

Quality & safety aspects of nuclear medicine practice: Definitions and review of the current literature

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Abstract

Current literature records a glaring discrepancy between the rapid developments and progress of medicine and the simultaneous deterioration of the quality and safety of the provided health care services. Bibliographic data as far as perceptions of quality and safety in nuclear medicine departments are concerned, are limited and frequently ambiguous. Most nuclear medicine departments provide the same types of services, but not the same quality of service, while patients' perceptions are not always matched by the perceptions of health care providers. The multidimensional nature of quality and safety, deriving from the different criteria and standards by which different groups of the population attempt to interpret and evaluate them, justifies these discrepancies, over most of quality's and safety's dimensions studied. Nuclear medicine's unique characteristic of using radiopharmaceuticals, exposing to ionizing radiation affects dramatically these perceptions, irrespective of whether quality and safety assurance measures already cover radiation protection, instrumentation maintenance, radiopharmaceutical handling, and the management of all the other aspects of patient care. On the other end of the spectrum, patient-centred practice, communication and proper information play as a well decisive role in ensuring patients' satisfaction.

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Introduction

In 2000 and 2001, the American Institute of Medicine (IOM) issued two reports: "To Err Is Human" and "Crossing the Quality Chasm", recording a glaring discrepancy between the rapid developments and progress of medical science and the simultaneous deterioration of the provided health care services. According to the first report, 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors, including design failure, human resources miss and errors in health care delivery [1]. Similarly, the second report showed the great "chasm" between the quality of health services, that modern care systems are supposed to provide -given the spectacular progress of medical science and technology today- compared to the relatively recent past and the quality of care that eventually most Americans receive [2]. Acknowledging that health care today fails too frequently to deliver its potential benefits, the question is raised why nuclear medicine services have to be the exception? Ambiguous and not always in agreement with the IOM as far as quality and safety of the provided health care services are concerned, are the conclusions of the literature in terms of perceptions of patients turning to nuclear medicine departments.

Definitions

Quality of healthcare services

The evaluation of the quality and safety of health services requires clear operationalized and conceptual definitions as the foundation to enable the approach and analysis of these terms. The quality and safety in the health care sector are two of the most controversial terms found in the literature, with many definitions seeking to interpret them. Their multidimensional nature lies in the different criteria by which different groups of the population attempt to interpret and evaluate them: from the researcher via the healthcare professional to the patient, society, organizations and all others involved in providing healthcare services [3]. According to Donabedian, the best-known definition of quality is the one given by Lee RI and Jones LW as the "eight articles of faith". Some of the articles included features or properties of the care delivery process and other objectives and targets of this process. The "eight articles of faith" strongly suggest that the criteria of

quality are value judgments on the various aspects, properties, components and dimensions of a process called medical care. Therefore, the definition of quality can be almost anything one wishes it to be and is mostly a reflection of the values and objectives of the health care system and society of which it is a part [4].

Harteloh in 2003 offers a review of definitions, concluding that: "Quality expresses the optimal balance between possibilities realized and a framework of norms and values". This definition reflects the fact that quality has an abstract character and does not exist as a distinct entity. It is a "construct" based on the interaction between various people, who agreed on certain standards (rules and values) and characteristics (capabilities) of each service [5]. Working groups, such as the IOM, attempted to determine the quality of health care according to certain standards, defining it as the "Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" [6]. The restrictions arising under the definition of Lohr KN include the following: Originally, degrees are attributed to the quality, negating its dipole character. The quality of the supplied product or service either does exist or it does not. There is no gradation in the degree of perfection. This definition also seems to equate quality only with positive effects of patient care. However, the presence or absence of quality in health care is not only defined by the result, but also by the procedures needed to achieve it. Moreover, while correctly "current professional knowledge" is emphasized, this definition does not seem to take into account the different conditions and the available options which depend on where healthcare services are provided. Finally, Lohr's' definition does not provide satisfactory explanations for researchers who wish to study quality based on a set of measures for its evaluation.

