Medico-Legal Issues in Radiology

Dr Lee Pheng Soon President 46th SMA Council

24 June 2005

Dear Dr Lee

Thank you for your letter of 23 June 2005 emailed to Dr Tim Hegan seeking the Society's views on radiologists accepting referrals from non-medical practitioners and patients. You invited us to comment on the medico-legal implications in particular, although this raises other complex issues such as professional accountability, financial interests, patient autonomy, public safety, expanding role of radiologists, gatekeeper functions and access to investigations.

The **medico-legal responsibility of the radiologist** when reporting X-ray films is the same whether they were ordered by a registered medical practitioner, a TCM physician or the patient himself. He has a duty of care to interpret the films correctly, accurately and having taken account of all the information available. The standard required is still that of a reasonable fully-trained radiologist, and it is likely that the Bolam test will still apply.

However, we would argue that the duty of the radiologist goes beyond merely **reporting** the X-rays. Radiological assessment nowadays involves complex imaging techniques, many of them invasive and involves considerable risks to the patient. He has to decide whether to **agree to the request**, having taken into consideration the source of the request, and whether the request is in the patient's best interest. Given that his clinical skills are limited, he has to depend on the referring physician's expertise in assessing the patient and with the help of this information, to **select the most appropriate** imaging modality. He has a duty of care to decide against tests requested which may harm the patient. Arguably, he takes on an additional burden in this area of responsibility when the request comes from a TCM physician or a patient without training or knowledge in radiological techniques and their hazards. He could be considered to have taken on an extended role in this situation, and would have to show that he has adequate training and experience in this extended clinical role.

The radiologist would also have a duty to **perform the test** to the required standard, and without harm to the patient. He has a duty to ensure that the interpretation is correctly applied, having considered the individual patient and his clinical circumstances. If he works with non-medically qualified practitioners, it could be argued that the responsibility for having the correct clinical input is his alone. Therefore, the responsibility for the **correct interpretation** of the imaging results, which is based on both the radiological and the clinical assessment of the patient, will also be his alone.

When things go wrong, the patient will sue whoever is perceived to be liable. This depends on who has a duty of care and whether he is in breach of his duty of care. For example, a TCM physician who acted beyond his expertise in requesting a femoral angiogram for a painful leg which he mistakenly thought to be a vascular problem, and the patient suffers contrast nephro-toxicity as a result, may be vulnerable since he would not be able to show adequate experience and training in recognising vascular problems in patients.

The radiologist who accepted the request and performed the test based on the TCM practitioner's input would also be liable if he subjected the patient to this invasive procedure without adequate clinical justification. He has a duty of care to the patient in ensuring that the test is clinically appropriate and is safe, since he is the expert in his field. It would be difficult for him to argue that he is not liable since he relied on a non-medically qualified practitioner's assessment of the patient. He would be expected to have assessed the patient himself (if he considers himself having adequate clinical expertise), or referred the patient to a medical clinician for appropriate assessment before subjecting the patient to any invasive procedure.

The regulation and accreditation of TCM practitioners following the passing of the TCM Practitioners' Act 2000 may improve accountability and lead to a more consistent standard of



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TCM practice. It will not by itself alter their expertise base unless changes are made in the TCM curriculum and training. Whether the Ethical Code of the Singapore Medical Council, which discourages doctors from associating with non-registered healthcare providers, still applies now that TCM practitioners are registered will have to be clarified with the SMC itself. It is clear however, that registration does not change the duty of care that radiologists have for their patients.

I hope you find this helpful but if you require further clarification you may wish to contact either myself or Dr Tim Hegan at the Society.

Yours sincerely,

DR MING KENG TEOH MEDICO-LEGAL ADVISER

Dr Ivor Thevathasan Chairman Professional Indemnity Committee

1 November 2005

Dear Dr Thevathasan,

Thank you for your recent email seeking the Society's views on teleradiology and the outsourcing of radiology services to other countries such as India and Australia. You expressed concerns about the possible use of unqualified radiologists from these countries, and how it impacts on the liabilities of doctors in Singapore when an adverse outcome results from management decisions based on the reports of these unqualified radiologists.

Teleradiology: Benefits and Issues

The development of PACS (picture archiving and communication systems) and the technology for transmitting vast amounts of radiology images across the world as digital signals has enabled radiology services to be outsourced with obvious benefits such as timely interpretation, secondary consultations, improved continuing education and the ability of users in different locations to view images simultaneously. However, it must be recognised that commercial pressures have been the main drivers of change here, although outsourcing radiology services using teleradiology can sometimes help to address local problems such as waiting times and shortage of radiology skills. The benefits from outsourcing, financial or otherwise, should be weighed against the difficulties such as the uncertain medico-legal framework, fragmentation of patient care and loss of accountability, as well as the longer-term strategic losses in local core skills and manpower resource.

