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ORIGINAL ARTICLE

Quality audits of nuclear medicine practices in a middle-income African setting

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Abstract

Introduction: The International Atomic Energy Agency (IAEA) introduced a Quality Management Audits in Nuclear Medicine (QUANUM) programme, to improve nuclear medicine practice standards aligned with international standards through self-assessments. The absence of quality management audits in nuclear medicine departments could potentially result in a compromise in the safety and quality of patient care. To date, there is no evidence that quality audits have been conducted in nuclear medicine departments of this middle-income country. This quality audit, therefore, assessed conformance to the IAEA QUANUM programme in four nuclear medicine departments. **Methods:** The study adopted a quantitative methodological exploratory approach. The IAEA QUANUM programme was used to audit nuclear medicine services' overall activity such as clinical practice, management, radiopharmacy, general and radiation safety, quality assurance, operations and services. The data was collected via document analysis in four nuclear medicine department identified as Sites A–D. **Results:** Overall results showed that Site A conformed with 247 out of 370 (67%) counts and non-conformed with 123 out of 370 (33%) counts whilst Site B conformed with 205 out of 342 (60%) counts and non-conformed with 137 out of 342 counts (40%). Site C conformed with 259 out of 345 (75%) counts and non-conformed with 86 out of 345 (25%) counts. Site D conformed with 166 out of 349 (48%) counts and non-conformed with 183 out of 349 (52%) counts. The study yielded 125 overall recommendations. **Conclusions:** All the sites demonstrated good compliance to international standards in radionuclide therapy. Site A complied poorly in strategies and policies, whilst Site B complied poorly in quality control of equipment. Site C showed poor compliance to human resource development and Site D showed aspects pertaining to administration and management as well as evaluation of quality systems.

Introduction

The non-invasive nature of nuclear medicine procedures has led to dramatic transformations in patient care.[1] Ongoing performance assessment of nuclear medicine departments is continuously required to provide accurate, high-quality images and should be conducted through clinical audits.[1] Clinical audits help to maintain a quality management system (QMS) in accredited nuclear medicine departments.[2] This maintenance improves radiation protection for patients, personnel and the public.[2] Clinical audits further signalise incorrect

practices, avoids and predicts radiation accidents.[2] A QMS is used to benchmark evidence-based departmental records to improve safety and ensure quality health care.[3] The Quality Management Audits in Nuclear Medicine (QUANUM) programme developed by the International Atomic Energy Agency (IAEA) aims to improve nuclear medicine practice standards to accepted international standards through self-assessment.[4] The QUANUM programme comprises a series of questionnaires designed to audit a nuclear medicine department's overall activity such as clinical practice, management, radiopharmacy, general and radiation safety, quality assurance and operations.[4]

Nuclear medicine departments in this middle-income country conduct regular quality control tests on their equipment. However, to the authors knowledge, no known auditing of their nuclear medicine departments was ever done before. It was, therefore, deemed necessary to address this gap. The purpose of this study was to assess whether the QMS of the four research sites meets international best practice standards and whether such systems provide a conducive environment for optimal healthcare measured against the IAEA QUANUM reference standards.

Methods

A quantitative exploratory methodological approach was followed to conduct this study. Four nuclear medicine departments in a middle-income African setting were used as the research sites. These departments were considered suitable because they were well-equipped and staffed and conducted most of the common nuclear medicine studies generally performed. The QUANUM programme consists of 16 checklists which in chronological order were as follows: strategies and policies, administration and management, human resource development, radiation regulation and safety, patient radiation protection, evaluation of quality system, quality control for imaging equipment, general clinical services, assessment of imaging diagnostic procedure, general radionuclide therapy, assessment of therapy, radiopharmacy operation level 1 and radiopharmacy operation level 2, respectively. Four checklists (i.e. 8, 11, 16 operational level 3 only and 17, respectively) were excluded from the study because procedures relevant to these criteria were not performed at the research sites. Data was collected between 15 November 2021 to 26 January 2022.

