The following are Teleradiology Standards prepared by our College (MRS) and submitted to the Ministry of Health. The Ministry of Health has not endorsed these standards yet. However, we hope they will serve as guidelines for our members.

Guidelines On Teleradiology In Malaysia

Introduction

With the inception of the Multimedia Super Corridor (MSC), telemedicine has been identified as a flagship applications. Teleradiology, which is the most mature and rapidly evolving branch of telemedicine, refers to the use of computers and telecommunication networks to transmit diagnostic images acquired at one location to another for primary review and interpretation as well as specialist consultation. In addition teleradiology requires more data capacity than other telemedicine applications. Thus telemedicine may have a large impact on teleradiology and vice versa. Rapid advances in telecommunications and computers have overcome many of the initial problems and the rising cost of health care are driving the need for establishing a cost-effective and efficient communication system. The increasing role of private health care providers in the overall health system is yet another factor, where teleradiology is seen as a vehicle for maintaining quality while containing cost in a competitive marketplace.

The benefits accrued to teleradiology include more timely interpretation of radiological images, greater access to secondary consultations in addition to providing improved continuing medical education, the ultimate objective of which is to significantly improve patient care.

In Malaysia, there has been a proliferation of vendors who have all been marketing their teleradiology systems but who do not inform the user of the true capabilities. The end-users are however lost as to the requirements of a teleradiology system. It is essential that any teleradiology system provides images of sufficient quality without clinically significant loss of spatial or contrast resolution from image acquisition through transmission to final image display. For transmission of images for display use only, the image quality should be sufficient to satisfy the needs of the clinical scenario.

These guidelines, which are adopted from the American College of Radiology on Standards on Teleradiology as well as the Royal College of Radiologists, hope to define

1. The objectives of a teleradiology system
2. Minimum requirements of the hardware and software,
3. Training, qualifications of personnel, including licensing, credentialing, liability,
4. Network & communication requirements,
5. Quality control
6. Quality improvement for teleradiology.

It is hoped that these guidelines will benefit the practice of high quality radiology.

Definition

Teleradiology is the point-to-point communication of radiological images for the purposes of primary reporting or radiologist advice or consultation. In contrast, picture archiving and communication systems (PACS) are used for the point-to-point transmission of radiological images for the purposes of review and patient management.

Objectives

There is still controversy regarding the exact role of teleradiology with proponents and opponents on either side. Most of these focus on the issues of economics, market share and quality of service. Nevertheless, the current objectives of teleradiology revolve around the ultimate role of making a primary diagnosis from transmitted images without review of the original images thus providing consultative and interpretative radiological services

1. In remote areas
2. In medical facilities without on-sites radiological support
3. In emergent and non-emergent clinical care areas
4. In on-call situations
5. In subspecialty areas
6. For CME for practising radiologists
7. For efficiency and quality improvement
8. As well as sending interpreted images to the referring doctors
9. For direct supervision of off-site imaging studies.

It must be borne in mind that these objectives listed above can never be comprehensive since the technology of teleradiology is constantly evolving. New goals will however continue to emerge and this list may change over time.

Qualification of Personnel

The radiological examination to be transmitted must have been performed by qualified personnel, which means a radiologist, radiographer, nuclear medicine technologist, or sonography technologist/sonographer. Even though it may be desirable to have a medical physicist and/or image management specialist on site, in the present context this may not always be feasible or practical. However, consultants may be employed to ensure proper installation and running of the equipment.

1. Radiologists

Interpretation of images must be done by a radiologist who has:

a. An understanding of the basic technology of teleradiology system used, its strengths and weaknesses (plus limitations) and therefore must be trained at a centre recognised by the Ministry of Health in the use of the teleradiology equipment as well as the necessary quality assurance procedures.

b. Registered with the Malaysian Medical Council to practice telemedicine

(Telemedicine Act 1997).

c. A basic minimum number of 100 examinations must be reported by the radiologist per month to maintain competence.

d. Demonstrated qualification for the particular diagnostic modality being transmitted through teleradiology.

e. To bear ultimate responsibility for the teleradiology service.

f. An understanding of the staffing and structural requirements prior to taking on a teleradiology service.

2. Radiographer/technologist

The radiographer/technologist should be

a. Certified by the appropriate speciality

b. Trained at a centre recognised by the Ministry of Health to properly operate and supervise the teleradiology system.

3. Medical Physicist

A qualified medical physicist is an individual who is competent to practise in medical physics with at least a Master Degree in Medical Physics

4. Technical Support

In the Malaysian context, this support may have to be initially provided by the vendor as part of the overall purchase agreement.

a. An individual who is employed to assess and provide problem-solving input, initiate repair, and co-ordinate system-wide maintenance programs to assure sustainable high-image quality and system function. This individual would also be directly involved with any system variances and expansion programs.

b. The individual should always be available in a timely manner in case of malfunction to facilitate return to optimal system functionality.

