Program of Radiation Protection of Patients (Argentina)

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Abstract: After an initial period of conviction for installing an active discussion on Radiation Protection of Patients inside the medical community, there were organized "working groups" in Radiodiagnosis, Radiotherapy, Nuclear Medicine and on radiation protection of pregnant women. These groups began systematical activities, which received a strong institutional support of the Argentine Society of Radiology, toward the implementation of a "Program of RPP" that is being put nowadays into practice. The rapid advances which are present in Medicine today, both in equipment and work protocol, determine that “norms and regulations never arrive on time” which is why it is paramount that health services have “systems of dynamic quality and continual improvement” that can be adapted quickly to changes.

This program has 6 principal aims and a series of targets to be fulfilled in successive stages:

Basic aims and short term targets:
1) To guarantee the Justification. First goal: Development of the "Prescription Guide" (achieved)
2) To optimize the radioprotection: First goal: Development of a "Manual of Procedures" (In process)
3) To prevent potential exposures. First goal: Design of a "Basic Quality System" in Health (achieved)
4) To achieve a qualification of the professionals by means of a process of certification and recertification (In process)
5) To spread PRP's criteria by means of chats, meetings and the use of the media and graphical means. (Partially fulfilled)
6) To establish criteria for the protection of patient and operators in Interventional Radiology by creating a referral service.

Strategies to cope with different interests within society are described. Main problems, failures and difficulties are also described.
The effective participation of the professional and technicians’ associations in the development of the program for radiation protection of the patient is a key aspect for the success of the whole national programme.

KEYWORDS: Radiation Protection of Patients; Procedures; Quality System; certification.

Introduction:
The aims of any national Program of Radiological Protection of the Patient can be established from the recommendations of the Congress of Malaga.
The implementation of the above mentioned aims in the society where we live requires the design of strategies for overcome the disadvantages and resistances generates by any new change.
The strategies must rely on a staggered planning that begins with the conviction of the medical community of which the benefits overcome at length the economic costs of the efforts to be performed.

Medical irradiations are undoubtedly the most important contribution to human exposure to artificial ionising radiation. Since its initial use Computed tomography has continued to evolve. Statistics show a growing trend in the number of practices as well as the number of installations.
Computed tomography is a powerful diagnostic tool, much more than any other imaging test; an extraordinary anatomical display that can be rendered in perfect 3D models, but medical x-rays also cause cancer. Just one body CT scan increase 1 in 1000 the chance of developing cancer, and the risk in children is even higher.
Anyway, the discussion of radiation risks must be tempered because the recognition of their benefits.
The quality of the practices, their justification and optimization are today a subject, which is relevant to scientific circles and regulating organisms.

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Today many medical associations of radiology are extremely concerned about the increase of unjustified doses, which have determined an increase in cancer in the population.

After the adoption of Directive 97/43/EURATOM and the Malaga Conference, most European countries have implemented action plans for the radiological protection of the patient including the search for consensus in relation to optimize doses and the criteria for justification. One example is Guide PR/118 for applying for diagnostic tests.

**Beginning of RPP activities in Argentina**

On 10 December 2004, activities began within this framework, when the first Seminar on Radiation Protection of Patients (RPP) took place, with the aim of opening an active debate on the subject within the medical community. Doctors in the fields of Radiodiagnosis, Nuclear Medicine and Radiotherapy were present as well as representatives from the Ministry of Health, regulatory organisms and different professional associations. During the Seminar, Guide PR/118 was presented and through a teleconference Dr. Michel Bourguignon, the Assistant Director of the Authority of Nuclear Safety in France presented their experience for the adaptation and adoption of these guides, which had been carried out in France.

After the first seminar, “4 work groups” were set up in Radiodiagnosis, Radiotherapy, Nuclear Medicine and Radioprotection for pregnant women and systematic activities were begun which received firm institutional support from the Argentine Society of Radiology. They ended with the elaboration of a “Program of Radiation Protection of the Patient” which is still implemented.

**Program of Radiation Protection of Patients**

The analysis of the existing situation determined that achieving some of the established aims could be too much for the willpower and/or amount of available economic resources and so it was decided to fix more realistic short term goals which could be achieved quickly, using the funds available to advance modestly but constantly without causing false expectations.

Aims such as the implementation of systems of quality in all health services, achieving top training for professionals and technicians all over the country, determining reference levels and achieving the use of protocol in all diagnostic tests through images, all require great effort and cannot be achieved immediately.

**Adaptation to technological innovation:**

The rapid advances which are present in Medicine today, both in equipment and work protocol, determine that “norms and regulations never arrive on time” which is why it is paramount that health services have “systems of dynamic quality and continual improvement” that can be adapted quickly to changes.

**Basic aims of PRP's program:**

1) **Justification:** That the patient realizes the radiological studies only when the same ones are due justified. To fulfil this aim a Guide of recommendations has developed to request studies, which it must be spread and implemented.

2) **Optimisation of the practice:** That the studies that should be performed are executed in such conditions that the doses got for the patient are the minimal necessary, in order to obtain the image necessary for the diagnosis, using, as far as possible, the appropriate "reference levels". It is recommended an special care for the most sensitive patients as the children and the pregnant woman. To fulfil this aim they must develop protocols to check the equipments and appropriate protocols of study for every case.