The IAEA audit criteria were used to evaluate applicable departmental processes via document analysis. The documents analysed inter alia, included a quality manual; written standard operating procedures (SOPs) for primary diagnosis management and supporting processes; updated copies of licences/accreditation documents; organisational flow charts and function descriptions as well as samples of referral letters. Other data analysed included patient waiting times and waiting lists; quality control/assurance data for relevant equipment and radiopharmaceuticals; radiation safety records; letters of appraisal/complaints and customer/stakeholder satisfaction surveys.

The QUANUM programme consisted of a spreadsheet that enabled assessment of the level of conformance (LoC) of each criterion specified above. A score system compared the LoC to the established IAEA standards/criteria. Scores ranged from 0 to 4 for each criterion, with the following rating system: 'Not Applicable', 'Absent or inappropriate', 'Planned or approximate', 'Partially conforming or partially implemented', 'Largely conform or largely implemented' and 'Fully conforming or fully implemented'. A 'not applicable' (N/A) score was given to criteria that did not apply to the research site and was not counted. The not applicable scores were excluded from the evaluation of the final results. If a requirement was 'absent or inappropriate', it received a score of 0; if it was 'planned or approximative', it received a score of 1; and if it was 'partially conforming or partially implemented', it received a score of 2. Rating scores of 0 to 2 qualified as 'non-conformance'. The score for 'largely conforming or largely implemented' received a 3 whereas fully conforming or fully implemented received a 4. A score of 3 or 4 was regarded as 'conformance'.

Ethics approval to conduct this study was obtained from the Research Ethics Committee (REC) of the Faculty of Health and Wellness Sciences at the Cape Peninsula University of Technology. During the data collection, all relevant ethical principles were upheld as contained in the Helsinki Declaration and later amendments.

Results

The results for each research site in this paper are referred to as Sites A–D. Figure 1 below summarises the overall conformity with respect to overall counts in relation to the QUANUM programme for the four research sites.

Each checklist criterion was referred to as counts and overall conformity. Figure 1 shows that Site A conformed with 247 out of 370 (67%) counts and non-conformed with 123 out of 370 (33%) counts whilst Site B conformed with 205 out of 342 (60%) counts and non-conformed with 137 out of 342 counts (40%). Site C conformed with 259 out of 345 (75%) counts and non-conformed with 86 out of 345 (25%) counts. Site D

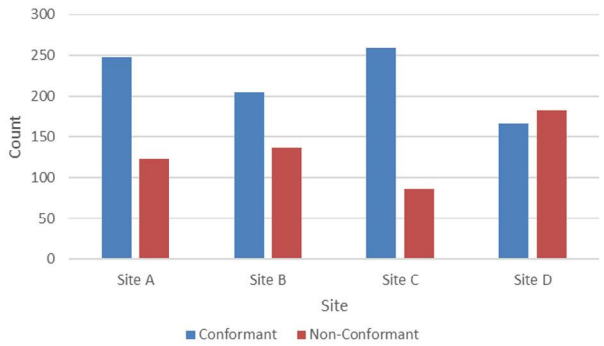

Figure 1. Summary of the overall conformity and non-conformity achieved for all four research sites.

conformed with 166 out of 349 (48%) counts and non-conformed with 183 out of 349 (52%) counts.

The ultimate score that was attained from all the conformances was calculated as a percentage of the total possible score by adding the individual scores. The individual scores of conformances in each checklist expressed in varying percentages are illustrated in Figure 2. As can be appreciated in Figure 2 conformance for strategies and policies ranged between 19% and 75%; administration and management ranged between 18% and 85%; human resource development ranged between 42% and 50% whilst radiation regulation and safety conformance ranged between 41% and 66%. Patient radiation protection ranged between 38% and 65% whilst evaluation of quality system ranged between 18% and 62%. Quality control for imaging equipment ranged between 20% and 85% whilst general clinical service ranged between 27% and 48%. Assessment of imaging diagnostic procedure ranged between 48% and 78% whilst general radionuclide therapy ranged between 52% and 95%. Assessment of radionuclide therapy ranged between 75% and 98% whilst radiopharmacy operational level 1 and 2 ranged between 40% and 58%, respectively.