Acknowledging these limitations, the IOM in the "Crossing the Quality Chasm" report proposes six specific aims "to continually reduce the burden of illness, injury and disability and to improve the health and functioning of the people":

- Safety: the degree to which health services are provided free of risks.
- Effectiveness: the degree to which appropriate care is provided, based on scientific knowledge to all who could benefit from it and is not provided to people either who do not need or who will not suffer by their absence (avoiding underuse and abuse).
- Patient-centred services: Providing health care that respects and responds to the patients' individual preferences, needs and values and ensures that the patients' principles guide all clinical decisions.
- Time relevance: the degree to which the patient receives health services when and as often as needed to avoid harmful delays for both those who receive them as well as for health professionals who provide them.
- Efficiency: the degree to which appropriate for each case, health services are provided with the lowest cost, without misuse of funds, equipment, supplies, energy and human resources and clearly without depriving them.
- Equitability: the degree to which provided care services do not vary in quality because of personal characteristics,

such as gender, ethnicity, geographical location and socioeconomic status of the patient [7].

Given the above, it is imperative to develop indicators to measure and evaluate the quality of care, based on certain quality standards. Quality indicators are not the measure of healthcare quality in itself but the methodological cornerstone for its evaluation as well as the identification of ways of improvement. There are no objective or subjective indicators, but instead validated and reliable ones, features assigned to them based on the size of the sample examined and the relevance to the intended target. Quality standards are de facto valuable tools for assessing the quality of care, as an integral part of efforts to ensure quality. They are considered valid when described by the criteria for the assessment of care, in terms of quality efficiency and when they meet the following characteristics: when they are measurable, specific, relevant and understandable, made commonly, when they can be achieved and reviewed periodically and finally able to reflect all aspects of care [8].

Historically, indicators with negative content have prevailed over any other feature. Mostly referred to in the literature as the 5Ds, death, disease, disability, discomfort, dissatisfaction initially used to be the main quality indicators. These indicators measure serious, unwanted and often avoidable procedures or results and events inpatient care which of course, at some point are considered to be acceptable [9]. The work of the American Academy of Nursing Expert Panel on Quality Health focused on the dissemination of the following positive indicators: self-care, health-promoting behaviours, quality of life due to healthcare, satisfaction, symptoms management, which are more suitable for nuclear medicine practice [10]. In the National Quality Forum in 2004, possible indicators are more fully described and classified into three categories:

- Clinical indicators: Patient-centered outcome measures, related to patient care,
- Business indicators: Nursing-centered intervention measures, related to professional practice and
- Administrative indicators: System-centered measures, related to the organization of health services provided [11].

Safe healthcare practice

A large body of the current literature places safety under the conceptual "umbrella" of quality in healthcare. The definition given to safety is abstract as well. Various approaches try to encompass all the components that characterize it. The cornerstone of health care services: "First do no harm" derives from the "fragile" nature of life and humans' health and reflects the fact that safety is an integral part of quality in health care services. Ensuring safety in provided healthcare services has become a major issue of public interest. A large number of individuals and organizations work on developing methods and systems for the classification and recording of possibly avoidable adverse events. These efforts are vital precursors to organize and prioritize areas for action and study the effects that may cause measures to avert medical errors [12].

As part of this activity, the Evidence-based Practice Center (EPC) at the University of California San Francisco and Stanford University (UCSF-Stanford), with collaboration from the

University of California Davis, was commissioned by the Agency for Healthcare Research and Quality (AHRQ) to review and improve the evidence base related to potential patient safety indicators (PSI) that can be developed from routinely collected administrative data. The term "safety practices" encompasses those which reduce the risk of side effects, associated with exposure to healthcare [10]. According to the EPC "patient safety" is characterized as the type of process or structure, which reduces the likelihood of adverse events, that may occur when the patient receives health care services. This definition is consistent with the dominant conceptual framework for patient safety, according to which education and radical changes to an installed system are proven to be more fruitful in reducing medical errors than a reprimand or punishment of some healthcare providers. However, this definition is characterized by basic restrictions. Initially, it does not define the essential differences between measures to ensure safety and the targeted practices applied to improve the quality of the provided health services. Another limitation which arises is the inability to review and record all the safety practices which are essential for each separate health section, such as nuclear medicine departments [13].

