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REVIEW ARTICLE

Quality management in imaging services

Gestión de la calidad en servicios de imagenología

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Abstract

In an imaging procedure with ionizing radiation, different elements are involved, and each possible failure in one of them can be associated with a detriment to its quality. The loss of quality has ethical and economic implications, which is why it must be managed intentionally. Therefore, it is recommended to establish a quality management system (QMS), which represents a standard framework for the administration that ensures correct execution and the desired results through compliance with a series of requirements on the different aspects or components of the service. To guarantee the success of a QMS, actions based on quality assurance (QA) and quality control (QC) must be established. When reviewing the Chilean regulations that regulate the use of ionizing radiation in medicine, we found that there is a deficiency in the concepts and applications in the requirements that refer to QMS, QA and QC. The purpose of this narrative review is to present an updated revision for health administrators and professionals on the rationale and purpose of a QMS, and QA and QC as its essential components, in imaging services.

Keywords: *Quality. Quality management system. Imaging. Quality assurance. Quality control.*

Resumen

En un procedimiento imagenológico con radiaciones ionizantes intervienen diferentes elementos, y a cada posible fallo en alguno de ellos cabe asociar un detrimento en la calidad del mismo. La pérdida de calidad tiene implicancias éticas y económicas, razón por la cual esta debe ser gestionada con intencionalidad. Así, se recomienda establecer un sistema de gestión de la calidad (SGC), que representa un marco estándar para la administración que asegura la correcta ejecución y los resultados deseados mediante el cumplimiento de una serie de requisitos sobre los diferentes aspectos o componentes de la atención. Para garantizar el éxito de un SGC se deben establecer acciones sustentadas en la garantía de calidad (GC) y el control de calidad (CC). Al revisar la normativa chilena que regula el uso de las radiaciones ionizantes en medicina, constatamos que existe un vacío de conceptos y aplicaciones en los requerimientos que hacen referencia a SGC, GC y CC. La presente revisión narrativa tiene como propósito presentar una revisión actualizada para administradores y profesionales de la salud sobre la justificación y el propósito de un SGC, y de la GC y el CC como sus componentes esenciales, en los servicios de imagenología.

Palabras clave: *Calidad. Sistema de gestión de la calidad. Imagenología. Garantía de calidad. Control de calidad.*

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Introduction

From the moment it is decided to perform an imaging procedure with ionizing radiation until the diagnosis is issued on the image obtained, a complex activity is carried out in which different physical processes, equipment and specialists are involved[1]. Failure in any link in this chain is associated with a detriment to the quality of the imaging procedure that has ethical implications (higher radiation dose to the patient and loss of diagnostic information from the image) and economic implications (increased costs for repeat examinations and lower performance in the number of examinations undertaken). For these reasons, quality in imaging care requires specific management.

To work with quality in an imaging service, it is recommended to establish a quality management system (QMS), abbreviated as a quality system, which must be part of the quality policy of the healthcare institution to which it belongs[2,3]. These systems were devised in the late 1940s for manufacturing processes, and over the years have developed to the point that internationally accepted standards now exist[4]. Essentially, a QMS is a standard framework through which a service provider can demonstrate that everything possible is being done to ensure that key processes are precisely defined, managed and controlled, so that any problem is quickly identified and investigated. This feedback loop for improvement is applicable to any process in an imaging service[3].

To ensure that the quality needs or expectations declared in the scope of the QMS are met, quality assurance (QA) actions must be established. Now, the detailed instruction to carry out these actions systematically by individuals on the facilities, processes and imaging equipment is known as a QA program (QAP) and includes quality management elements and quality control techniques (QC)[3,5].

In practice, one should ask: how can an imaging service measure the real performance of the quality with which it is working? And the answer would be: through QC (in many texts, QC tests or the QC program are indicated as synonyms for QC), with procedures that allow the results to be compared with the declared standards and that guide preventive actions or corrective measures to maintain or regain compliance with the standards. It is then about verifying that the structures, systems and components are in accordance with predetermined requirements[3,5].

When reviewing the Chilean regulations that regulate the use of ionizing radiation in imaging services, we found that there are gaps in the concepts and applications when talking about QMS, QA, QAP and QC. The closest regulation that exists is the *Norma General Técnica N° 214 de mamografía* (General Technical Standard No. 214 for mammography), which only refers to QC[6].

For all of the above, the purpose of this narrative review work is to prepare a consultation document for radiologists, medical technologists and medical physicists, which contains sequentially, in a pedagogical and summarized format, the main aspects to take into account when managing quality in an imaging service.

Development

Concept of quality

Quality refers to the ability that an object or service has to satisfy implicit or explicit needs according to a parameter, a fulfillment of quality requirements. Quality is a subjective concept related to the perceptions of each individual to compare one thing with any other of the same kind, and is influenced by factors such as culture, the product or service, needs and expectations[7].