The radar plots illustrated in Figures 3–6 below provide an overview of each individual site's conformance to the QUANUM criteria. Each spoke represents the conformance to the checklists.

Discussion

Strategies and policies of the Nuclear Medicine Services should be in line with specific health service objectives developed at the national/regional level of a country.[5] National health policies, strategies and plans (NHPSPs) are critical in outlining a country's vision, policy goals and strategies to safeguard its population's health.[6] NHPSPs provide a framework for dealing with various issues needed to enhance health outcomes, including those connected to the sustainable development goals (SDGs) and other national priority health challenges developed by the Southern African Development Community.[6,7] This study showed that Strategic development plans for global activities and policies were absent at a departmental level at three sites, and there were planned regional expansions at the remaining site. If Nuclear Medicine Services (NMS) does not provide a full range of services, a policy should guide access to such services at another institution.[6] Although patients are referred for additional or specialised examinations to other facilities, no policy was in place at a departmental level for all four research sites.

All the research sites had a good compliance to the checklist related to radionuclide therapy. Site A had high level of compliance to clinical services both diagnostic and therapy and in quality control of equipment related checklists. Site B showed good compliance to strategies and policies and both diagnostic and therapy services. Site C had high level of compliance to checklists related to administration and management, quality control of equipment and both imaging diagnostic and therapy services. Site D showed compliance to checklists related to strategies and policies and radionuclide therapy.

There were no written standard operating procedures (SOPs) at three sites. The majority of SOP's were in place at one site but needed to be reviewed in a proper format as recommended by Shestapolova and colleagues.[8] An SOP can include figures, graphs, tables or photos to help visualise and understand the actions stated in such procedures.[8] An SOP is an effective tool for increasing healthcare quality and safety, and its integration into everyday processes at medical institutions is essential. SOPs should be updated regularly to reflect current or new requirements, personnel technical capabilities and technological advances.[8]

None of the sites in this study performed any internal review of the competency of staff members. Senior management should ensure an organisation's operational effectiveness and efficiency by documenting essential individual competencies and ongoing assessment.[9] As a result, worldwide professional regulations have become more stringent.[10] Many countries have strengthened competency criteria for healthcare practitioners by establishing minimum knowledge, abilities and attitudes standards.[10] Continuous assessment of these competency criteria is thus at the top of strategic healthcare planners' agendas.[10]

None of the sites had mechanisms to provide professional education and development opportunities. Continuous radiation safety and protection training is provided for only some staff categories at only three sites. Continued professional development of nuclear medicine

