Review paper

Moving beyond quality control in diagnostic radiology and the role of the clinically qualified medical physicist

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ARTICLE INFO

Article history:

Received 30 December 2016

Received in Revised form 2 February 2017

Accepted 8 April 2017

Available online 12 April 2017

Keywords:

Quality control

Quality assurance

Clinical audits

Diagnostic radiology

Clinically qualified medical physicist

ABSTRACT

Quality control (QC), according to ISO definitions, represents the most basic level of quality. It is considered to be the snapshot of the performance or the characteristics of a product or service, in order to verify that it complies with the requirements.

Although it is usually believed that “the role of medical physicists in Diagnostic Radiology is QC”, this, not only limits the contribution of medical physicists, but is also no longer adequate to meet the needs of Diagnostic Radiology in terms of Quality.

In order to assure quality practices more organized activities and efforts are required in the modern era of diagnostic radiology. The complete system of QC is just one element of a comprehensive quality assurance (QA) program that aims at ensuring that the requirements of quality of a product or service will consistently be fulfilled. A comprehensive Quality system, starts even before the procurement of any equipment, as the need analysis and the development of specifications are important components under the QA framework.

Further expanding this framework of QA, a comprehensive Quality Management System can provide additional benefits to a Diagnostic Radiology service. Harmonized policies and procedures and elements such as mission statement or job descriptions can provide clarity and consistency in the services provided, enhancing the outcome and representing a solid platform for quality improvement.

The International Atomic Energy Agency (IAEA) promotes this comprehensive quality approach in diagnostic imaging and especially supports the field of comprehensive clinical audits as a tool for quality improvement.

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1. Introduction

Diagnostic radiology represents the vast majority of population exposure to man-made radiation, according to the data from the UNSCEAR Report 2008 [1]. However, although this has been well proven and data demonstrate that there is even a trend for further increase, diagnostic radiology is often inadequately covered in terms of appropriate quality procedures and competent medical professionals that can guarantee its safe and effective use.

For many decades, since its introduction, diagnostic radiology only involved low complexity equipment that could deliver very small amount of radiation dose to the patient and this has created the belief that any quality assurance initiative or intervention other than system installation and service was pointless [2]. However, the technology has rapidly evolved and we are now way beyond this point, both in terms of equipment complexity, which has significantly increased, and patient dose, which can now reach very high, even deterministic values. Furthermore, the importance of accurate diagnosis for the patient management has created a new reality in which the requirements for quality have been tremendously expanded. This is the reason why the concept of quality has been completely transformed in diagnostic radiology and the well-known quality control has been replaced by a more comprehensive framework of quality, within which the clinically qualified medical physicist has a leading role, due to his/her skills and competences [3,4].

However, especially in low and middle income countries imaging equipment is often left without proper supervision of its performance for long periods, and some kind of quality assessment, in terms of performance evaluation only takes place during inspections for licencing purposes. This is certainly inadequate to ensure safe and effective performance of the equipment, let alone to ensure that a diagnostic facility provides high quality services, which, further to the component of the equipment, should include elements related to the staff and the procedures.

Under its mandate to promote the use of atomic energy for the Health, Peace and Prosperity, the International Atomic Energy Agency (IAEA) has been continuously working with its Member States to strengthen this new era by supporting the evolution of the quality requirements beyond the traditional Quality Control.

2. The system of quality

In order to adequately comprehend the new requirements for quality services in diagnostic radiology, one has to clearly define the term *quality*. This is done by the International Organization for Standardization [5] defining quality as “degree to which a set of inherent characteristics of an object (product, service, process, system) fulfils requirements (need or expectation that is stated, generally implied or obligatory)”. Specifically for Healthcare, the World Health Organization (WHO) describes the six dimensions of quality that require for a Healthcare system to be [6]:

- Effective
- Efficient
- Accessible
- Acceptable/patient-centred
- Equitable and
- Safe

The structure of quality, as defined by ISO [5] has several different levels with different objectives and procedures involved. The International BSS [7], requires the existence of a management system, which is considered to “reflect and include the concept of ‘quality control’ (controlling the quality of products) and its evolution through ‘quality assurance’ (the system for ensuring the quality of products) and ‘quality management system’ (the system for managing quality)” Fig. 1.

