

## Clinical Governance: Application in Nuclear Medicine

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### Editorial

It seems useful to us to submit a brief statement on the **basic elements** of Clinical Government (1) and think of its operational application within Nuclear Medicine.

One of them is represented by Technology Assessment (TA). As for TA, we can say that now its standards are entered permanently in the current health care management. In fact, it has been acquired that there is a need to address, before every action in the field of health care, some points that make this process intelligible and usable.

A health technology is the practical application of one knowledge in order to prevent, diagnose and treat a disease (2). Therefore this term is not only related to devices and equipment, but also embraces clinical procedures, prevention programs, pharmacological treatments and the organization-management. Inter alia, the term assessment in the field of medical technologies is used to define a process of multidisciplinary analysis inherent a given technology; its features include efficacy, safety, directions of use, costs, cost-effective relationship, and therefore involve not only the exclusively clinical, but also sociological, economic and ethical field.

In particular, TA covers the following aspects:

- performance
- clinical safety
- effectiveness
- inexpensiveness
- social, legal, ethical, and political impacts

The purpose of TA is to assist and advise those who have decision-making power in the health care sector in defining health policy choices. The choice can be implemented at all levels:

- in evidence-based medical practice that involves the physician and/or the health care worker
- in the management that involves the hospital: buy or not a particular technology to the hospital or to send patients to other centers for treatment
- in health policy that involves health authorities: whether or not to carry out certain health programs(e.g. screening)

A complete TA process involves the realization of numerous steps:

- Identification and choice of priorities for the technology object of study
- Technology consideration in terms of need, efficiency, effectiveness, appropriateness, equity, safety
- Collection of evidence
- Context analysis
- Interpretation of evidence and data
- Results and recommendations
- Diffusion and dissemination of obtained results
- Implementing the results in practice
- Impact obtained from the valuation monitoring

TA therefore has to be understood as a systemic and interdisciplinary process essential to the correct instruction of decision-making dynamics and guarantor of optimization solutions pursued, as well as the transparency of these changes towards all actors involved.

TA is a powerful means of connection between the "scientific-technical" and the "decision-making" sector (3), place that the latter shall ensure the conditions for its implementation and, above all, that gets used to request its

performing. At moment we can only hope that this system, in the hands of all "actors" called to use it, each one in its own competence, becomes a powerful support for health management (4).

Another of the many branches that constitute the ideal Clinical Governance tree is represented by clinical Risk Management (5).

Is then configured the Clinical Risk Strategy, namely just that: to adopt a series of procedures and structures that will tackle the root of risk in hospitals, starting with a radical change of mentality in the physician; he must be willing to accept the mistake as an integral part of his profession and, above all, to be able to learn from it.

Attend a process of risk management involves the identification of errors in patient care and its motivation (6). The goal is to learn from these events to ensure all actions necessary to prevent the same from occurring in the future will be taken. It should in any case be taken into account that in the hospital practice, the error is as much a management problem as of the structures, of men as of resources. What then is meant for medical error? As medical error is understood the final chain of a number of factors related to the sanitary macro process of diagnosis and treatment. Those produce adverse events that damage the patient's health, so that in practice prevent or delay its actual return to a state of well-being.

The responsibility of the error depends on causes related to human factor and to the technical quality of the performance, but it can also be attributed to the organization of business systems and diagnostic, treatment and care pathways (7). So the subject who actually makes the mistake is not said to be the most person in charge. Any intervention involves a certain degree of risk. Obviously zero risk (as in most of human activities) does not exist. In certain circumstances danger of error grows exponentially: emergency room, surgery, intensive care, and gynecology were detected contexts at peculiar risk of error. To dimension the error area, is commonly used analyze near misses, that is, errors that are narrowed or avoided in extreme. These are situations where the potential risk is high and because they have not resulted in a fatal outcome, can be precious. Not only are more easily documented than real error, but allow highlighting the causes and risk factors that can lead to an error and then eliminate them.

In 1993 GL Henry (8) identified the following situations as those most frequently followed by errors:

- The shift change and task interchange, both for doctors and nurses
- Patients who return for an unscheduled visit
- Patients transferred from another structure that are more serious than expected
- Patients who, for various reasons, leave the hospital against medical advice
- Patients leaving the emergency room without being visited
- Performances performed by young doctors or in training without the supervision of a manager
- Telephone tips without visiting the patient

According to the Vanderbilt Hospital's risk management manual, most complaints by patients or family members do not depend much on the will to obtain material compensation but rather from a number of factors, in three words: lack of communication (9). So here is identified another key component of the dynamics that regulate the relationship between those who have hospital facilities (sick people, their relatives and friends or tutors) and those who provide health care (doctors, technicians, nurses, hospital auxiliaries, and even administrative).

