A NOTE ON THE QUALITY MANAGEMENT IN SPECIMEN COLLECTION FOR NUCLEAR MEDICINE

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ABSTRACT

Nuclear medicine physicians use radioactive pharmaceuticals to diagnose, and sometimes treat, a range of diseases. Nuclear medicine technologists may perform the following tasks: perform laboratory procedures including blood and specimen collection, quality control testing, ensure the safe handling, storage, disposal of radioactive materials, prepare and administer radiopharmaceuticals as tracers to demonstrate the function of organs in the body. Presently, quality control is the primary important task in the management of all laboratories. Due to the good governance concepts, accountability of the whole laboratory processes is the main focus of current concern in laboratory medicine. Due to the laboratory quality cycle, reliability cannot be achieved in a clinical laboratory through the control of accuracy in the analytical phase of testing process alone, but also the concern in the preanalytical phase including the specimen collection procedure, request form control, control of sample acceptance and sample holding, must be carefully practised with quality through the whole laboratory cycle.

INTRODUCTION

Nuclear medicine physicians use radioactive pharmaceuticals to diagnose, and sometimes treat, a range of diseases. Nuclear medicine technologists may perform the following tasks: perform laboratory procedures including blood and specimen collection, quality control testing, ensure the safe handling, storage and disposal of radioactive materials and prepare and administer radiopharmaceuticals as tracers to demonstrate the function of organs in the body.

Since the specimen collection is the early phase of laboratory test in nuclear medicine, therefore, the quality management of this phase is necessary.[1-7] In this article, we discuss the quality management in the blood specimen collection for nuclear medicine laboratory.

WHY WE MUST HAVE THE QUALITY MANAGEMENT IN THE BLOOD COLLECTION FOR NUCLEAR MEDICINE?

Presently, quality is the primary importance in the management of all laboratories. Due to the good governance concepts, accountability of the whole laboratory processes is the main focus of current concern in laboratory medicine. Due to the laboratory quality cycle, reliability cannot be achieved in a clinical laboratory through the control of accuracy in the analytical phase of the testing processes alone.[7] There should be a certification on the whole laboratory processes, but not on the single analytical process. Precision and accuracy of analyses are not only determined by the analytical procedures but also by preanalytical factors, such as contamination and loss during sampling and sample preparation. Under the broad umbrella of the preanalytical phase, the followings may be included, such as

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test requesting forms design, specimen collection, handling and processing before complete distribution of test samples to multiple work stations

As previously discussed, the specimen collection can be mentioned as the important component in the preanalytical phase of the laboratory analysis. According to the study of Wiwanitkit, the error in this phase is higher than in the other two phases (analytical and post analytical).[7] Since the error in any phase of the laboratory processes can result in the aberrant and unacceptable results, which can affect the quality of the health care. Therefore, the quality management for the specimen collection is needed. Although the quality management need a lot of time but it is better than no quality management.

WHAT ARE THE ASPECTS THAT QUALITY MANAGEMENT IS NEEDED IN THE BLOOD COLLECTION FOR NUCLEAR MEDICINE ?

1. SPECIMEN COLLECTION PROCEDURE

Specimen collection is the direct process in contact with the patients. The procedure must be based on the medical scientific principle and must be done gently. Since the Patient Right is proposed, the asking for the informed consent of the patients before every specimen collection is needed.[5] Nevertheless, since this procedure can bring the complication to both patients (such as fainting, hematoma) and practitioners (such as needle stick injury), the proper risk management is needed.[5-7]

Also, this process can be classified as an important service business, the application of such the quality system such as the 5S, the ISO and the HA is probable.[1-7]

2. REQUEST FORM CONTROL

The request form is the main way for communication between the physician and the laboratory technicians. The physicians should provide the full necessary data for the laboratory to be used as the basic data for validation of the analytical results. Such an improper request forms such as omission, incompleteness and hard-to-read hand writing should be rejected by the laboratory. Furthermore, presently the requests that are not rational and unnecessary should also be rejected by the clinical pathologists of the laboratory.[1]

To cope with the problem of the manual request, the laboratory information management system (LIS) becomes the new tool for this problem. Based on the LIS, the laboratory can directly receive the request from the physician without delay and can be used for the further validation of the result as the double check up system.[5]

3. CONTROL OF SAMPLE ACCEPTANCE

Considering the laboratory workflow, the service of the laboratory starts from the receptions of requests,specimens and request forms, to distribution of the laboratory results to the patients (for Out-Patient Division) and clinical wards (for In-Patient Division).