2.1. Quality control

Quality control (QC) represents the most basic form of quality-related activities and its main objective is to ensure that a system or a service fulfils the established quality requirements [5]. It is thus a snapshot of the system performance and a reactive process to compare the performance against certain standards. Even though the concept of quality control is relatively well developed in the field of diagnostic radiology, there is often a misconception even at this basic level, and QC is seen only as a series of measurements on a piece of equipment. As noted by members of the Task Group 151 of the American Association of Medical Physicists (AAPM), “Quality control in medical imaging is an ongoing process and not just a series of infrequent evaluations of medical imaging equipment” [8].

Performance testing is just one element of quality control and represents the baseline of the structure of quality. It is just intended to verify consistently reliable and safe function of all pieces of imaging equipment. Several recommendations and guidelines have been published to support the measurement of any system performance, either in the beginning of its lifetime, or routinely to throughout its lifetime.

According to the International BSS [7], “measurements of the physical parameters of medical radiological equipment should be made by or under the supervision of a medical physicist”, who, in certain cases, can delegate certain responsibilities to other staff, such as the radiological technologist.

QC is this component of quality that is frequently confused as the sole role of the medical physicist in diagnostic radiology; however, as very vividly described in the AAPM report 74 “the vampire-physicist who only appears at night and only leaves reports is not providing appropriate service to the client” [9].

2.2. Quality assurance

As noted even by its name the main objective of Quality Assurance (QA) is to provide confidence (assurance) that the system will

Fig. 1. Simplified structure of the System of Quality.

continue to perform according to the established quality requirements [5]. It is thus a reactive process to prevent defects or inadequacies that may affect performance.

According to the international BSS [7] registrants and licensees of radiological facilities shall ensure that QA systems are in place and that corresponding requirements are “fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks”.

In diagnostic radiology this QA framework includes the element of QC, and is associated to the whole imaging chain as linked to the patient. The important point that should be clarified is that the QA program should start even before the installation of any system, with the implementation of a need analysis, followed by the drafting of specifications and corresponding evaluation of the offered systems [10]. QA includes all aspects of medical imaging technology such as room and workflow design, equipment selection, equipment purchase, installation oversight, acceptance testing, commissioning, quality control, on-going equipment maintenance and support, and disposal at the end of the equipment's useful life.

2.3. Quality management

According to ISO9000 definitions, quality management is considered to be the overall umbrella for all quality concepts and it includes all activities that organizations use to direct, control and coordinate quality. Quality management can include establishing quality policies and objectives, and processes to achieve these quality objectives through quality planning, quality assurance, quality control, and quality improvement [5].

There are seven quality management principles, as described by ISO [11]:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

The proper application of these principles in diagnostic radiology can yield significant benefits for the department, which should assign a person or persons in the role of quality manager with the responsibility of implementing and maintaining the quality management system. To facilitate proper implementation of the quality management system, a quality committee should be established to provide periodic review and evaluation of the facility's QA program. The committee should consist of physicians, radiographers, medical physicists, nurses, administrative and other staff, as appropriate.

3. Monitoring quality in diagnostic radiology

As is the case in many aspects of everyday life, also in diagnostic radiology the term *quality* is very common and usually every department considers that it offers high quality services. And it might well do, however the primary question in this case is “how do we know that we provide high quality services?”, since, without proper criteria, quality is just a vague concept, rather than an actual achievement. Only concrete evaluation and quantification processes can demonstrate quality and these processes include objective measurements and peer review.

Table 1

Example of the content and structure of a Quality Manual for use in a diagnostic radiology Department.