According to the ISO 8402:1996 standard, quality is "the totality of features and characteristics of a product or service, which entail the ability to satisfy pre-established or implicit needs"[8]. For its part, ISO 9000:2015 indicates that the quality of an organization's products and services "is determined by the ability to satisfy customers, and by the intended and unintended impact on relevant stakeholders. The quality of products and services includes not only their intended function and performance, but also their perceived value and benefit to the customer"[9].

When talking about the quality of particular goods or services (in our case, an imaging service), we must take into account the three levels at which quality is measured[10]:

- Expected quality: it is the level of quality of the product or service that is expected by the customer and may be influenced by external factors, such as the comments or opinions of third parties.
- Perceived quality: it is the customer's perception of the product or service. It is very subjective and difficult to measure quantitatively.
- Real quality: this level of quality uses statistical data and considers all the factors that can influence the final result.

Quality management system

It represents the framework to support the operation of the institution with the objective of continuous quality improvement, and incorporates[11]:

- The organization's objectives and policies.
- Documented procedures in accordance with these objectives and policies.
- Description of the technical and professional roles of the staff.
- Written best practice instructions for staff.
- Monitoring, recording and auditing of practices.

This set of interrelated and interactive processes allows the imaging center's quality policy and objectives to be achieved.

The organization shall establish, document, implement and maintain a QMS, and continually improve its effectiveness in accordance with the following requirements:

- Identify the processes necessary for the QMS and its application throughout the organization.
- Determine the sequence and interaction of these processes.
- Determine the criteria and methods necessary to ensure that both the operation and control of these processes are effective.
- Ensure the availability of the resources and information necessary to support the operation and monitoring of these processes.
- Monitor, measure and analyze these processes.
- Implement the necessary actions to achieve the planned results and continuous improvements of these processes.

Quality assurance

QA is a set of planned and systematic actions necessary to provide adequate confidence that an item, process or service (in this case, an imaging service) will satisfy certain quality requirements.

For the Organización Panamericana de Salud (Pan American Health Organization), the QA is "a management instrument used to ensure that each examination or treatment in a radiology department is necessary and appropriate for the patient's medical problem. The procedures must be performed in accordance with previously validated clinical protocols, by adequately trained personnel and with properly selected and functioning equipment, to the satisfaction of users and referring physicians, under safe conditions and at a minimum cost. Therefore, a QAP should include periodic reviews of referral standards, clinical protocols, continuing education opportunities for staff, facility inspections, equipment evaluations, and administrative procedures related to the purchase of supplies and billing. Its maximum goal is the best patient care"[12].

Table 1. List of minimum actions that a quality management program for an imaging service should cover

Equipment specifications
Acceptance/commissioning tests
Quality control
Evaluation of equipment performance through tests and acceptance criteria (these are the quality control tests themselves)
Image rejection/repetition analysis
Image quality evaluation
Corrective actions
Dosimetry and calibration
Documentation and records
Audits
Risk assessment

For its part, the International Atomic Energy Agency (IAEA), in its *International Basic Standards,* defines QA as "a function of a management system that provides confidence that specified requirements will be met. Planned and systematic measures are needed to provide adequate confidence that an item, process or service will satisfy certain quality requirements; for example, those specified in the license"[13].

Finally, the World Health Organization proposes as a definition of QAP an "organized effort by the staff of a facility to ensure, with certainty, that the diagnostic images produced by said facility are of sufficiently high quality to give, in all cases, an adequate diagnostic information, at the lowest possible cost and with the minimum radiation exposure to the patient"[14].

Table 1 summarizes the minimum aspects that should cover the QAP in an imaging service.

Quality control

QC is an essential part of the QA and its program. It includes operations intended to evaluate the characteristic parameters of the operation of a piece of equipment that can be measured and controlled, in order to verify whether their values are within the required tolerance margins to ensure its correct operation[9]. Depending on the objectives pursued and the means available, three types of QC[1] stand out:

- Acceptance tests: try to demonstrate that the equipment meets the specifications of the purchase contract,

the manufacturing specifications and the legal requirements applicable in each country.
- Status tests: are a control that typically involves the measurement of technical parameters with the objective of establishing the "reference status" of an equipment or component at a given time. Status testing must be performed by qualified personnel.
- Consistency tests: they begin starting from the reference value of one or more parameters representative of the operation of the equipment, measured in the acceptance or status tests. The parameters are periodically re-measured to compare their value with the reference value, and thus monitor and ensure the stability of the equipment's operation over time.

Recently, the IAEA developed for the countries of the Latin American and Caribbean region a QC protocol that describes a battery of tests for radiodiagnosis, called TECDOC 1958[15].

Figure 1 summarizes the conceptual relationships, levels of globalism and hierarchy between the QMS, the QA and the QC within the framework of the search and continuous improvement of the quality control within an imaging service.