Based on the recommendations for ISO 9002 system for the hospital by the Technology Promotion Association (Thailand-Japan),[2] the laboratory quality committee should decided that the rate of preanalytical mistakes is a quality indicator of the laboratory. As previously described, the definition of the "mistake in the preanalytical phase" is any defect during the preanalytical phase, including all processes before complete distribution of test samples to multiple work stations, that influenced in failure of further laboratory processes.[7]

These preanalytical mistakes include physician's order missed, patient misidentification, specimen collected in insufficient

quantity, inappropriate container used, inappropriate quality of specimen, specimen lost in transit and etc.[7]

Briefly, all medical technologists in all units of the laboratory were asked to pay maximal critical attention to all received requests. These personnel were provided with a special notebook in which any "suspect" sample was recorded, together with all pertinent information. Then consultation to the head of medical technologist of the unit was done. The head of medical technologist rechecked and reviewed all reported cases before making final decision. In cases that the preanalytical mistakes were made from final decisions, they were recorded into the specific record form.[7]

4. SAMPLE HOLDING[1,5]

Since sometimes the transportation of the specimen from the collection unit to the laboratory cannot be immediately performed, therefore, the proper sample holding is necessary. The two factors to be concerned in sample holding are the holding time and conditions. Some analyses such as the hormone are too labile and cannot be kept for a long time in the room temperature. The decision to use the proper temperature refrigerator to keep it is necessary.[1] Indeed, the authors recommended the immediate transfer of the collected samples to the laboratory for analysis since any delay, the result of the analyses may be changed.

Another point to be concerned is the quality of the equipment used for the keeping of the sample. Refrigerator is an important equipment to be mentioned. This equipment should be subjected to regular maintenance and calibrated for the correct temperature. Sometimes the temperature in the refrigerator is not proper and the user doesn't know, it may result in the expiration of the collected samples.

CONCLUSION

Today, the quality system for clinical laboratories must include the promotion of accuracy in the analytical phase as well as the assurance of the reliability of preanalytical and postanalytical activities.

In order to reduce the preanalytical mistakes originated in the care units, a regular feedback system (such as distribution of protocol for proper specimen collection) to the clinicians and personnel outside the laboratory is also designed in our setting.

REFERENCES

1. Young DS, Bermes EW. Specimen collection and processing : source of biological variation. In: Burtis CA, Ashwood ER, eds. Clinical Chemistry. Philadelphia, WB Saunders, 1998, 33-52
2. Pruksaptitikul S. ISO 9002 system for the hospital. Bangkok: Technology Promotion Association (Thailand - Japan) 1998
3. Sim P. ISO 9000:2000 revisions and their implications. Med Device Technol 2000; 11: 45-47
4. Sirchia G, et al. Implementation of a quality system (ISO 9000 series) for placental blood banking. J Hematother 1998; 7: 19-35
5. Boonchalermvichian C, Wiwanitkit V. Collection of medical specimen. Chula Med J 2001; 45: 1079 – 89
6. Wiwanitkit V, Na Ayuddhaya A. ISO 9000 quality system in medicine. Khon Kaen Hosp Med J 1998; 22: 51 – 8
7. Wiwanitkit V. Types and frequency of preanalytical mistakes in the first Thai ISO 9002:1994 certified clinical laboratory, a 6 - month monitoring. BMC Clin Pathol 2001;1:5