1. Leadership & strategy	
1.1	Mission statement: mission & vision
1.2	Demographics: population served
1.3	Department organization
1.4	Strategic planning & action planning
2. Resources	
2.1	Human resources and qualifications
2.2	Infrastructure (rooms, facilities)
2.3	Imaging equipment
2.4	IT systems and infrastructure (including data security)
2.5	Additional equipment
2.6	Financial resources
3. Radiation safety	
3.1	Radiation safety committee
3.2	Radiation safety local rules
3.3	Radiation safety manual
4. Quality	
4.1	Quality assurance committee
4.2	Quality assurance and quality control
4.3	Plans, actions and records of continual improvement
4.4	Documentation control
4.5	Incident reporting system
5. Clinical guidelines	
5.1	Pre Examination Preparation
5.2	Examination Procedures
5.3	Post Examination Procedures

3.1. Documentation

Although a documentation process is time consuming and considered to be highly unproductive, its importance, in the form of a quality manual, is vital within any quality management system. Documentation acts internally as a reference point to the employees for the quality objectives and policies of the department, while at the same time describes the procedures necessary to achieve these objectives. Externally, it can inform partners about the implemented quality management system but also serve as evidence of compliance with quality requirements.

In order to be effective, organized team work is required to ensure that the manual is properly maintained and updated, being available to be utilized by all involved stakeholders. While it should be as comprehensive as possible, at the same time it has to be brief but also clear and consistent to allow implementation. In the modern digital era, a traditional hardcopy quality manual might not be necessary, as it could be integrated in the IT system of the facility (HIS/RIS/etc.), providing easy access to all staff. A simple example of the content and structure of such a document, as developed by a group of IAEA experts is given in Table 1.

3.2. Performance indicators

“Measurement is the first step that leads to control and eventually to improvement. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it”. This quote, attributed to H. James Harrington, a pioneer of quality, summarizes the concept of one key element of quality, quantification. Since the continuous improvement should lead to measurable results it is necessary that any quality system should have clearly defined performance indicators, often mentioned as Key Performance Indicators (KPI).

The team should discuss in order to identify relevant KPIs that can demonstrate improvement since the initial steps of the process, while being relevant to the practices and internal bottlenecks identified in the department. As the process of quality matures, the same applies to the KPIs that can evolve accordingly. The medical

Table 2

Examples of simple Performance Indicators that can be utilized in a diagnostic radiology department.

Patient or procedure identification error rates
Number of equipment under a regular QC program with established procedures
Number of examinations for which local doses exist
Number of incidents reported (eg. contrast medium reactions, cardiopulmonary collapse, patient falls)
Number of hours of training per year (internal and external) for the staff of the department
Number of procedures documented and utilized
Percentage of standardized radiological procedures with established examination protocols
Number of complaints from all stakeholders (referring physicians, patients, staff, etc)
Image rejection and retake rate and analysis of the results.
Turnaround time for different examinations and patients (emergency, enternal, in-patients)

physicist has a leading role in the development and monitoring KPIs, especially more technical ones, due to the relevant background and familiarity with measurement and quantification processes. Some examples of KPIs that can be utilized to monitor the performance of the department can be found in Table 2.

3.3. Dosimetry

The primary objective of diagnostic radiology is to produce diagnostically adequate images and radiation dose is the unavoidable side effect of the imaging process of the patient. As radiation dose is associated with some potential risk, it should be kept to the minimum, without however jeopardizing the outcome of the procedure.

Dosimetry in diagnostic radiology is usually performed for one of the following reasons:

- Equipment performance testing
- Development of guidance levels – optimization (including DRLs)
- Patient specific dosimetry (risk estimation).

Under the framework of quality, dosimetry plays a crucial role, as each of the abovementioned points can be associated with different components and to some extent can be utilized as a performance indicator to evaluate the quality of services. Dosimetry as part of performance testing, used for the “calibration” of the X ray source [7] is an important part of QC, verifying proper and consistent performance. Dosimetry of standard radiological practices in order to derive typical doses and allow consequent comparison with established DRLs can trigger quality improvement activities through optimization, while patient specific dosimetry can be directly linked with the requirement of safety in radiological practices.