Equipment Specifications

The heart of a teleradiology system consists of the acquisition modalities, and transmission of the image either over a local or wide area network with display of the images at the remote site. Although the specifications for teleradiology equipment will vary in the individual facilities, certain minimum requirements are necessary to ensure that the image quality and availability are appropriate for primary diagnosis & radiological consultation.

a) Integration and networking

With the greater use of PACS systems, teleradiology is being increasingly seen as an extension of these systems. Therefore for all new equipment acquisitions and consideration of periodic upgrades, compliance with latest Digital Imaging and Communication in Medicine Standard (DICOM) is strongly recommended. Integration with the Hospital Information System (HIS) and being Health Level 7 (HL) compliant are also issues, which must be addressed. This is to ensure that correct patient demographic data is transmitted between locations.

b) Image format

Depending on the matrix size of the images being evaluated, there are basically two

basic categories of teleradiology equipment:

- Small matrix size (e.g., computed tomography (CT), magnetic resonance imaging (MR), ultrasound, nuclear medicine, digital fluoroscopy, and digital angiography) where a data set should provide full-resolution data (typically 512 x 512 resolution at minimum 8-bit depth) for processing, manipulation, and subsequent display.

- Large matrix size (e.g., computed radiography and digitised radiographic films) where the data set allowing a minimum of 2.5 line pairs per mm spatial resolution (or 2K by 2K) at minimum 10-bit depth should be acquired.

c) Acquisition or Digitisation:
It is essential that the studies, which are being transmitted, are of the highest quality possible. In addition, patient name, identification number, date and time of examination, name of facility or institution of acquisition, type of examination, patient or anatomic part orientation (e.g., right, left, superior, inferior, etc.), amount and method of data compression should also be transmitted. The capability to record a brief patient history is desirable. As stated earlier these examinations must have been performed under the supervision of a radiologist or other trained physician.

i) Direct image capture
Where the total image data set (preferably using a DICOM format) as produced by the digital modality (both in terms of image matrix size and pixel bit depth) are transferred to the teleradiology system. This is the most desirable mode of digital image acquisition for primary diagnosis as there is full window capability.

ii) Secondary image capture
This again depends on the size of the matrix of the images. For small matrix images, digitisation using a film digitiser or video frame grabber is acceptable provided that the matrix size is as large or larger than that of the original image by the imaging modality. Using video frame grabbers, the images should be digitised to a bit depth of 8 bits per pixel or greater. However for the large matrix images, digitisation can only be done using either a CCD or laser film digitiser. The images should be digitised to a matrix size corresponding to 2.5 line pairs per mm or greater, measured in the original detector plane with a bit depth of 10 bits per pixel or greater.

d) Data Compression
This is usually done to facilitate transmission and storage provided there is no reduction in clinically diagnostic image quality. The compression can be divided into two broad categories i.e. reversible/lossless and irreversible/lossy. Although lossless compression has been advocated, recent lossy compression using wavelets may be acceptable. However caution needs to be exercised as the types and ratios of compression used differ for both the type of imaging study as well as the teleradiology system used. Clinically proven information from the vendor is necessary prior to attempting such compression especially the irreversible type. Again compression should only be carried out under the direction of a qualified radiologist.

e) Image transmission
The type and specifications of the transmission devices used will depend on the needs of the practice as well as cost. However, whichever mode is used, for the purposes of primary diagnosis or consultation, transmission of data should occur without any distortion or degradation of data. The transmission system shall have adequate error-checking capability. The ease of integration of the teleradiology system with other systems should also be a consideration.

f) Display Capabilities
Display workstations used for official interpretation and employed for small matrix and large matrix systems should provide the following characteristics:

i) Luminance of the gray-scale monitors should be at least 170 cd/sq.

meter (50 foot-lamberts), a refresh rate of at least 60Hz with no distortion.

ii) Care should be taken to control the lighting in the reading room to eliminate reflections on the monitor and to lower the ambient lighting level as much as is feasible.

iii) Provide capability for selection of image sequence;

iv) Capable of accurately associating the patient and study demographic characterisations with the study images;

v) Capable of window and level adjustment, as well as inverting a white-on-black to a black-on-white display;

vi) Capable of pan functions and zoom (magnification) function;

vii) Capable of meeting guidelines for display of all acquired data;

viii) Capable of rotating or flipping the images provided correct labelling of patient orientation is preserved;

ix) Capable of calculating and displaying accurate linear measurements and pixel value determinations in appropriate values for the modality (e.g., Hounsfield units for CT images), if those data are available;

x) Capable of displaying prior image compression ratio, processing, or cropping,

xi) Elements of display that should be available include:

Matrix size;

Bit depth; and

Total number of images acquired in the study.

xii) A means of producing a hard copy may be helpful if secondary referral to a neurosurgeon, etc is required.

