QUALITY ASSURANCE IN NUCLEAR MEDICINE IMAGING

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INTRODUCTION

Nuclear medicine uses tracers, tiny amounts of radioactive substances, to diagnose or treat the disease. These substances pass harmlessly through the body. As they are radioactive, their movement can be detected with special devices, yielding a wealth of information about bodily processes. The essence of nuclear medicine is that it can visualize changes in the function and biochemistry of body organs and tissues. Measurement of such changes offer unique information for diagnosis and therapy that can't be obtained through other tests. One of the great benefits of nuclear medicine is that regional abnormalities in the body often can be detected before an abnormality is noted in overall organ function, before the patient feels something is wrong. Similarly, regional chemical changes can be measured before abnormalities can be found in the concentration of chemical constituents in blood or urine. Early detection allows a disease to be treated before it becomes advanced, when these are generally a better outcome.

The technology for detecting radiotracers in the body advanced rapidly. In 1957, a Geiger Muller counter was used to discriminate hot and cold thyroid nodule, which helped to decide the likelihood that the nodule was benign or malignant. Later the motor-driven scintillation detector was designed by Benedict Cassen to produce images of distribution of radioactivity from thyroid gland. One year later, in 1958, Hal O. Anger invented the scintillation camera, an imaging device which made it possible to conduct rapid dynamic studies. It also improved static images and, when used with Tc-99m, reduced the radiation dose to the patient. Over the past half-century, radiation detectors have evolved into sophisticated Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT) scanners with their associated computer processing and display systems.

QUALITY ASSURANCE AND QUALITY CONTROL: DEFINITIONS

Quality Assurance in diagnostic nuclear medicine has been defined by WHO in 1980 in three objectives as:

1. Improvement in quality of the diagnostic information.
2. Use of the minimum amount of radionuclide activity to ensure the production of the desired diagnostic information.
3. Effective use of available resources.

In Thailand, quality in health care is currently being addressed, followed by the project on Hospital Accreditation which includes the quality standards for hospital services and nuclear

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medicine in the near future.

Although formulated differently from different viewpoints, the objectives of the above concern quality assurance leading to **the best care with the least radiation burden to the patient.** A quality assurance program that meet these objectives covers the total diagnostic process from the request to perform the procedure to the report and follow-up. These include nuclear medicine service, organization, facilities, staffing, radiopharmaceuticals, instrumentation, pro-cedure, evaluation of results and training.

Quality Control in nuclear medicine started in 1977 and covered wider issues and human aspects of quality assurance. (Rhodes 1977).[1] Various organizations such as American Association of Physicists in Medicine (AAPM), Hospital Physicist's Association UK (HPA) the International Atomic Energy Agency (IAEA)[2] the World Health organization (WHO)[3] had prepared the recommendation for quality control procedures of imaging devices. Recommendations were made for quality control of all nuclear medicine instrumentation.

Quality control testing falls into three basic levels

ACCEPTANCE TESTING

The first, crucial step in quality control of an instrument is the initial evaluation or acceptance testing. Acceptance testing means not only confirming that the instrument performs according to specifications, but also means evaluation performance under conditions that will be encountered in clinical practice. Manufacturer's specifications only provide a few essential performance characteristics, so that a full set of acceptance tests, covering the range of clinical needs, has to be developed. The users should not accept an instrument that fails to conform to specifications. An instrument that fails to operate correctly at installation has a great likelihood of never being satisfactory. Acceptance testing should be carried out before the instrument is put into clinical use.

Acceptance tests can be difficult especially for an inexperienced user. A user may be confronted with unfamiliar instruments and computer software. Special test devices or phantoms are needed. Quantitative studies are essential in order to compare results with specifications and to provide baseline values for future comparison. It is recommended that the acceptance tests should be performed by the user and the representative of the vendor. If there is only inexperience, then employ an experienced, qualified consultant to assist with the tests.

REFERENCE TESTING

A reference test is a test of an instrument whose results proved a measure against which future performance of an instrument may be comprehensively assessed. (WHO 1982).[3] The tests may be identical to acceptance testing, or may be simplified versions. These reference tests form part of the initial testing program. There after they form periodic tests to be made if malfunction is suspected, after a major failure has been repaired, after component replacement, and after an instrument is moved to another site. Since they are made periodically, exact details of the test need to be documented along with the results, so that the test can be reproduced and results compared with the previous results.