3) **Prevention of potential risks:** That take forecasts to avoid the occurrence of accidents and / or serious injuries in the patient, especially for radiotherapy and the intervention radiology where the risks are larger. To fulfil this aim quality systems must develop sustainable that the persons in charge of the practices could apply.

4) **Qualification and Training:** To get that the whole involved personnel has a suitable qualification including the doctor prescriptor and to the whole team of the services of radio diagnosis, radiotherapy, intervention radiology and nuclear medicine. To fulfill this aim courses must be dictated, realize evaluations must be performed, education material and to adapt the system of professionals' recertification.
5) Diffusion of PRP's criteria: That does a suitable diffusion of the criteria and principles that are applied in the radiological protection of the patient, the recommendations of Malaga and PRP's national Program in the whole health community and the related institutions as: the competent authorities, medical associations, managers of services of health, benefit societies, companies of maintenance and of some form the own patients.

6) Intervention Radiology: The problem of interventional radiology is that every day there are more specialists non-radiologists that use different technologies without having a suitable preparation and training in radiological protection. This determines an increase in the damages that are produced in the patient from erythema or radiodermitis up to ulcers that need surgery. The situation is more risky even for the patient and the operator when there are used equipments that are not designed neither prepared for interventional radiology. There was done a systematic work of control of the doses received by the patient and the operators during different practices of interventional radiology in the Service of Radio Diagnosis of the Hospital Italiano of the City of Buenos Aires. The target of the work was to establish guidelines, reference levels and protocols of work for the radiological protection of the patient that they could be applied in other services, especially for those services led by specialists non-radiologists. The results were also used for designing the questionnaires of the program of re-certification. There was done the follow-up of different conditions of work in order to optimize the operative parameters minimizing the risks of radiation, reducing the doses of the patient and simultaneously that of the operators.

Details of the activities carried out and state of the project:

1) Justification
The aim is to improve clinical practice supporting the prescribing doctor’s task by developing a “Guide for Prescription Criteria” to improve the link with the professional responsible for the test. The aim of the justification of the practice is that “the benefit obtained is more important than the damage occurred” and to avoid unnecessary radiation on patients.

Guide PR/118 in Spanish of the European Community was used as a basis as too the equivalent Guide in French prepared by the French Society of Radiology (SFR) with the support of the National Office of Nuclear Safety (DGSNR) and the National Agency of Accreditation in Health (ANAES).

In order to be able to adapt it to the particular practices developed in the country, 11 committees of experts were set up through the Argentine Society of Radiology. Head and Neck: Dr. José Luis Sanromá and Dr. Ezequiel Salas; Spine and Locomotor system: Dr. Guillermo Azulay and Dr. Marcos Hjelt; Circulation: Dra. Patricia Carrascosa and Dr. Pérez Arenasa; Chest: Dr. Juan Carlos Spina and Dr. Eduardo Diez; Digestive: Dr. Salvador Merola and Dr. Alberto Seehaus; Kidneys and Urinary: Dr. Gustavo Saubidet and Dr. Alejandro Beresñak; Gynaecology and Obstetrics: Dr. Diego Elías and Dra. Fernanda Dovasio; Breast: Dr. Roberto Rojas and Dr. Gustavo Mandsler; Orthopaedics: Dr. Osvaldo Velán and Dr. Rubén González Villaveirán; Cancer: Dr. Juan Mazzuco and Dra. Adriana Dieguez; Pediatrics: Dr. Fernando Gentile and Dr. Roberto Pittaluga.

The Guide has already been evaluated and adapted to local practices and is being judged by the associations of the specialities which order the tests such as paediatrics, orthopaedics, intensive care, nephrology, rheumatology etc so as to attain their approval.

Given the importance of having a system to measure the effect of the new Guide on prescriptions for radiological tests, 10 common syndromes which require image tests (pediatrics and adults) were chosen in order to assess the type of tests that are ordered before and after the application of the Guide in public and private hospitals as well as through medical schemes and insurance.

This first aim of “guaranteeing justification” is carried out in four stages:
- The issuing of the Guide was validated and approved by professional associations and then presented in the National Radiology Congress in 2007 (Stage completed)
A second stage of diffusion, information, promotion and training in the use of the Guides for all professionals using it. (Stage completed)

A third stage of evaluation of the obtained results and the presentation of a report to the health authorities justifying its issuing as a legal requirement.

A fourth stage consisting of the Guide being issued by the acting authorities ensuring its full use in all health areas and making sure that doctors not following the recommendations, do so. Its use would be compulsory but not its strict application as the decision is always up to the doctor based on the analysis of each individual case.

The rational use of the techniques of diagnosis through images will contribute to the suppression of unjustified tests, a simple measure which is an efficient use of radioprotection. Prioritizing the principle of justification seems to suggest a change in paradigm in the current approach to the radiation protection of the patient. In this way the prescribing doctor acquires new relevance, who, together with the specialist in diagnosis through images, radiotherapy or nuclear medicine, will be responsible for the application of the principle of justification.