g) Acceptance testing

There needs to be definite criteria for the acceptance of teleradiology equipment as is required for any imaging medical equipment. This is to ensure that the equipment meets the criteria set in the tender/purchase agreement, which hopefully meet the minimum standards as stated in the various sections. In addition safe, consistent, robust and complete transmission and interpretation of image data can be performed. In addition the availability of necessary technical support must be a prime consideration in the selection of a teleradiology system.

h) Archiving and Retrieval

If electronic archiving is to be employed, the guidelines listed below should be followed:

i) Teleradiology systems should provide storage capacity capable of complying with current regulations regarding medical record retention. Images interpreted off-site need not be stored at the receiving facility, provided they are stored at the transmitting site.

ii) Each examination data file must have an accurate corresponding patient and examination database record, which includes patient name, identification number, examination date, type of examination, facility at which examination was performed. It is desirable that space be available for a brief clinical history.

iii) Prior examinations should be retrievable from archives in a time frame appropriate to the clinical needs of the facility and medical staff.

iv) Each facility should have policies and procedures for archiving and storage of digital image data equivalent to the policies that currently exist for the protection of hard-copy storage media to preserve imaging records.

i) Service agreements

Clearly written protocols that include the following are necessary to ensure that a department or practice provides quality teleradiology services:

i) A designated radiologist to be available.

ii) Turn-round time for the report.

iii) Designated destination for the report

Security

Teleradiology systems should provide network and software security protocols to protect the confidentiality of patients' identification and imaging data and this includes the most recent anti-virus system. The system being used must be verified to be safe prior to be used. There should be measures to safeguard the data and to ensure data integrity against intentional or unintentional corruption of the data. The proposed security regulations should include

a) Establish and document policies and procedures for granting employees and other users different levels of access to the teleradiology information.
b) Establish on-going internal audit control mechanisms to record and examine the security system. These would include log-ins, file access and security incidents.
c) Implement authentication procedures to ensure that users are who they claim to be which would include automatic log-off and unique user identification.
d) Corroborate that the data has not been altered in an unauthorised way. This may be accomplished by using one

of a variety of ways including check sum, double keying, and digital signature.

e) Adopt technical security measures to protect information transmitted over a network, prevent its interception and perusal by unauthorised users, and block external intruders from gaining access to the system. When using open networks, e.g. the Internet, this may require some form of encryption. Implement integrity controls and message authentication to ensure that the data transmitted matches the data sent, as well as alarms, event reporting, user authentication and audit trails.
f) Assessing responsibility for security to a specific individual or organisation. Responsibilities would include all matters related to the management and supervision of all data security.
g) Provide ongoing training for all staff members on the need for confidentiality as well as the venerability of data. Procedures to protect privacy should also be stressed.
h) Ensure that there is adequate supervision of those who maintain and have access to the data.
i) Provide contingency plans for system failure, emergencies and disasters. Periodic backup of data should also be considered.
j Physical access should also be adequately controlled to minimise the possibility of improper access.
k) Certification that the hardware and software meets the security standards set.
l) There must be adequate conformance to the Electronic Signature Act 1997 for the use of electronic signatures

Reliability and Redundancy

Written policies and procedures should be in place to ensure continuity of care at a level consistent with those for hard-copy imaging studies and medical records within a facility or institution. This should include internal redundancy systems, backup telecommunication links, and a disaster plan. A maintenance contract with the vendor for a fixed callout time must be present.

Medico-legal issues

The Telemedicine Act 1997 requires that the patient must give consent for the images that are used for purposes of teleradiology. Radiologists practising teleradiology are required to have the Annual Practising Certificate (APC), and must also state all the institutions being served by the teleradiology service. The radiologist performing the official interpretations must be responsible for the quality of the images being reviewed.

Documentation

Communication is a critical component of teleradiology. Radiologists interpreting teleradiology examinations should render reports in accordance with that of the American College of Radiology (ACR)

Quality Control and Improvement

Any facility using a teleradiology system must have documented policies and procedures for monitoring and evaluating the effective management, safety, and proper performance of acquisition, digitisation, compression, transmission, archiving, and retrieval functions of the system. The quality-control program should be designed to maximise the quality and accessibility of diagnostic information.

A test image, such as the SMPTE test pattern should be captured, transmitted, archived, retrieved, and displayed at appropriate intervals, but at least monthly, to test the overall operation of the system under conditions that simulate the normal operation of the system. As a spatial resolution test, at least 512 x 512 resolution should be confirmed for small-matrix official interpretation, and 2.5 line pairs per mm resolution for large-matrix official interpretation.

As a test of the display, SMPTE pattern data files sized to occupy the full area used to display images on the monitor should be displayed. The overall SMPTE image appearance should be inspected to ensure the absence of gross artefacts (e.g., blurring or bleeding of bright display areas into dark areas or aliasing of spatial resolution patterns). Display monitors used for primary interpretation should be tested at least monthly. As a dynamic range test, both the 5% and the 95% areas should be seen as distinct from the respective adjacent 0% and 100% areas.

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