

Regular Quality Management Audit in Nuclear Medicine Services - A Dynamic Approach of Self Improvement

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INTRODUCTION

QUANUM stands for quality management audit in Nuclear Medicine practices. This is a means by which nuclear medicine facilities can demonstrate the level of patient care they provide. It can be done by doing a self-evaluation that is internal audit and by external evaluation. The quality management (QM) program is vital for better patient care and an essential tool in the modern health system (1). Nuclear Medicine Services (NMS) are expected to maintain quality management system (QMS) to provide high quality patient care. International Atomic Energy Agency (IAEA) has been providing technical and professional support in NMS to its member states for long time. Expert group of IAEA including nuclear medicine physicians, medical physicists, radiopharmacists and technologists have taken decision to develop QM audit tool on 2006. Recently IAEA has published a manual "Quality Management Audit in Nuclear Medicine Practices (QUANAM)" (2, 3). IAEA has inspired to implement QUANAM in NMS in its member states especially in developing countries by overcoming economic constraints and busy schedule of professionals to upgrade themselves. Actually this excellent methodology tool helps to identify the opportunities for improvement. The objective of this review article is to discuss the need of QMS in NMS, formation, different aspects and scope of QUANAM. Its possible implementation in Nuclear Medicine Departments of developing country like Bangladesh in accordance of QUANAM manual will be discussed. We also intend to describe shortly the

initiation story of QUANUM at National Institute of Nuclear Medicine and Allied Sciences (NINMAS).

QUANUM

The QMS standardizes the processes to ensure consistency in providing high level services to patients, referring physicians and other stakeholders in safe environment. Auditing is essential for well functioning NMS. The quality audit process has to be patient-oriented, systematic and outcome based. The authority or director of NMS has to be committed to the development; implementation and improvement of QMS. There should be audit plan (4, 5). Following things are to be encountered for QMS- the quality policy, ensuring defined quality objectives, meeting customer's needs as well as regulatory requirements, planning and properly managing resources and conducting management reviews. A comprehensive audit is to be done on defined methods using a tool covering all aspects of NMS. Both internal and external audit are recommended periodically. Implementation of a timetable for both internal and external audits should become part of the NMS's calendar. The essential pre-requisites of QUANUM audit are openness of local team and for audit team trust with respect and discretion for local team. Audit comprises of audit preparation, audit process and post audit exit briefing. Audit of a nuclear medicine department deals with almost everything from reception to exit of waste material. Every steps of service should be documented and follow a structured methodology or standard

operation procedure (SOP). Methodology document includes the following key areas-

- Management
- Human resource development
- Safety aspects of patients, staff, public and environment.
- Equipment reliability and performances
- Clinical services (diagnosis and therapy)
- Hospital radio pharmacy and laboratories.

It is essential to perform audits according to standardized audit practices including:

- Entrance briefing
- Assessment with systemic review of the questionnaires
- Set of minimum requirements
- Definition of conformance and nonconformance
- Exit briefing
- Reporting

Entrance briefing

The entrance briefing is required to introduce the audit team and the staff, finalize the agenda, and to discuss the objectives, methods as well as the details of the audit. The auditors should assure the staff and patient confidentiality.

Assessment:

The overall activity of the NMS, from the initial referral of the patient, radiopharmaceutical preparation, patient preparation, execution of the procedure, data analysis, the reporting and follow-up will be evaluated. The facility, including premises, layout and classification of area, equipment and staff will be assessed.

A series of checklists have been developed for documentation of audit methods (3, 4, 5). These checklists are comprehensive and non-exhaustive tool for quality assessment. During assessment of checklists users are advised to consider updated nuclear medicine professional society guidelines as well as relevant literature. Professional judgment is advised to apply to

ensure an adequate level assessment.

The checklists are not designed for regulatory purposes, investigation of accidents, interdepartmental comparison and not meant for assessing the quality and safety of clinical research and do not cover ethical issues.

The assessment includes:

- Complete tour of the premises
- Review and evaluation of procedures and all relevant documentation, including review of treatment records
- Observation of practical implementation of working procedures
- Staff interviews
- Meeting with the management of the institution and /or associated educational institution
- Review of the previous audit (self-assessment according to QUANAM)
- Filling the audit checklists

The responsibilities of the audit team are to collect all management and operational information such as:

- Updated copies of licenses/ accreditation documents
- Organizational flow chart and functional descriptions
- Samples of standardized operation procedures (SOPs)
- Sample of study reports
- Copies of data regarding patients' waiting times
- Updated information on waiting lists
- Copies of quality control data for relevant equipment
- Radiation safety records
- Copies of letters of appraisal/complaints
- List of deviations and non-conformances
- Customer/stakeholders satisfaction surveys (2, 3, 7).