ROUTINE TESTING

The purpose of the routine test is to assure that a level of quality is maintained and to determine deterioration with time. An instrument may fail or perform malfunction at any moment, but routine test supplies a degree of confidence in the instrument performance up to the last routine

test performed and assessed. Routine testing should be simple, test of the total system, be sensitive to small changes in component performance, and not be time consuming. Not only is a comparison of results with previous test but also a comparison of results obtained over a period of weeks. Subtle changes can occur which may only become evident by such comparisons.

Quality control is, however, not the actual act of doing the test, but the immediate evaluation and action upon its result. The most important aspect of routine testing is that it does not just become daily exercise, the results of which are stored away unheeded.

RECORD /LOG BOOK

Assurance of quality requires that a record or logbook be started at installation to document the history of an instrument. This record may be the only means of following recurring malfunction, obtaining maintenance satisfaction or providing commencing evidence of the need for component replacement. Such a record ideally includes:

-Details of problems and their solutions.

-Environmental and operational conditions at the time of malfunction

-Service response time

-Details of service carried out

-Maintenance reports and reference test results.

This log should also record whether a patient's nuclear medicine study showed artifacts, was compromised, could not be completed, or could not be started due to the instrument failure.

ACTION THRESHOLDS

The final stages of any quality control are the decision-making and follow–up processes, which determine whether or not the instrument is functioning properly and can be used, or whether it needs repaired. For the evaluation to serve its purpose, objective quality control assessment and limits of acceptability that provide action thresholds are required. This implies objective comparison of quality control test results with reference standards that represent optimum performance. Prior knowledge is required of what is optimum, what is measurable, and how much deterioration from optimum is acceptable for the completion of the clinical procedures. The latter is, perhaps, the most illusive part of quality control: when does deterioration in instrument performance lead to clinically misleading results?

INTERLABORATORY COMPARISON STUDIES

One way to assess the quality of the clinical use of imaging instrument is through interlaboratory comparison studies, using hardware or software phantoms. This is a quality control method that permits assessment of the total imaging performance on a national or international level. The laboratory measures or images the phantom using its usual clinical method, evaluated and reports its results. In this way the instruments as well as the persons performed the test and those evaluation results are tested. Comparison of an individual's results with those from others and feedback of individual performance enables a laboratory to reappraise and improve its performance.

QUALITY ASSURANCE OF NUCLEAR MEDICINE SOFTWARE

Software quality control monitors programs at installation, after program modification, after system modification and in case of suspected failure. For testing a particular clinical software package, clinically validated patient studies are needed. These enable comparison of results from different computers and algorithms,

definition of radionuclide patterns and quantitative parameters for normal function and typical disorders. Such clinical studies are "Software Phantoms".[4] Phantoms could also consist of mathematics simulations and data acquired from hardware phantoms that simulate clinical data, However, real patient studies are essential because they provide authentic data and read biological variation that the software will encounter in practice.

HOSPITAL ACCREDITATION

Quality Assurance of nuclear medicine imaging is only a small part of the broader quality assurance objectives. In order to implement a total quality assurance program, quality standards for the whole service must be defined. Accreditation is then a means of recognizing compliance with the quality standards. For nuclear medicine, these quality standards apply to organization structure, staffing, facilities, purchase and storage of materials, radiopharmaceuticals preparation, quality control and servicing of equipment, all activities concerning a patient study, personnel training and quality assurance evaluation.

CONCLUSION

Quality assurance has until now been voluntary, but legislation is imminent. Each person and each aspect of the service contributes to the quality of the patient care provided by a department. The radiation protection of the patient is an additional factor, so that the diagnostic information is obtained with the least administered radiation. A wellplanned and performed quality control program for instrumentation and software is just one step towards achieving this. The most essential ingredients are the human aspects, which include continual care, awareness, observation and readiness to act when any deficiency is encountered. To achieve continuous quality improvement, motivation of personnel is perhaps the most vital ingredient of all.

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