Health care organizations must, for the purpose, have the following:

- An effective clinical risk management process that encourages reporting of critical accidents and is understood by all the health personnel
- An effective management of claims

In addition, it is necessary to ensure that all clinical staff, including specialists, is subject to regular evaluation, with the aim of ensuring the maintenance of skills and competences, also through participation in professional updating meetings.

However, it cannot be kept that all of these factors create resistance to error communication and monitoring by both those who do it, and by those who are assisting. It is especially for this reason, for facilitating a communication of the error or near missing, that the medical error necessarily needs some sort of depenalization.

The use of radioisotopic sources in unsealed form, such as that occurring in the daily practice

of Nuclear Medicine, is the one that entails the greatest possibility of error or accident.

Below are listed the most likely error situations inherent in the various phases of the Nuclear Medicine health care processes (10):

### *Examination prescription*

1. patient identification
2. assessment of the opportunity (justification)
3. appropriateness estimation
4. possible contraindications
5. preparing the patient

### *Preparation of the performance*

1. drawing up and printing of the daily program
2. patient and type of service identification
3. history and prediction of adverse reactions
4. labels compilation
5. preparation of the radiopharmaceutical
6. identification of the radiopharmaceutical in relation to the patient and the type of service

### *Performance execution*

1. patient identification
2. time and type of service identification
3. patient positioning and technical performance of the service, patient identification
4. data elaboration
5. iconographic reproduction
6. labels identification

### *Reporting and delivery*

1. patient identification
2. images and quantitative data analysis
3. writing, recording, transcription and printing of reports
4. reports authentication and signing
5. reports and iconographic reports enveloping
6. reports delivery

In the use of radioactive sources, in particular if easily movable, in addition to the *safety* procedures, *security* procedures should also be introduced. The particular historical moment that the international community is going through, characterized by the attention to the

prevention aspects of possible terrorist threats, requires particular attention to all aspects related to the management of security. Among the many and possible forms of aggression, attention is drawn to the eventuality in which the sources of ionizing radiation normally used for medical purposes are used improperly. Hence it is to be developed a security strategy for the prevention of abnormal events to the threat purposes in health structures that use ionizing radiation. The application of the "risk management" to the sanitary installations employing ionizing radiation requires the definition of instruments to analyze the different scenarios to determine which of them are most sensitive to the threat and, being aware of the criticalities of each scenario, identify the "levers" on which to act to mitigate the risk (11). Obviously, as stated above, Nuclear Medicine has represented one of the fields of greatest application of the search for strategies favoring Nuclear Safety. It is true that considering the characteristics of the radionuclides used in Nuclear Medicine it is clear that, in fact, a possible misuse of these substances does not take place at a real risk for the population, in deterministic terms. In fact the energy emitted by both the photonic and electronic components, the half-life and the quantities normally held or produced of the radioactive isotopes used are not such as to cause concern in this regard. However, any news of the subtraction, and then maybe the discovery in a public place, of a source of ionizing radiation stolen inside a health facility, could have psychological consequences on the population certainly not irrelevant (12). One of the most relevant components associated with Nuclear Medicine is that represented by the presence of radioactive waste that are, in short, almost all solid and liquid radioactive waste with a short half-life (less than 75 days) and low activity.

Based on the above, three moments can be identified in the management of ionizing radiation sources within healthcare facilities:

1. taking charge of the radioactive material on arrival
2. use of the material according to established diagnostic / therapeutic procedures
3. disposal of outgoing radioactive waste

The identified security measures mainly concern:

1. arrival of the ionizing radiation source

2. procedure for the custody of access keys
3. access control
4. access to "controlled areas"
5. documentation relating to each source
6. locals used for storage and handling
7. separation of areas
8. locals for radioactive waste storing
9. video surveillance systems
10. alarm systems
11. control of personnel recruited in outsourcing

An additional benefit for achieving results in the pursuit of nuclear safety is the training of all the actors involved. At the end of the training process, the participant must be able to:

- a) identify risks from ionizing radiation in the working environment
- b) identify and understand the meaning of signposting and in general of safety measures and procedures
- c) know and implement the management procedures and correct use of ionizing radiation sources
- d) use the radiation measuring instruments correctly and interpret the results as far as they are concerned