Conformance and non-conformance statement

To complement the audit activities a spreadsheet has been developed. This tool allows selecting the level of conformance for all the checklist. QUANUM is intended to provide a working format for self-assessment using a systematic approach. Even if not all questions apply to

all services, the result should accurately reflect the level of operation and/or service. An answer marked 'Not Applicable' (NA) is perfectly acceptable and should not be deemed as poor performance.

A scoring system has been designed to evaluate the level of conformance (LC) as indicated below:

- 0 - Absent or inappropriate
- 1 - Planned or approximate
- 2 - Partially conform or partially implemented
- 3 - Largely conform or largely implemented
- 4 - Fully conform or fully implemented

The items 'Absent or inappropriate', 'Planned or approximate' and 'Partially conform or partially implemented' fall in the category of 'Non-Conformance', whereas the elements 'Largely conform or largely implemented' and 'Fully conform or fully implemented' are classified as 'Conformance'. Items marked as NA will not be included in the assessment of the final scores. The scores are used to build a Radar plot to enable visual presentation of the overall results. In addition, specific Radar plots will be produced for analysis of clinical observations. Radar plot is a graphical illustration of the level of conformance achieved during the quality assessment. Each spot represents the LC for one specific checklist.

In general, reference will be made to IAEA technical documents or other external standard setting bodies. Any non-conformance will be spelled out by the auditors. The seriousness and urgency of corrective actions should be transparently discussed and agreed by the auditors and auditees. Corrective actions provide opportunities for improvement of the NMS.

Exit briefing

The preliminary feedback of the auditors will be documented and presented to the staff of the NMS and any other relevant key person during an interactive exit briefing. This includes time for questions and an open discussion on all the findings of the auditors. The institution should be encouraged to give an immediate response to the assessment. The steps intended by the

institution to react to the recommendations should be part of the action plan. With the aim to define priorities, non-conformances should be characterized as:

- **Critical:** issues impacting the safety of patients, staff, caregivers and/or environment that should be promptly addressed (within days or weeks). Discontinuation of the concerned activity might need to be considered.
- **Major:** issues impacting the capacity of the NMS to adequately perform its activities that should be addressed in a timely manner (e.g. 3-6 months).
- **Minor:** issues that may be object of optimization, to be accomplished within a defined time period and re-evaluated during the next audit.

Particularly where a critical non-conformance has been found, the action plan should be sent to the audit team for further interaction. If appropriate, the service has the responsibility of notifying the regulatory authorities.

Report of audit team:

The audit report should contain conclusions formulated in simple language, identifying critical, major and minor priorities with clear and practical recommendations. Moreover, the report should identify the issues that can be resolved, improved or implemented by the NMS alone, without significant financial, technical, managerial or professional contribution from outside. If the service wishes to expand or introduce new activities, additional recommendations can be made (7, 8).

Dissemination of report:

The full report of the audit should be sent to those people identified during the exit briefing, e.g. the head of the NMS and other staff members who were important to the audit. If the audit was performed through local or national authorities, the audit team's report should be submitted to them for dissemination according to their requirements. Recommendations made in the report should be directed to the respective institution and the referring organization, if applicable (2, 3).

Follow-up:

The purpose of the follow-up is to verify that the NMS has fulfilled the action plan as previously agreed with

the audit team. If a follow-up audit is organized to check the completion of the action plan and the achieved improvements in the NMS, it should be carried out preferentially by the same audit team (7, 8).

Initiation of QUANUM in Bangladesh

QUANUM audit was included in the work plan of the TC project - BGD6025 in 2013 during the project design phase. IAEA expert Mr. S. Somanesan during his expert visit in June 2014 has introduced QUANUM and developed awareness at NINMAS. He has also provided some guidelines and sample SOPs of Singapore General Hospital for audit preparation. On December, 2013, two participants from Bangladesh also received training from Singapore General Hospital under IAEA expert Mr. S. Somanesan.