Although some practical guidelines exist in countries such as the UK, the ethico-legal concepts surrounding this innovation remain unclear. It is best to identify the legal implications and necessary guidelines to safeguard patients and physicians before considering outsourcing radiology services. The most important issues are those of accountability, duty of care, liability, quality, misdiagnosis, responsibility, security and patient confidentiality.

Responsibilities and Guidelines

The hospital executive board or the manager responsible for outsourcing has to ensure that the outsourced services are reliable. He has the responsibility to ensure that the outsourced radiologists are adequately experienced, qualified and accredited to satisfy the needs of the outsourced service. He would be well advised to seek the advice of the local College of Radiologists or the Radiology Department in the hospital as to what constitutes adequate experience and qualification. He should also consult the Ministry of Health and be familiar with their broad guidelines on these issues. You may also find it helpful to refer to the existing professional guidelines in countries such as the UK, US and Australia.



Qualifications and Certification of Radiologists

The definition of a 'qualified radiologist' is normally based on the country where the patients are treated, but qualifications alone are nowadays only the start of a longer journey towards being allowed to practise. More important for professional clinical practice is certification or accreditation. This usually requires the physician to be not only suitably qualified, with a diploma which is recognised or accepted in that country, but also having completed training in approved posts, having the requisite experience and satisfied other set criteria. In the US for example, states such as Florida, Montana and Oregon require the out-of-state radiologist to be licensed or board-certified locally to be able to care for patients in that state. It is likely that any civil litigation brought by patients against medical practitioners practising in another country would be heard in the patient's own jurisdiction.

Quality and Security

The teleradiology system in place has to be reliable with respect to the three issues relating to data security: privacy, authenticity and integrity. Safeguards aimed at limiting access to only those authorised to have access, and to prevent breach of patient confidentiality needs to be in place. Privacy and authenticity can be resolved by using audit trails, electronic signatures and levels of passwords. Adequate backup systems are needed to prevent accidental loss of data. Encryption is one method to protect data and encryption software is available to prevent the original data from being altered, sometimes fraudulently. The integrity and quality of the transmitted data is the responsibility of both the sender and receiver. Therefore, agreed protocols and clear lines of accountability are essential in the setting up of this service. The transmitted images have to be of sufficient quality with safeguards against image degradation during digitisation and transmission to enable the outsourced radiologists to interpret the images with confidence. It could be considered negligent for a radiologist to produce and examine images of substandard quality by reason of inferior equipment or inexperience. Doctors have an obligation to ensure that the report they depend on came from a reliable source, and that the radiologists are qualified.

Accountability

The clinician doctor would normally be accountable for the patient management decisions they make. They have a duty to consider all the available information, weigh up the evidence, consider the different options and make an informed decision. They are therefore unlikely to escape liability even if a bad radiology report had contributed to the decision made which resulted in an adverse outcome. Clinical management decisions are based on a combination of facts, not just on radiology reports. Even so, the outsourced radiology service needs to provide clinicians and radiologists caring for patients with the reassurance that there is a system of accountability for the reports.

Professional Liability

In teleradiology, it is arguable whether there is a doctor -patient relationship between the remote radiologist, who acts more like a consultant, and the patient. However, it may be argued that a duty of care exists once the radiologist accepts a request to provide medical services, and if the radiologist's report becomes part of the patient's medical records, even though proximity and foreseeability could be harder to establish. The radiologist responsible for the report may be in breach if it can be shown that he has not taken sufficient care when interpreting the films or in producing his report. Another factor to consider is that in teleradiology, the radiologist does not have access to the patients for clinical examination, or patient records, when verification is needed. Thus, it may be advisable to inform patients that the risk of misdiagnosis is higher. Radiologists are therefore well-advised to phrase their reports in such a way that the clinician responsible for the patient will always be reminded not to depend on the report alone when making decisions.

Case law and legislation have yet to catch up with this rapidly developing area of healthcare. It is not yet clear how the legal process is going to be tested, and how liability is going to be apportioned between the hospital, the remote radiologist and the clinician in charge of the patient. I hope the brief outline of the medico-legal issues surrounding teleradiology has been helpful. If you need further clarification on any particular issue, please feel free to get in touch with me.

Yours sincerely,

DR MING KENG TEOH
INTERNATIONAL MEDICO-LEGAL ADVISER

