients may also undergo reactions to injections of contrast agents, which may include urticaria, hypotension, breathing difficulties and, at worst, cardiac arrest. Some complications may be due to a failure to follow proper practice or established departmental or national standards. Examples include failure to evaluate the patient carefully in terms of blood clotting parameters, histories of allergy and inadequate review of previous radiographs or other imaging investigations. The incidence of sepsis may be high, if proper aseptic techniques are not in place.

Complications may also occur, if equipment being used breaks down or is inappropriate for the examination or treatment. The management of the department should ensure that the equipment is properly maintained and that replacement programmes follow the appropriate national or European standard. Consumables should be of a recognised standard and should be in-date at the time of use.

Therapeutic procedures should not be undertaken unless they have the realistic prospect of improving the individual patient's well being. Many patients who referred for interventional radiology have significant co-morbidity (19, 20).

It is essential that the radiologist and the patient's clinician liaise closely when decisions regarding the choice of procedure and the management of complications are made. At any one time a named doctor who may or may not be a radiologist should have overall clinical responsibility for a patient (21).

### 2.2.2. Consent

There is often a reluctance by radiologists to explain all complications of the procedure to the patient on the grounds that this may deter patients from having an investigation or therapeutic procedure that will be of benefit to them. However, patients have a right to be involved with, and to agree to all decisions with regard to procedures being undertaken upon them and may only make a reasonable decision when all the positive and negative factors have been explained.

In seeking consent the radiologist must ensure that:

- the patient is competent to give consent,
- the information provided is timely, accurate and understood by the patient,
- consent is given without duress.

Sufficient information must be given to the patient to ensure that they understand the nature and are aware of all consequences and any significant risk of the examination or procedure proposed. Information should be made available on the basis that the risk was of a kind or magnitude that no reasonably prudent medical person would fail to make the disclosure or what a reasonable patient might expect (22). The decision to obtain oral or written consent will depend on the complexity of the procedure and the degree of potential side effects. A permanent record of the obtaining of consent should be made in the relevant health records. It is often advisable to explain the complications to the patient in the presence of a reliable witness and the patient should be fully in control of their faculties. Similar care should be



applied when seeking consent for investigations that involve intimate examinations. Information leaflets describing the examination to be performed, which can be given to patients prior to the obtaining of formal consent are of value as they enable patients to seek clarification, if necessary, and reduces the stress on patients.

### 2.2.3. Risk Management Considerations

- Proper departmental protocols should be in place for all investigations in order that potential complications are identified prior to the investigations and all attempts are made to eliminate or, when not possible, to alleviate them (23).
- Procedures should be reviewed and complications should be audited and compared to national and international standards where available. Individual radiologists may consider keeping a database of all patients on whom they have performed procedures, any adverse events and overall outcome. However, such a database must comply with any national data protection legislation. Special training should be instigated, if complication rates are inappropriately high (23).
- All radiologists should be aware of the risks of injecting contrast agents and should have a comprehensive knowledge of the substance being injected. Protocols must be in place for dealing with reactions. All members of the radiology department should be trained in resuscitation to the appropriate level. Radiologists should regularly review their resuscitation skills especially in the light of reduced incidence of complications following the introduction of low osmolar contrast agents.
- The hospital management should ensure that appropriate nursing support is available within departments of radiology in order to monitor and support patients during invasive procedures. They should be aware of the techniques being undertaken and be able to assist the radiologist during the procedure, if this is required.
- There is increased use of sedation and analgesics particularly in interventional radiological procedures and many of these agents have a central depressant effect on respiration and cardiac output. Radiologists must be cognisant of the pharmacology of these agents and of the specific management of adverse reactions. Sedated patients should be monitored with appropriate monitoring devices and there should be sufficient qualified staff to enable this monitoring to take place. Anaesthetic support is required for the unconscious patient, for seriously ill patients who may be at risk or if complications of a cardio-respiratory nature occur (23).
- It is the responsibility of the individual radiologist undertaking the procedure to ensure that the complications have been explained to the patient and that, where appropriate, the patient has signed the consent form. It is preferable, although often not possible, for consent to be established and the form signed outside the radiology department prior to the investigation in order to reduce pressure on a reluctant patient to acquiesce to having the examination. As already indicated above, radiologists should keep records of all procedures and any untoward incidents so that these can be reviewed in order to avoid future mistakes. Patients undergoing invasive procedures should have an appropriate clinical examination prior to the procedure and their clinical status should clearly be established and recorded, as clinical features claimed to be new following the procedure can only be refuted, if they were clearly shown to be present prior to the procedure.

### 3. Communication

Failure of communication is an important source of radiological mishaps and can result in an inappropriate investigation being performed on an individual patient or the wrong patient being sent for an examination (3).

#### 3.1. Information needed by Radiologists

There may be insufficient clinical information on the request card which may also be inadequately filled in and signed. In the absence of good clinical information, inappropriate investigations may be performed and as some examinations have a high radiation dose, it is important that inappropriate examinations are not undertaken on patients, particularly on children.