Figure 1. Main concepts involved in the framework of continuous quality improvement in an imaging service.

Discussion

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), in its latest report on the levels and effects of exposure to ionizing radiation, confirmed that medical imaging exposures, and in particular CT radiation, continue to be the largest contributor to exposure to ionizing radiation from artificial sources in the population. For this reason, rational use of radiation must be made in order to reduce the probability of the appearance of stochastic and non-stochastic effects associated with it[16].

Imaging procedures, also called diagnostic imaging, are multi-step processes through which information regarding anatomy and physiology is collected and displayed using modern technology. Unfortunately, numerous sources of variability, both human and equipment factors, can produce images of low diagnostic information or poor quality. If not adequately controlled, this can result in repeated exposures that increase both patient dose and diagnostic service costs, and possibly decrease the accuracy of the diagnostic interpretation of images. This in turn can result in decreased satisfaction of customers and stakeholders such as physicians, providers, insurance companies, employees and patients, ultimately meaning for the healthcare provider, the loss of business and income[10].

In 1986, Hendra[17] already pointed out the need for a QMS that applied to the entire radiological process in order to achieve "right first time" results, and in 1996, Kirk et al.[18] demonstrated that such a system can be successfully implemented in a large imaging department.

It is important to note that a QMS must be designed specifically for each imaging service, and is not limited to a collection of procedures, tasks and documents. In this sense, the general principles requirements of a QMS described above are not intended to be a sequence, but rather a relationship between requirements that can be represented as a cycle. Its starting point is the purpose of the organization and the structure with which it is designed to fulfill them (areas, positions and processes for the governance, management and operation). This is followed by planning the actions to implement and assign responsibilities to achieve concrete and defined results in quantifiable terms. The cycle continues with the implementation of the plan of action and concludes with the analysis of the results and the identification of areas of opportunity for continuous improvement. To facilitate effective communication of the QMS processes, their description is typically compiled in a quality manual, which in addition to describing the procedures and associated records also shows how the different processes interact and incorporates a clear description of the actors and their responsibilities[3]. Therefore, the QMS is the broadest concept and contains the QA actions, the definition of the QAP to be applied and the QC of the imaging equipment (Fig. 1).

The introduction of a QAP involves expenses to perform the QCs, either to acquire the appropriate instrumentation and maintain the radiation meters properly

calibrated, or to hire a qualified third party to perform the tests with the required regularity. It will also be necessary to consider the time invested in performing the QCs, during which the clinical use of the equipment is interrupted, as well as the time of specialized personnel required to perform the QCs and evaluate the results. The benefits should be appreciated on two levels: the first and most relevant is the improvement of the quality and safety, because QC tests allow optimizing the doses given to patients and reducing the occupational radiological risk of healthcare personnel; and in the background, the QC contributes to improving the active time of the equipment with a lower number of unforeseen stops, longer useful life and increased capacity to care for a greater number of patients and with less consumption of expendable material. This represents better management of the imaging service.

Finally, three considerations are worth mentioning:

- First, it is important to indicate that this QA is key to working under the safety culture standard for practices with ionizing radiation promoted by the IAEA[13].
- Second, the implementation and execution of a QMS for an imaging service is not conceivable without the active participation of radiologist doctors, medical technologists and medical physicists, where each one represents a key link for the virtuous functioning of the processes involved.
- Third, the Brazilian legal framework published in 2022 on the "health requirements for the organization and operation of diagnostic or interventional radiology services and the regulation of exposure control for doctors, occupational workers, and the public, resulting from the use of diagnostic or interventional radiological technologies," could be reviewed and used as basic input to update Chilean regulations, given that due to geographical proximity, economic and cultural realities, it is more comparable to what we have and can achieve[19].

Conclusion

QA, more than a fashionable concept in an imaging service, has ethical and economic implications derived from the use of ionizing radiation, the high impact of diagnostic imaging on health care and the importance of adequate and profitable management, given the complexity of the equipment and the high level of specialization of the healthcare professionals in imaging. For this reason, quality must be managed through a QMS, which represents the support framework for the functioning of the institution and is understood as a set of interrelated and interactive processes that allow for achieving the organization's objectives and continuous improvement of its quality and safety plan for patient care. It is key that a QMS be designed specifically for each imaging service, so that it is consistent with its policies and organizational structure. For the correct functioning of a QMS in imaging, the QAP must incorporate the QC of the equipment by qualified personnel. For the success of a QMS, the active and coordinated participation of radiologists, medical technologists and medical physicists is essential.

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Conflicts of interest

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Ethical considerations

Protection of people and animals. The authors declare that no experiments have been carried out on humans or animals for this research.

Confidentiality, informed consent, and ethical approval. The study does not involve patient personal data nor requires ethical approval. The SAGER guidelines do not apply.

Declaration on the use of artificial intelligence. The authors declare that they have not used any type of generative artificial intelligence in the writing of this manuscript.

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