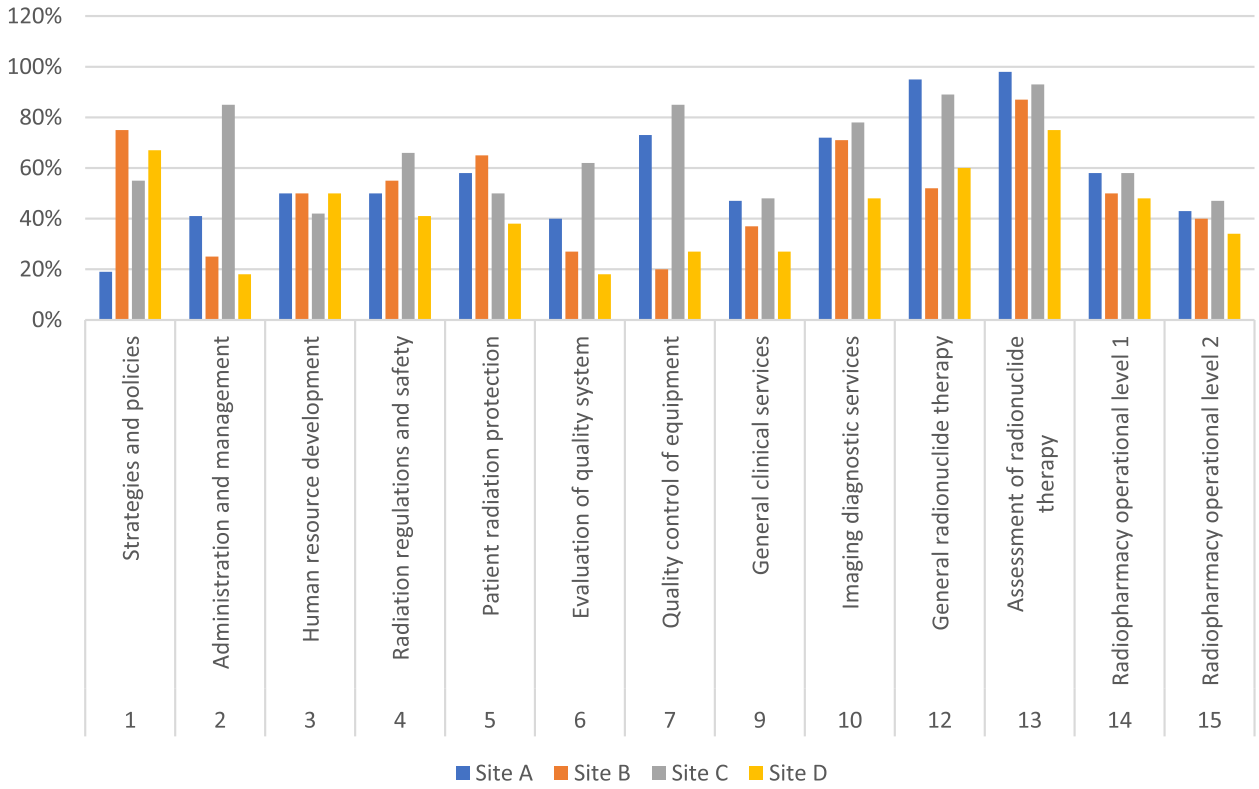

Figure 2. Summary of QUANUM audit conformance per criteria calculated in percentages for all four research sites.

staff should be an ongoing process with good planning and organisation, it should be easy to provide further education and training at all professional levels.[9] Periodic accreditation of nuclear medicine staff should be part of continuing education and staff training programmes.[9] Thus, ensuring staff members have the latest knowledge and skills to provide the best possible service.[9]

None of the sites in the study had the classification of sections of the department into controlled or supervised areas. All nuclear medicine departments should have areas classified as controlled or supervised.[11] Controlled areas include preparation and administration areas, storage and areas accommodating patients.[11] Supervised areas include waiting areas for patients receiving radiopharmaceutical injections and imaging rooms for examinations.[11] Two sites did not display radiation signs in the local language at the entrance of a supervised and controlled area. These signs should also inform pregnant or breastfeeding women to notify the relevant personnel of their pregnancy status.[11]

None of the facilities regularly monitor workplace contamination and lacked assessments and surveys of working areas and associated equipment. The radiation monitoring devices in all the facilities required to be calibrated. An NMS must regularly calibrate all radiation-detecting instruments.[12] This calibration must be traceable to a recognised primary or secondary standard, as it can drift over time and become inaccurate.[12] All four research sites needed a clear, concise and definite emergency plan posted visibly in places where their need was anticipated.

None of the sites performs self-assessments or audits. These assessments determine compliance with IAEA requirements and evaluate the need for corrective actions, emphasising opportunities for improvement and enhancing performance.[13] None had a system to assess satisfaction (patient, referring physicians/third party). The satisfaction of patients and referring physicians is one component that merits special attention in a quality assurance programme and is identified as an essential quality indicator used to measure the achievement of the service delivery system.[11,14]

Although there is a practice of inquiring about pregnancy and lactation before administering radiopharmaceuticals, none of the sites had an SOP in place. One of the definitions of misadministration is incorrect doses and extravasation.[15] Using a wrong administration route can cause a significant amount of