However, as diagnostic radiology covers a very large spectrum of different techniques and modalities, relevant dosimetry can become complicated and only trained professionals, such as medical physicists are competent to adequately perform it. It is the responsibility of the registrants and licensees to ensure that “dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols” [7].

3.4. Clinical audits

According to the European BSS [12], a clinical audit is “a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of prac-

tices, where appropriate, and the application of new standards, if necessary”.

This audit process should be an inherent component in any quality system as it represents the way that services are perceived by our peers and it involves evaluation of data, documents and resources for checking performance against standards. It is essentially a process of fact finding and interpretation and, as such, provides an efficient tool for improvement of quality. Therefore, it should be clear that clinical audits are not designed for (i) licencing purposes, (ii) investigation of accidents or reportable medical events or, (iii) investigation for entry into cooperative clinical research studies.

The general principle of audit imposes the requirement that the auditors have to be independent of the service or process to be

Fig. 2. The IAEA Human Health Series No.4 on Comprehensive Clinical Audits of diagnostic radiology Practices: A Tool for Quality Improvement (QUAADRIL) [13].

audited. However, often clinical audits can be internal, even within the same health care institution, when the principle of independence is implemented by nominating auditors from different departments of the same institution. Internal audits should be routine activities within a good quality system [13].

Emphasis has recently been placed on external audits, in which the auditors are external to the institution to be audited and thus totally independent. The value of external audits lies mainly in providing the audit with more universal and broader perspectives, removing the possible inability of internal auditors to recognize, in their own environment, the weaknesses and limitations which may involve long-standing or routine practices.

External auditors are the experts that through independent and unbiased review of the facility practices and procedures are able to better identify weaknesses and suggest interventions that would result in quality improvement. According to the IAEA audit methodology [13] (Fig. 2) the audit team will consist of a multidisciplinary peer review panel with expertise to cover all different aspects of diagnostic radiology and should be familiar with clinical audit methodology. The composition of the audit team will usually include as a minimum: a radiologist, a diagnostic radiology medical physicist and a radiographer or diagnostic radiology facility manager.

4. Discussion

Quality improvement is a continuous process and the development of a comprehensive quality management system is a tool in this process and not the aim. This new quality framework should be based in three pillars; human resources, procedures and equipment.

Comprehensive quality systems are becoming more and more popular in diagnostic radiology and could become a *de facto* standard in the near future, as a comprehensive way to install and maintain quality practices. One of the important requirements for the initiation of any effort to develop such systems is the management commitment, as without it any effort will deteriorate and eventually collapse. A limiting factor is the financial constraints that might apply, as developing a formal quality system requires resources and staff time. However, the cost of non-quality is much greater and in the long term the management and organizational improvements that will come as a result of the quality system will make it cost effective, for example by optimizing the workflow, reducing costly errors and minimizing equipment downtime.

Competent professionals, such as clinically qualified medical physicists are required in order to support this effort and their role is now more apparent than ever, as is the competent professional to lead the quality management of the physical and technical aspects of radiation medicine, such as development of institutional policies and procedures for the safe and effective use of radiation,

supervision of quality assurance (QA) and quality control (QC) procedures, and dose assessment and management.

The need for medical physics support in diagnostic radiology has been recognized and highlighted by international organizations and professional societies [3,4,7], and medical physics services are no longer a recommendation for diagnostic radiology departments but a requirement in order to actually develop procedures that can result in high quality services. Compromising the medical physics services in diagnostic radiology means recognizing and accepting the delivery of sub-optimal services to patients.

5. Conclusions

Technology advancements have completely transformed diagnostic radiology over the period of the last few decades. Although this has apparent benefits for the patient care, it also requires the adoption of a more systematic approach for quality to ensure safe and effective services. The basic concept of quality control is no longer adequate for diagnostic radiology and has to evolve into a more comprehensive framework for managing the quality of the services to patients, rather than controlling it.

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