Patients' safety failure may result by clinical, organizational or technical errors, inadequate communication (between medical and/or nonmedical staff and patient, or between practitioners, etc.) and improper patient management (wrong referral or misuse of resources etc.), indirect failures involving organizational culture, protocols/processes, transfer of knowledge, and external factors [10]. The identification, review and recording of errors occurring during the healthcare delivery require the development of standardized "tools" that can capture and potentially prevent events which threaten patients' safety. Although there are obvious difficulties, this attempt will trigger the in depth-understanding of the extent of the current safety problems and hopefully lead to the development of interventions designed to ensure quality and safety in health care for both patients and providers. Under these circumstances, the AHRQ developed and established the PSI [12]. As PSI is defined the ratio of the adverse events (complications, medical errors etc.) to all patients that have undergone a certain procedure (examination, intervention etc.), in a department or healthcare organization. Patient safety indicators detect surgical complications and other iatrogenic adverse events, controlling for possible problems faced by patients, that result from exposure to the healthcare system and which can be prevented by the introduction of measures and changes to the system. Although the development of the PSI is important progress in the evolution of the methodology for monitoring and ensuring patient safety, the fact that they refer to complications or side effects associated with hospitalization mostly in surgical, obstetric and pathological clinics, substantially limits the possibility of using them in other special sections such as Nuclear Medicine departments. Moreover, this study identified and evaluated indicators that could be constructed using administrative data and not more detailed clinical data. Finally, their application by several task groups proves

that PSI depend so much on hospital records that they become particularly susceptible to changes and limitations in these databases. Therefore, the sensitivity of PSI is limited to certain adverse events and compromised by the data and the manner of recording by each hospital, creating plenty of room for improvements [14].

The United States Nuclear Regulatory Commission (USNRC) defines a medical event in nuclear medicine as a radiopharmaceutical dose administration involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or administered dose differing from the prescribed dose when the effective dose equivalent to the patient exceeds 0.05Sv (5rem) to the whole body or 0.5Sv (50 rem) to any individual organ. The definition and procedures for handling misadministrations of radiopharmaceuticals are set out in the Code of Federal Regulations (10 CFR-35) [15]. Medical events are extremely unlikely to occur as a result of any diagnostic nuclear medicine procedure. Most have been related will be related to the radioiodine isotope I-131. However, when a medical event is recognized, regulations for reporting the event and management of the patient must be followed. The details are determined in part by the kind of material involved and amount of the adverse exposure of the patient. All medical events must be reported to the radiation safety officer, regulatory agency, referring physician, and affected patient. Complete records on each event must be retained and available for NRC review for 10 years [16].

Adverse reactions to radiopharmaceuticals are extremely rare because the pharmaceutical is formulated in a subpharmacological dose that should not cause a physiological effect. When they occur, they are usually mild and rarely fatal. In order to reduce them, quality control in the nuclear pharmacy is mandatory, including control of radionuclide, chemical and radiochemical purity. Other quality control procedures are aiming at ensuring the sterility and apyrogenicity of administered radiopharmaceuticals. However, in a busy nuclear medicine practice, radiation accidents (accidental spills of radioactive material) invariably occur. The spills are divided into minor and major categories, depending on the radionuclide and the amount spilled. In dealing with both minor and major spills, an attempt is made to keep radiation exposure of patients, hospital staff, and the environment to a minimum. Each laboratory is responsible for developing its own set of written procedures. The radiation safety officer must restrict access to the area until it is safe for patients and personnel.

The limitations and problems arising from the implementation of safety practices are also described by other authors. Shojania et al. (2001) with their report "Making health safer" set the foundations of safety in medical care, gaining ardent supporters, while at the same time raise debates [13]. Institutions and healthcare organizations are encouraged to adopt safety practices, which "promise" to prevent and reduce adverse effects that result from exposure to medical care. Safety is the major priority on health with huge amounts of funds and working hours to be invested in it. However, the results of these efforts do not appear to be as expected [17].

Some of the most popular safety practices proved to be insufficient, posing fundamental questions about the role of evidence-based medicine in the quality and safety of the provided health services [18].