Another key area for health services is that represented by the Appropriateness. The Italian law on health (13) puts the appropriateness among its founding principles and to the art.1 says:

*"...are excluded from the level of support provided by the NHS the types of care, services and health services that:*

- *do not meet the principle of efficiency and appropriateness or whose effectiveness can not be proved on the basis of scientific evidence available and are used for patients whose clinical conditions do not match those recommended;*
- *in the presence of other forms of assistance aimed at meeting the same needs, which do not comply with the principle of economic efficiency in the use of resources or do not guarantee an efficient use of resources as regards the organization and provision of assistance "*

Appropriateness is a single term to synthesize a set of behaviors that caregivers should put in

place to improve the quality of health care for citizens, healthy and sick. A word which, therefore, summarizes the systematic search for performance and effective services, the optimization of the relationship between costs and health interventions, the definition of fair and ethically justified priorities in healthcare sector.

The term "appropriateness" referring to a health intervention, has different meanings and can be defined as such:

- when it has a scientifically proven clinical efficacy
- when the resulting benefits to the patient outweighs the risk, justifying the provision
- when it is carried out with the lowest consumption of resources in relation to the modalities and times possible, tending to the best treatment with less expense

The spread of the use of numerous and diverse imaging methods, could be attributed to situations of intellectual laziness, but often, in practice, it comes from a "defensive" attitude of the doctor petitioner, and even of the radiologist. The "thrust" of the patient/client in the need of diagnosis and of solution to his problems is also often responsible. Otherwise the improper use of imaging can arise from the reduced or absent understanding of the role of the diagnostic itself in the various clinical situations, regarding the timing of its use and the modality of choice; in essence do not adhere to the principles of Evidence Based Medicine.

It can be objected that appropriateness could also concern the value of a negative test, to exclude the disease. This consideration derives from a study by Simpson based on a retrospective research carried out investigating the chest CT requests by family doctors (14). In fact, the aforementioned authors argue that a negative but inappropriate test, that is a bad choice of the test, only delay the diagnosis, expose the patient to a riskiness or even provide false positives.

One aspect that should not be underestimated in the use of diagnostic imaging is that reducing the use of inappropriate methods can reduce the exposure of patients, workers and the entire population to ionizing radiation.

The issue of appropriateness strongly introduces a pivotal element in the field of health services, namely that of Quality. The Italian health care legislation (13) sets often a close link between



the overall quality of care and appropriateness of services rendered.

Often when we talk about quality in health care we refer to different approaches (15). So we must first try to identify the set of management activities that determine the quality policy of the entire health company: *planning - control - objectives - responsibilities*. Equally essential is the identification of stakeholders, the actors of the system, that are more frequently represented by staff and patients, but also suppliers, associations, communities in general. Isolating specific assistance processes and taking into account only the needs of a single interested part can be an excessive exemplification. Improving clinical quality at elevated levels involves a great synergy between the clinical and management domains. In other words, the health company as a whole is a unique process which in turn is made up of corporate macro-processes related to both clinical and organizational activities (17). In short, a network of processes in turn divided into individual operating procedures, and the whole must be harmonious and synergistic. In turn, the health company's business must be assessed in the context in which it works, that looks to a higher level of the Quality System, which will be regional, national, international. Therefore, not only the quality of a single service or of a single structure, but also the overall quality of a single Region (at least in all cases in which supra-regional programs operate, in which the improvement of a part takes place by the virtuous or otherwise positive behavior of another party) depends by the operation of the system itself. There couldn't be, then, more consistent conclusion: at least in health care, the consideration of product and process quality can not be considered exhaustive, having to take in account the quality of links regulated directions and rules that govern it, in other words the system quality.

In conclusion Evidence Based Medicine, Continuous Quality Improvement, Social Reporting, Guidelines, Protocols, Procedures, Care Profiles or Therapeutic Diagnostic Paths, Disease Management, Accreditation, Technology Assessment, indicators, updating, peer review and risk management are the essential cornerstones of clinical governance. The clinical governance presupposes the creation of environments that promote the empowerment of the individual professionals and professional communities to which they belong. With respect to the adoption of

professional behavior appropriateness oriented and based on the best scientific evidence available. Its application in the management of healthcare companies turns out to be the most effective way of achieving proper performance in the widest sense of the term.

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