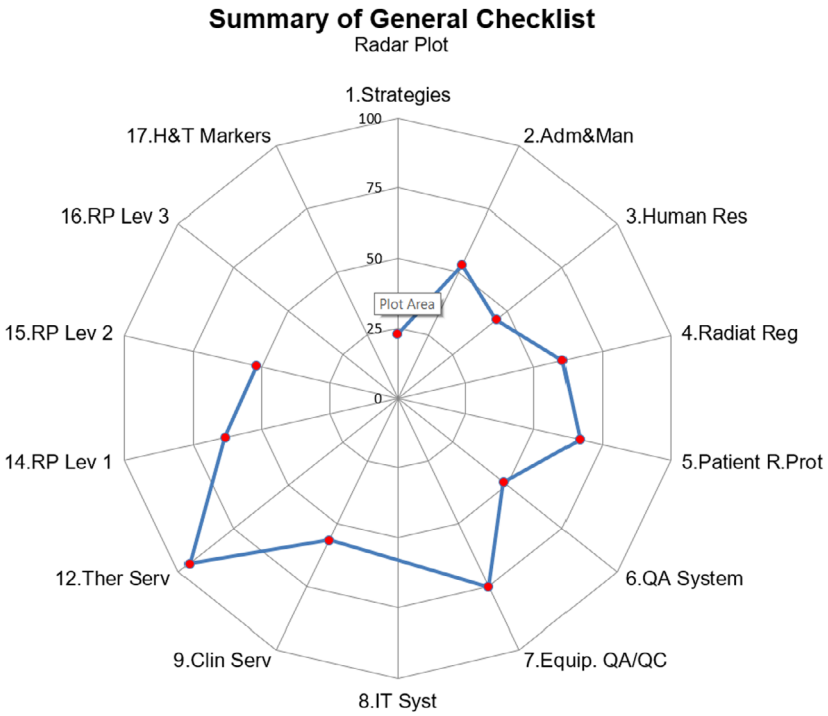

Figure 3. Radar plot for Site A showing conformance of 19% for Strategies and 98% for Assessment of Radionuclide Therapy. Legends for radar plot: 1. Strategies = Strategies and policies; 2. Admin & Man = Administration and management; 3. Human Res = Human resources; 4. Radiation Reg = Radiation regulation and safety; 5. Patient R Prot = Patient radiation protection; 6.QA System = Evaluation of quality assurance system; 7. Equip.QA/QC = Equipment quality assurance/quality; 8.IT Syst = Information technology systems (not scored for any research site); 9. Clinical Serv = General clinical services; 12. Ther Serv = General radionuclide therapy; 14. RP Lev 1 = Radiopharmacy operation level 1; 15. RP Lev 2 = Radiopharmacy operation level 2; 16. RP Lev 3 = Radiopharmacy operation level 3; 17. H&T Markers = Hormone and tumour markers.

absorbed exposure at the injection site, particularly if the radiopharmaceutical has a long retention period and the volume is small.[15] A deviation of 25% from the required activity in most diagnostic applications is considered acceptable.[15] None of the four sites had a procedure to avoid the misadministration of radioactive and non-radioactive pharmaceuticals.

All four research sites lacked a procedure to address and report any adverse event adequately. Adverse reactions are usually minor and self-limiting, requiring little or no treatment.[12] Since such incidents are uncommon, they should be reported to the product manufacturer and national authorities.[12] None of the research sites conducted quality control on radiopharmaceuticals. Quality control of the generator eluate and radiopharmaceuticals involves testing for molybdenum breakthrough, aluminium ion contamination test, sterility, pH and radiochemical purity.[16] Before patient administration, a radiochemical purity test, utilising a thin layer chromatography test, should be carried out on the first batch of radiopharmaceuticals.[16]

The treatment files in all the sites did not identify their patients according to the SOP, which should have been established. Although the treatment report was drafted in a format, there needed to be a reference to a specific SOP for all the facilities.[5] None of the sites had documentation on handling any incidents or adverse events recorded in the files nor a post-treatment feedback system in place. At one site, there was a record concerning how this department determines patient preparation. However, there needed to be more traceability of all patient-related data in the hospital files.[5] Some of the files at one research site, did not indicate availability and checks for any medicinal potential interference with the current radionuclide therapy.

