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Accreditation of Medical Imaging in Korea

Developing a System for Better Healthcare

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Lack of Quality Management Hits Patients

In 2000, changes in the national medical reimbursement system allowed the rate of self-referrals to increase. Also, the abolition of government restrictions on the installation of radiological equipment resulted in an increased rate of bad-quality images made by unchecked secondhand units. Besides this, many physicians and radiologists were unaware of the concept of quality management. In 2001, a nationwide survey of the quality of radiological imaging performed by the Korean Food and Drug Administration (KFDA) and the Korean Radiological Society (KRS) showed a significant failure rate for CT, mammography and MR imaging (see Fig. 1).

On January 19, 2001, the National Assembly of Korea approved Acts on quality management for these underperforming imaging modalities. By these Acts, quality management of specific medical equipment was launched by the Ministry of Health and Welfare (MHW). In collaboration with the Korean government, the KRS developed guidelines and standards of quality management, including test procedures, test frequencies and limiting values for clinical image and phantom examination.

The Acts defined five areas for inspection, that is, personnel requirements, equipment and facility, quality control records, phantom images and clinical images. Annual inspection requires participating facilities to meet minimum quality standards. Also reviewed are records for personnel requirements, equipment and facility, quality control sheets and inspection of phantom images. Every three years, an on-site survey and evaluation of clinical images are added. New equipment must be certified prior to commencing operations.

Government's Role in Monitoring Quality

The Korean government now prohibits the use of failed equipment. For the operation of MRI, a facility must employ a full-time radiologist and technologist. CT and mammography require at least part-time radiologists for supervising the quality management of equipment (see table 1). Facilities must perform scheduled quality control tests, that is, daily/weekly, monthly, quarterly, semi-annual, and annual tests, and document the results on quality control log sheets. Standard phantom testing is used for evaluation of the efficiency of equipment, of phantom images, and of either film records or onsite survey. For clinical image tests, each facility submits typical clinical images for review and evaluation.

Further, the KRS established the Korean Institute for the Accreditation of Medical Imaging (KIAMI), a government- authorised agency for medical image accreditation. KIAMI's mission is to improve the quality of patient care through improvement of the quality of medical imaging. KIAMI is composed of over 200 volunteer radiologists working as inspectors. All mammography, CT, and MRI units in Korea must be inspected by KIAMI to be accredited and certified by the MHW every year. Medical equipment that does not meet the quality standards of KIAMI is banned from use

by the government.

Rates of Quality Inspection

In 2005, of 4,236 medical imaging units, 3,773 underwent quality inspection; this includes 1630 mammography, 1547 CT, and 596 MRI units. In 2006, of 4,648 medical equipments, 4,038 underwent quality inspection; this includes 1804 mammography, 1586 CT, and 648 MRI units. 463 (i.e., 11%) in 2005 and 610 (i.e., 13%) in 2006 of the tested units did not receive inspection due to withdrawal or disuse.

The failure rate was 8.75 % (327/3773) in 2005 and 11.5 % (468/4038), in 2006 respectively. The failure rate of pilot studies prior to launching an accreditation programme was about 25 - 30%. In 2005, the failure rate of clinics, hospitals and general (tertiary) hospitals was 7.8% (128/1662), 10.0% (121/1211) and 3.8% (39/1035), respectively. Of the 327 failed units, 135 were accredited at second or third trials. However, 120 (3.2%) were withdrawn, and 72 were suspended for use. Total disuse rate was 15% (615/4196).

The number of obsolete imaging units manufactured more than ten years ago or with an unknown manufacturing date was 1760 (47%) in 2005, and 1535 (38%) in 2006, respectively. The failure rate of second-hand or obsolete equipment was much higher than that of new equipment.

Remaining Problems with Accreditation System

Considering the fact that the failure rates had been much higher on our nationwide survey performed before the launch of quality management on 2001, this result implicates improvement of the quality of medical imaging performed at certified units. Elimination of poor quality second-hand equipment has led to decreased reexamination rate, results in decreased medical fees and the radiation exposure of patients. We expect that the quality of medical imaging will be further improved after our next scheduled inspection (onsite survey and evaluation of clinical images) starting during the course of 2007.

However, we still have several problems to be solved. Still we have a conflict of interest among the stakeholders, medical consumers (insurance payer), government (operating medical insurance), radiologists and referring doctors. To elicit a consensus for the quality control of medical imaging among stakeholders is our continuing mission. To overcome internal conflict within the radiological society is another mission. Our future perspective includes: propagation of social agreement on quality management, training and education of specialists in quality management, expansion of the field of quality inspection for other radiological equipment, and establishment of standard protocols for clinical imaging.



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