Years after "To err is human" Leape and Berwick wonder "what we have learned?". They conclude that although progress since then has been slow, the IOM stimulated a broad array of stakeholders to engage in patient safety, and motivated hospitals to adopt new safe practices, finding that the pace of change has to accelerate further [19]. Despite more than a decade of efforts, the clinical quality and safety of outpatient care delivered to American adults have not consistently improved. Deficits in care continue to pose serious hazards to the health of the American public [20]. In contrast, others seem to be effective when applied in a controlled, limited - research environment but proved inadequate in clinical practice. As shown, the field of safety in health needs further improvement, which must be strengthened and guided by systematic research [21].

Conceptions of nuclear medicine care services

Literature's conclusions as far as perceptions of quality and safety in nuclear medicine departments are concerned, are limited and frequently not what one would expect. Several nuclear medicine departments provide the same types of services, but not the same quality of service, while patients' perceptions are not always matched by the perceptions of personnel [22]. Moreover, as correctly emphasized by Freudenberg et al., nuclear medicine has a unique characteristic: the use of radiopharmaceuticals and exposure to ionizing radiation, with which most patients are not familiar. This dramatically affects their perception of quality and especially safety. Therefore, subjective perception of radiation – usually independent of any scientific risk assessment – is a decisive factor in the choice for or against submission to any diagnostic or therapeutic nuclear medicine procedure. This does not even regard the perception of the quality and safety of the received care services [23]. The nature of nuclear medicine practice requires quality assurance procedures, which are necessary to comply with regulations mostly concerning radiation risk and instrumentation performance. Furthermore, following the advent of regulations on radiopharmaceuticals, quality assurance programs are now being developed that specifically address issues related to the production and use of radiopharmaceuticals for diagnostic and therapeutic purposes. Thus, quality assurance measures within a nuclear medicine environment already cover radiation protection, instrumentation maintenance and radiopharmaceutical preparation, handling and delivery, in addition to the management of all the other aspects of patient care, which may affect patients' satisfaction [24].

Consequently, while several reports have been issued, including guidelines on how qualitative and safe management of patients in nuclear medicine departments should be done, limited data are available worldwide in terms of the level of service provided [25]. In accordance with Lucignani's results [24], our literature review highlighted a significant number of papers dealing with quality assurance in

nuclear medicine. For instance, instrumentation quality control (QC) is of vital importance both in the context of acceptance testing, which should be performed after installation and before the instrument is put into clinical use [26], and in routine QC testing, which should start after installation of the instrument, as well as after acceptance testing, and must continue regularly throughout an instrument's lifetime [27]. The good radiopharmacy practice is described in the "Guidelines on Good Radiopharmacy Practice (GRPP)" [28] as well as in the "Guidance on current good radiopharmacy practice (cGRPP) for the small-scale preparation of radiopharmaceuticals" [29] issued by the Radiopharmacy Committee of the EANM. This document provides detailed and practice-oriented guidance for needed personnel and resources, quality assurance, documentation systems, preparation and process controls, acceptance criteria, dispensing of patient doses, radiopharmaceutical distribution, record keeping, periodical self-inspection and complaint handling, to ensure safe and qualitative use of radiopharmaceuticals at all stages from their production to their distribution and disposal. Finally, several reports have been issued as far as radiation protection is concerned. "Applying Radiation Safety Standards in Nuclear Medicine" published by the International Atomic Energy Agency (IAEA), establishes requirements on the legal persons responsible for designing, running and decommissioning practices involving ionizing radiation [30].

Medical and non-medical personnel of nuclear medicine departments are responsible for ensuring both the appropriateness of the diagnostic and therapeutic procedures and the associated patient doses as well as their satisfaction by the received services. However, as has been mentioned previously, the bibliographic data in terms of patient satisfaction derived from nuclear medicine practice are limited and scattered. In their descriptive study, based on a questionnaire which was designed to assess patient satisfaction, Reyes-Pérez et al. (2012) demonstrated a high degree of patient satisfaction from the organization of the nuclear medicine department, the attitude of the staff and the cleanliness of the premises, with further improvement needed as far as a waiting list and the planning process of diagnostic and therapeutic interventions were concerned. There were no statistically significant differences in patient satisfaction in regards to their social-demographic characteristics, except for age. Specifically, it was observed that patients over the age of 70 years were more satisfied and recommended the department more than those under 47 years [31]. In agreement with the foregoing, another paper coming from Spain confirms that overall satisfaction was high in most of the patients. Waiting time was the dimension with the lowest level of satisfaction and subsidiary to improvement plans, while the primary spontaneous complaint by their patients was due to the waiting list [32].