The European Directive 97 / Euratom (17) states that all investigations involving radiation require justification. This must be undertaken by someone who is appropriately trained, usually a radiologist, or under the auspice of previously agreed protocols, by radiographers, cardiologists, dentists etc. In order to undertake the justification, sufficient clinical information must be provided by the referring physician. The European Referral Guidelines (24) may assist the referring physicians to request the most appropriate investigations, but it remains the role of the radiologist to decide which investigation to undertake bearing in mind the risk-benefit ratio of the various choices.

The radiologist must also receive any information regarding previous examinations that have been undertaken and whether previous results have affected clinical management and have been acted upon.

The clinical information provided should clearly identify the area of the patient that is under review as there is no excuse for an examination to be a failure due to the incorrect area being imaged. Mistakes in the labelling of the examination must also be avoided, as the absence or invisibility of a RT/LT marker may result in inappropriate treatment.

#### 3.1.1. Risk Management Recommendations

- Departments should have established procedures for the receipt and recording of clinical information. This may be written on the request document or the clinical notes or be in the form of an electronic referral.
- Radiologists must ensure that the appropriate information is available before justifying an examination.
- Radiographers should not undertake any examination without adequate clinical information.
- Radiologists undertaking CT and MR studies or invasive procedures should be provided with detailed clinical notes.
- The patient should be questioned prior to any examination to ensure that there is no mistaken identity and that the symptoms are related to the area to be examined.
- The patient should be asked about previous studies, adverse reactions and in some situations, current medication.

Delay in reading an examination and providing a diagnosis may result in the radiological images being taken from the radiology department before being interpreted, if no PACS system has been installed. This is a particular problem where the management have employed insufficient radiologists for the workload of the department. This may also occur, if examinations are undertaken out of hours and urgent evaluation of the study is required. The hospital department or health care facility should ensure that there is sufficient radiological manpower available to provide immediate reports on high-risk patients where clinical management requires urgent therapeutic decisions. The cost of failing to provide this resource may be significantly greater than the investment.

#### 3.2. Communication of Reports

The communication of the report of the examination is an important source of error (23, 25, 26). It is essential that procedures are in place to transmit the report of the examination as quickly as possible. The management of the hospital, health care facility and the radiology department should review the pathway of the examination report to assess whether there



are sources of delay and whether the financial implications of delays or mistakes against the cost of having adequate systems and technology are in place in order to provide a timely report.

Where an urgent clinical situation is present or there is a major unsuspected finding which involves urgent patient management decisions, the radiological opinion should be transmitted directly to the attending physician. This may be a verbal communication between radiologists and the responsible clinician, which may be time-consuming, and a clear record of the conversation should be made in the clinical notes (26). In these circumstances a formal report still remains an essential record.

It is important that the report of any examination, when issued, arrives quickly at its appropriate destination and is read by the referring source. The receipt of the report and the action taken should be recorded in the patients notes.

### **3.2.1. Risk Management Recommendations**

- A timely report should be issued by the radiologists.
- All films removed from the department should be returned promptly. A hospital-wide PACS system would resolve the problem of films being unavailable for reporting.
- Radiologists should review the methodology and documentation of reports. Properly trained medical secretarial support should be provided and departments may wish to assess the financial viability and appropriateness of voice-recognition-recording systems.
- Radiology on-call arrangements should be clearly defined and be appropriate to the severity and complexity of the clinical conditions being dealt with by the hospital.
- The use of teleradiological systems for emergency reporting is now established in some centres, but robust safeguards need to be in place (27).

## **4. Dealing with Errors**

Multi-observer review of individual examinations has demonstrated that inter-observer variation may be considerable especially in subtle cases and that accuracy, sensitivity and specificity of individual investigations varies depending on a number of factors (8). The process of risk management recognises that there will be cases where accurate radiological diagnosis is not possible. Radiology is not histology. This will be an important factor when comparing the performance of the radiology department and individual radiologists. Patients must be made aware of the fact that investigations are not always diagnostic or without complications and this should be part of the patient information and communication.

The discrepancy between retrospective review of an image or an outcome in a patient and the original report should not automatically be viewed as an error. A radiological investigation is often only part of the diagnostic information of a patient and imaging may be undertaken early in the course of an illness when findings are subtle. Radiology involves judgement under conditions of uncertainty and bias (8) and although reporting discrepancies have the potential to adversely effect patient management this is usually not the case, because of the overall context of clinical decision-making.

### **4.1 Procedures to deal with Errors**

When errors occur, radiologists should have agreed procedures to deal with such events:

- The essential details of the error should be explained to the patient involved.
- The details of the error or accident or complication should reviewed
- If the error is significant, counselling should be offered to the patient.
- Appropriate treatment should be instigated as quickly as possible.
- The department should have protocols to deal with all untoward incidents.
- Untoward incidents should be reported to the hospital so that they are in advance aware of potential claims against them.