Limitation

This study had some noteworthy limitations. Some of the questions in the QUANUM tool were lacking in clarity, which hampered selection of conformity or non-conformity for some criteria. This might have influenced some of the results. The authors suggest that for such future studies, training on the QUANUM tool by the IAEA should be offered, or a pilot study/pre-audit/

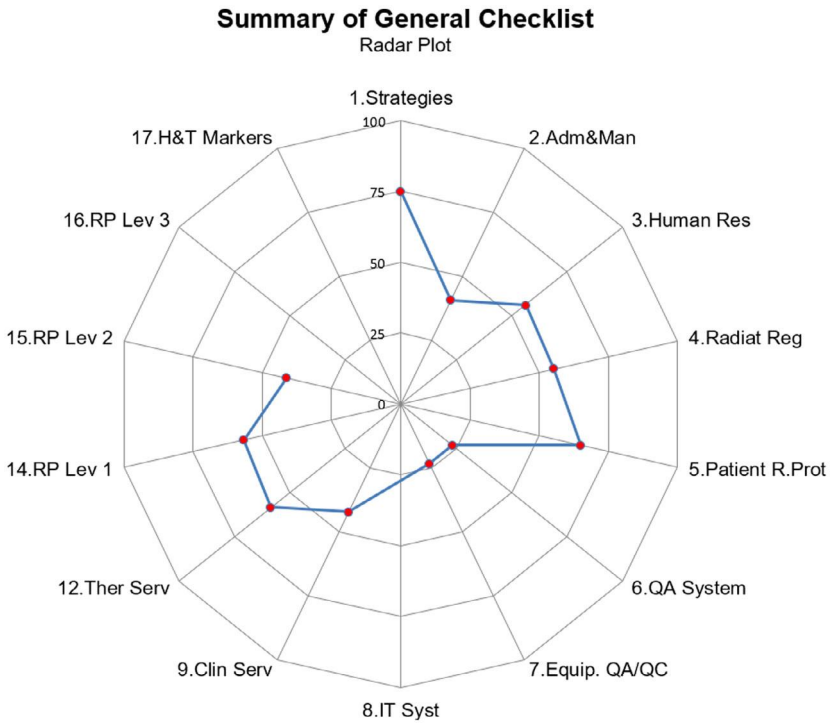

Figure 4. Radar plot for Site B showing conformance of 20% for Quality Control of Equipment and 87% for Assessment of Radionuclide Therapy.