Acknowledging the great impact of waiting on the perception of service quality, De Man et al. (2005) conducted the first study examining the link between waiting and various dimensions of perceived service quality in nuclear medicine. They state that expected waiting time is not only a personal

expectation about the duration of the waiting period but also incorporates the effect of service design as well as individual characteristics. They demonstrated that patients underestimated the waiting time before radiopharmaceutical administration and the total waiting time, while they overestimated the waiting time before scanning. Their results showed that the total subjective waiting time has more impact on the perceived reliability dimension than any other service quality dimension, concluding that explaining the causes for delay will increase patients' perceptions of the reliability of a nuclear medicine department [33]. Similarly, Lledó et al. (1995) in their case-control study, showed that when information is supplied to patients, their anxiety decreases before a diagnostic procedure, and significantly improves their perception of the factors that generate satisfaction among them [34].

Satisfaction with information and communication has been also examined by Langen et al. (2006). Clarifying that the term "patient satisfaction" involves dimensions such as satisfaction with the nursing and daily care, as well as with the information and medical care and satisfaction with the hospital environment, they found that the patients were generally satisfied to a rather high degree with the information they received during the hospital stay. The greatest satisfaction was with understandable information, while they were least satisfied with the explanation of further treatment plans. Langen's working group took a step forward by highlighting the psychological distress, like anxiety and depression that follows hospital admission, which plays a decisive role in patients' perception of quality and safety of the provided healthcare services. However, it is worth mentioning that their study was conducted in the observational, surgical and medical gastroenterological department at Ullevål University Hospital, Norway, which is a different setting than nuclear medicine departments [35]. It is therefore unsure how far exactly these results can be extrapolated to nuclear medicine.

Exposure to ionizing radiation has been always an issue of great importance for nuclear medicine patients. It dramatically affects their perception of safety and quality of the provided services and differentiates nuclear medicine from any other hospital department, perhaps except for radiology departments. The instinctive fear-related reactions to ionizing radiation mostly expressed as fear, anxiety, panic, and phobia, often create obstacles to effective patient treatment in nuclear medicine interventions [36]. In their survey about perceived radiation risks, Mihai et al. (2007) demonstrated that although the anxiety towards radiation varied with the education status, with lowest values among medical university graduates and highest among public school graduates, including both primary and tertiary graduates as well as non-medical university graduates, it remained significantly higher among the general population compared to radiation workers and medical doctors without professional exposure, who was examined as well [37]. Moreover, professional knowledge towards nuclear medicine issues, as expressed by medical doctors' (MDs) familiarization with ionizing radiation, vary when they reach the point of clinical work. Psarouli et al. (2002) found that although doctors of different specialties argue that they are sufficiently educated in nuclear medicine issues only 5.8% of them

answered all basic radiation physics questions correctly, while they seem to be unfamiliar with radiation protection issues. They concluded that is imperative for the physicians to be informed and properly educated on basic concepts of nuclear medicine, not only regarding its usefulness as a diagnostic tool but its physical concepts as well, to ensure professionals' and patients' satisfaction [38].