#### 4.2. Discrepancy and Difficult Diagnosis Conferences

There is a natural reluctance to admit one's own errors especially in public and there is hesitancy in informing others. Risk management, however, is dependent on the acceptance that mistakes will be made and that things will go wrong. The key is to try to anticipate them and to alleviate them or to accept the appropriate level of inevitability. In good risk management practice it is therefore essential to have a forum where reporting discrepancies, errors, near misses and complications are demonstrated and evaluated. The natural reluctance to participate should be resisted (28). This can be alleviated to a significant degree:

- if anonymity is maintained.
- if presentations at the meetings are anonymised.
- if written reports are made by peers at the meeting giving the same information as the original reporting radiologist and a consensus is reached whether an error or discrepancy occurred (29).
- The process is treated as educational and not punitive with a clear no-blame-culture.

Discussions should conclude with an analysis of how the error or discrepancy could be avoided in the future. However, although this process may contribute to the reduction of risk, there currently seems to be no correlation between discrepancies so reported and the incidence of complaints and litigation (30).

Problem cases can be collected for discussion in a number of ways including:

- Reviewing reports for difficult diagnoses.
- Complex techniques revealing missed or misinterpreted plain radiographic lesions.
- Reports from clinico- or patho-radiologic review meetings where outcome can be discussed and related to the radiological report.

Discrepancies may be due to various factors including:

- Failure to review hidden zones,
- Inappropriate Kv limiting recognition of lytic zones or fine calcification,
- Improper positioning,
- Inadequate or misleading clinical information,
- Poor technique in sonography, CT and MR.

A confidential record of the cases discussed should be made identifying

- the perceived reporting discrepancy,
- whether the discrepancy was confirmed on consensus peer review,
- whether others made the same decision,
- the outcome.

The original reporting radiologist should be informed of the case in a confidential fashion and the clinical team should be informed of the discrepancy, if they are not already aware, to ensure that harm to the patient is avoided.

If process or system factors contributed to or caused the discrepancy, then these should be recorded along with the steps taken to rectify them. Any general lessons learnt should be promulgated throughout the department.

Finally patients have a right to know of errors that have adversely effected their care management. Communication of this information to the patient must be undertaken in a sensitive manner after discussion between the radiologist and the clinical team.

#### 4.3. Critical Incident Reporting

Errors that lead to mismanagement with resultant significant morbidity or mortality should be recorded as critical incidents and should be reported to the hospital or practice management.

What constitutes a radiological critical incident needs to be clearly defined in advance and not decided arbitrarily on a case by case basis. The critical incident process should be used appropriately to avoid errors being covered up or radiologists being unfairly treated.



## 5. Equipment

The hospital, health care facility or departmental management should ensure that equipment which is old or not in good condition or which could cause risk during an investigation, is replaced. Poor-quality images may be produced which may lead to misdiagnosis, if undertaken on equipment which is below accepted radiological standards. The acuity for the detection of lesions and a decrease in size of the lesion visualised may be improved by equipment development (7). Equipment breakdown during invasive procedures may have serious consequences as many of the examinations and procedures are undertaken on patients who are seriously ill. The duration of the procedure may be lengthened because of equipment malfunction increasing the risk of complications and investigations which have to be terminated due to equipment failure may also result in serious outcomes. Equipment should, therefore, be up to date, should be serviced regularly and a proper maintenance and replacement programme should be in place. It must be recognised that access to the latest technology may not always be possible, but it is important to understand in risk management terms that the quality of the examination and the accuracy of the report may depend, in part, on the specification of the equipment and that investment in high specification, modern equipment will reduce risk and that it is unacceptable and high risk for the patient to be investigated on sub-standard equipment.

There is a duty of radiologists to advise the hospital or health-care facilities' management of deficiencies in equipment which may contribute to patient risk and this advice should be recorded (31).

## Conclusion

**The quality of a radiological report depends on a number of important steps which have been outlined in this report. The essence of risk management is to review all potential reasons for an inaccurate report in advance so that an evaluation can be made as to whether procedures can be put in place to avoid them and whether such procedures are clinically significant or cost-effective. The financial and patient risk of not instigating changes where they are deemed to be helpful should also be clearly understood and balanced against the difficulty and cost of the solution. Errors meetings are a way of discussing mistakes with the intention that all radiologists will learn from them and modify their practice, if practicable. Errors are more likely to be detected in general reporting where there is a wider participation of radiologists, but CT and MR are also a major source of error. In specialist areas which may only have one radiologist involved, errors are less likely to come to light. It must also be recognised that with the benefit of hindsight, follow-up films and further investigations, a correct diagnosis can be made which was difficult or impossible on the original examination. It is hoped that this review will assist departments of radiology to set up the necessary structures to undertake risk management recognising that errors are intrinsic and inevitable and must be dealt with objectively.**

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