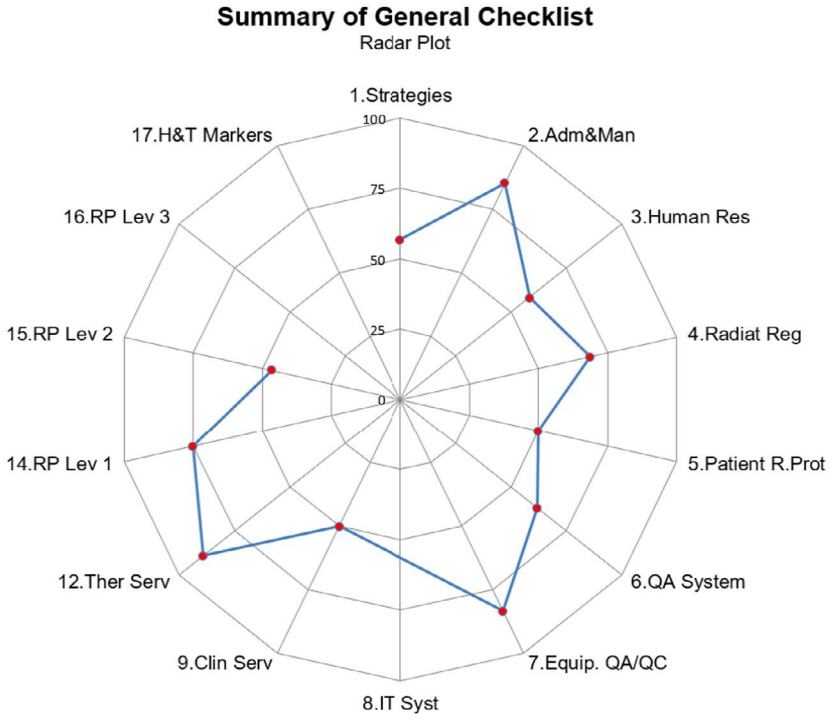

Figure 5. Radar plot for Site C showing conformance of 42% for Human Resource and 89% for Therapy Services.

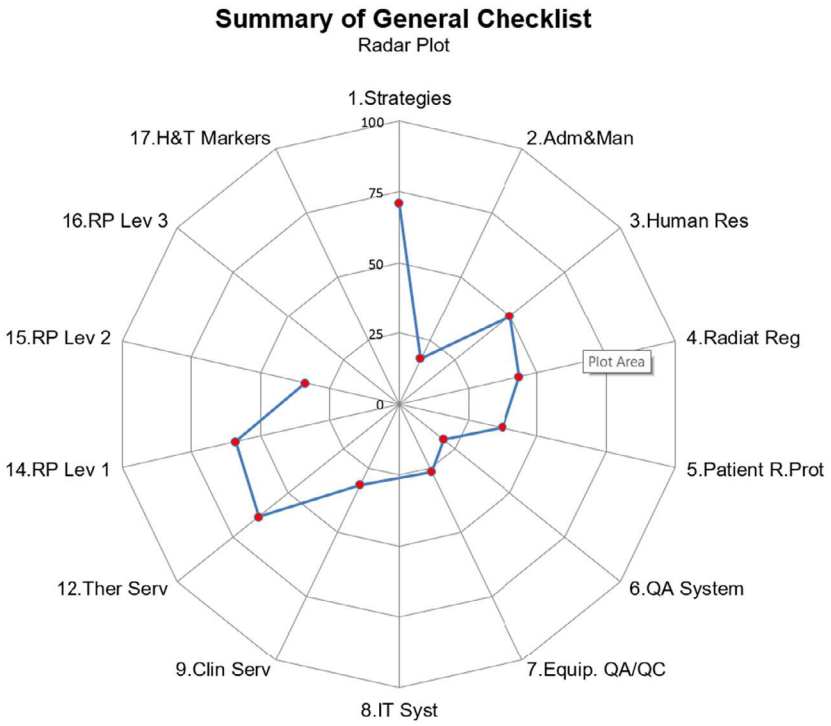

Figure 6. Radar plot for Site D showing conformance of 18% for Administration & Management and 67% for Strategies.

internal audit should be conducted before the actual data collection at any research site.

Conclusion

Implementing a QMS should be a calculated choice to raise the level of quality/treatment offered by any nuclear medicine service. This study highlighted the absence of SOPs. Stricter adherence to SOPs should be encouraged when available, and more detailed training on creating them should be provided. SOPs should be compiled to ensure more organised and standardised everyday activities. Implementing routine internal audits and, as necessary, follow-up external audits should help with radiation safety and other quality issues. Managers of the research sites can use the findings of this study to assess areas where improvement in service delivery or operational matters can be developed and implemented. Such improvements will not only benefit the patients they serve but may potentially also result in positive changes amongst the professional practice standards of staff.

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Conflict of interest statement

The authors declare no conflict of interest.

Data Availability Statement

Data for this research study are available via the CPUT data management system and will be available upon request.

Ethics statement

Ethical clearance was obtained from the Research Ethics Committee, Faculty of Health and Wellness Sciences, Cape Peninsula University of Technology. Certificate number: CPUT/HW-REC 2021/H25.

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