QUANUM at NINMAS

Recently a QUANUM and a national workshop on “Quality Management in Nuclear Medicine with QUANUM Audit at NINMAS” was held in Dhaka, Bangladesh, from 27– 31 July 2015. It was organized by Bangladesh Atomic Energy Commission (BAEC) and International Atomic Energy Agency (IAEA) under the IAEA-TC project BGD6025 on “Improving Management of Oncological, Cardiovascular and Inflammatory Diseases Particularly Tuberculosis”. Five quality management experts from IAEA were present as audit experts in this workshop and conducted the audit. The experts were Professor. Sobhan Vinjamuri, Lead Consultant and Professor of Nuclear Medicine, Royal Liverpool University Hospital, United Kingdom; Mr. Thomas Neil Pascual, Division of Human Health, IAEA; Ms Nonglak Vilasdechanon, Vice Head, PET-CT and Cyclotron Center, Chiang Mai University, Thailand; Mr. S. Somanesan, Senior Principal Radiation Physicist, Dept. of Nuclear Medicine and PET, Singapore General Hospital and Mr. Ihab Rajeh, Clinical Imaging Supervisor, PET-CT Cyclotron Services (Nuclear Medicine Technologist) HMC-NCCCR-PET-CT Center for Diagnosis and Research, Doha, Qatar.

The workshop was started with an inaugural session and entrance briefing for external audit team at NINMAS

auditorium on 27th July, where Chairman and Member, Bio Science, Bangladesh Atomic Energy Commission were present. Director of NINMAS and Prof. Shamim Momtaz Ferdousi Begum welcomed external team and took major role as members of internal audit team and auditee. Furthermore, several Nuclear Medicine personnel of different discipline from multiple institutes of NM of the country were participated as observers in the workshop. About 20 local responsible members from NINMAS were involved in the audit procedure.

Pre audit preparation and internal audit at NINMAS

1. Development of awareness on QUANUM among the staffs of NINMAS through several meeting and discussions.
2. Appointing an internal audit team and functioning.
3. Up-gradation of Technical Manual of Nuclear Medicine procedures.
4. Introduction of several record books, log registers and practicing of record keeping.
5. Development of several SOPs for NINMAS.
6. Development of patient record files in QUANUM point of view.
7. Up-gradation of hot lab safety and radiopharmacy handling.
8. An internal audit was carried out according to IAEA check lists and scoring system.

The scoring of internal audit was sent to IAEA experts for their pre audit assessment.

External audit by IAEA experts at NINMAS

The audit was started with entrance briefing by the auditors. The auditors assessed and reviewed the questionnaires with internal audit team. They extensively interacted with members of internal audit team and concerned persons. If needed, they also summoned the other persons with friendly gesture. They scrutinized all the written documents as mentioned in checklists. Experts focused on the Strategies and Policy, Administration and Management, Human Resource Development, Radiation Regulations and Safety, Patient

Radiation Protection, Evaluation of Quality System, Quality Control of Equipment, Computer Systems and Data Handling parts. The scoring was done by using the IAEA check lists.

The simultaneous workshop on QUANUM AUDIT has provided the opportunity to the observers to orient with above mentioned checklists or aspects and was expected to act as cornerstones of local practice in future.

Exit briefing of external audit at NINMAS

At the end of the audit the feedback of the auditors had been documented and presented to relevant key persons and the staffs of NINMAS. This exit briefing session was interactive with questions and an open discussion on all the findings of the auditors. The exit briefing has included positive appraisals and non-conformances. They also addressed critical issues, major issues and minor issues. This comprehensive audit report indicated priorities, together with an action plan and recommendations. This had been submitted to IAEA by the audit team.

Fulfillment of critical issue recommended by external audit team at NINMAS

To handle any medical emergency every Nuclear Medicine personnel must need basic life support training. It was one of the critical issues to be addressed at NINMAS. A training program on Basic Life Support was organized with collaboration with the Department of Anesthesiology, BBSMM University for NINMAS after QUANUM audit. Twenty Nuclear Medicine personnel, five physicians and fifteen technologists participated in a day long training program followed by certificate distribution.

CONCLUSION

Regular quality audits and assessments are vital for modern nuclear medicine services. The first QUANUM audit was a real challenge for our institute. The successful introduction and completion of the audit could be accounted as a mile stone of Nuclear Medicine in Bangladesh. The non conformance issues are still our concern and have to be faced with commitment and dedication. Adequate planning and administrative support is the need for implementation of recommendation of audit. We have Diversity of Nuclear Medicine services and multidisciplinary involvement should be taken into account for quality service of Nuclear Medicine. Through this report we would like to convey the message to the other Nuclear Medicine establishments of the country to start their preparations for future QUANUM audit.

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