As with the perceptions of radiation hazards that differ between patients, nuclear medicine personnel and health care professionals of other specialties without radiation exposure, great chasms have been demonstrated between the perceptions of quality and safety of the provided nuclear medicine services as well. As originally mentioned, the multidimensional nature of quality and safety in healthcare services derives from the different criteria and standards by which different groups of the population attempt to interpret and evaluate them: from the researcher to the healthcare professional, to patient, society, organizations and all those involved in providing healthcare services. Following their fundamental characteristic, it is not surprising that perceptions of quality and safety differ among these groups. In order to assess patients' and professionals' perceptions, Lee and Yom examined the difference between the expectation and performance in all of the dimensions of service quality in 2007. The mean scores of nurses' expectations were higher than the mean scores of their performance. The largest difference between expectations and performance was in the tangibility dimension, while the smallest difference was in the dimension of empathy. In contrast with the service quality, the mean scores of patients for overall satisfaction with nursing and medical care were significantly higher than those of nurses. This indicates that patients as consumers are more satisfied than nurses are as providers [39]. Similarly, a year earlier Langen showed that despite the enhanced level of anxiety, their patients were generally satisfied to a rather high degree with the information, communication and support. The staff overestimated the patients' degree of psychological distress and environmental strains following admittance to their hospital and underestimated the degree of satisfaction [35].

Analogous conclusions arise when reviewing the limited available studies conducted in nuclear medicine departments. Discrepancies on quality perceived by the patients versus professionals on the quality of a nuclear medicine department were documented by Rodrigo-Rincon I two years ago. This cross-sectional study was carried out using two questionnaires: a validated patient experience questionnaire and a quality perception questionnaire for professionals. An agreement was low between the quality perception of patients and professionals. The patients scored the quality of service higher than the nuclear medicine professionals did. According to the author the fact of getting the opinion of the two main actors (professionals and patients) can help health organizations to detect areas for improvement, and better the quality of the service provided to patients [40]. Fifteen years earlier De Man et al. (2002) compared the service quality perceptions of patients and those of personnel after distinguishing the service quality dimensions of nuclear medicine (tangibles assurance, responsiveness, empathy,

convenience). They found that personnel perceived all service quality dimensions as poorer than patients did, except for empathy. Personnel have the perception that they are providing a lot of individual and personal attention and that they understand the needs of patients, which may explain why patients perceive this dimension to be not as good as staff perceived it to be. It was clarified that personnel underestimated patient satisfaction with their department and that nuclear medicine services will have to optimize their physical and process component and the technical skills of personnel if they want to increase patient satisfaction and patients' perception of service quality [22]. These observations answer the question set by Lucignani and Del Sole: what kind of quality would we want if we were the patient? Placing the individual patient at the centre of multiple activities in the nuclear medicine department is the answer and the key to satisfied patients [24].

Perceptions in terms of safety and quality in the provided services between patients and nuclear medicine personnel are not the only contradicting ones. In 2008 García Vicente examined the perception and satisfaction level of referring physicians requesting scans as final users of the nuclear medicine department. The indicators evaluated were: physician's information about available tests, test indications and diagnostic information, accessibility, delay in the examination and reception of the diagnostic report, usefulness of diagnostic information and overall satisfaction with the department. Surprisingly, it was found that less than half of the physicians considered that they had sufficient information about the tests, revealing a disturbingly low level of knowledge in terms of nuclear medicine practice. However, the overall satisfaction was high, except for the delay between test performance and report reception that could be improved [41]. We found these conclusions quite disturbing taking into account the vast majority of patients who have to be managed both by nuclear medicine physicians and physicians of other specialties, especially when effective collaboration includes not only diagnostic but also therapeutic procedures.

In conclusion, current literature has yielded limited yet conflicting results regarding quality and safety in nuclear medicine practice. The controversies over the definition of quality and safety in healthcare services as well as its multi-dimensional nature derive from the different criteria and standards by which different groups of the population attempt to interpret and evaluate them. Per their fundamental characteristic, it is not surprising that perceptions over most of quality's and safety's dimensions differ among these groups. Most nuclear medicine departments provide the same type of services but not equally qualitative. Nuclear medicine physicians struggle constantly to balance between the guarantee of patients' prognosis and their psychological and social wellbeing. Quality assurance procedures, compliance with regulations mostly concerning radiation risk and instrumentation performance and clinical practice based on evidence-based medicine and guidelines do not seem to be enough. Patient-centred practice, communication and proper information play a decisive role in

ensuring satisfied patients. An informed patient who is aware of all complications of a given procedure or treatment is more likely to be tolerant of it. Therefore, proper communication between patients and healthcare providers not only at points in therapeutic decision making but throughout the entire disease trajectory. Proper education is the only mean for the physicians and other non-medical staff to achieve this.

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