2) Optimising Radioprotection:

The aim of optimising practices is for tests to be carried out through techniques that ensure minimum irradiation for the patient without affecting the quality necessary for the image. Several difficulties related to the large quantity of equipment with out of date and imprecise information were pinpointed. Based on statistical research carried out in 6 provinces 15,000 pieces of equipment (Rx and TC) have been counted plus approximately 350 centres of nuclear medicine making an estimate of 25,000 in the country.

Ensuring that all these health services have personnel qualified in RPP and that all the equipment operates in the right conditions, is a difficult task, which requires appropriate strategies. Although it is compulsory to register the parameters used in each test in the country, in fact this is not always complied with and the health authorities do not always have the resources to control all the services efficiently. This situation makes the carrying out of statistical research on the true practices and techniques in the country difficult.

The parameters of radiation are established by technicians in accordance with the protocol of traditional bibliography, with the teaching of their professors or with techniques established by the manufacturers of the equipment. These techniques are not necessarily good enough to be able to obtain images of good diagnostic quality using a lower dose of radiation for the patient.

One of the proven factors which most affects this dose received by the patient is the repetition of tests. In Argentina at the present time, there is no register of parameters of radiation used on each patient in tests of ionising radiation although generally there are registers which allow the analysis of the quantity of x-rays either for tests repeated for some reason: incorrect posture of the patient, lack of quality control of the equipment, fixed parameters which do not coincide with the real parameters etc.

This second aim “Optimizing Radioprotection” is carried out in four stages:

- Collection of information used locally and in other countries in order to develop different studies, such as operative parameters, reference levels, work protocol, quality control, registers etc (Stage in completion)
- A second stage of analysis of the existing information by groups of specialists in order to produce “Manual of work protocol” to minimize the dose involved both in the patient and the operators and public (Stage in development)
- A third stage of quantitative evaluation of the results obtained in order to present a report to the authorities and:
a fourth stage consisting of the issuing of recommendations by medical associations and/or authorities for the full use of the Manual of work protocol.

However, there is no point in establishing work protocol without a minimum of quantity control of the equipment, which will at least ensure that the real operative parameters correspond to the indications of the instruments. This is why training and accreditation of those responsible for the maintenance of the equipment should be carried out at the same time. Work on awareness is being done for this reason through their different associations.

3) Preventing potential exposure

The “general conclusions” of the Conference of Malaga show two basic elements to achieve the RPP: training and coaching as well as the implementation of quality systems, the latter being particularly important to prevent potential exposure, especially in those installations where potential risk from radiation is greater.

Most health services do not have the necessary means available to adhere quickly to international standards, so a standard which ensures the existence of the essential elements in a quality system must be designed to then be able to obtain automatic and accessible accreditation for all health services. One cannot demand something that only a few can comply with when it is likely that 90% of the Health Services in Argentina and in the rest of the world do not have a formal quality system available yet.

At the same time the health services do not have either qualified or trained personnel to lead a certification or accreditation project and most of them do not have the resources available to hire external consultants, especially public hospitals.

The scenario described represents a challenge for the Regulating Authorities who must determine “how to ensure that installations comply with an acceptable standard of quality without it placing an impossible strain on their budget?”

The methodology used in the design of quality systems can be divided into two categories: Reglamentary Approach and Analytical Approach.

The Reglamentary Approach is the application of the requirements of a given standard without necessarily going through a previous analysis of their own operative processes. Each requirement is linked to an element or activity which is developed in the productive organization and each activity is assigned a “criteria control”. The reasoning is the following: “if each activity can be the source of failure or error, then each one should be controlled individually so as to control the group of activities of the organization”.

In this way, “criteria control” appears: design control, supply control, document control, register control, material control etc etc.

On the other hand, the Analytical Approach is based on the “detailed analysis of specific processes” to identify the causes of the failure and deviation and to then prevent them which is why different tools and methodology are used to a greater or lesser complexity.

Within this approach we can find methodologies which use systematic evaluation tools for processes, such as HazOp, FMEA, DMAIC, APS, HACCP, 8D, ANOVA and others. The new version of the ISO-9001:2000 is a standard hybrid one which contains two approaches: its General Criteria (4.1) requires the identification and analysis of the processes and the rest of their contents including requirements for controlling the system following “criteria for control per activity”.

In the design of the Basic Guide general criteria (4.1) of the ISO 9001 : 2000 were used. The application of the Analytical Approach requires deep knowledge of the processes while the Reglamentary Approach requires greater knowledge and experience in the use of the standards of quality. This is important as far as the use of external consultants in the organization is concerned and has a great influence on the cost of the design of the system.

Basically, it is considered that: “If the detailed analysis of the processes is carried out as well as the necessary preventive measures of control and the work is documented, it is not necessary to comply with the other requirements”.
This third aim “Prevention of potential exposure” is carried out in four stages:

- Design of a Guide to implement a basic system of quality (Stage in completion)
- A second stage of diffusion of the Guide through professional associations.
- A third stage of quantitative evaluation of the results obtained in order to present a report to the health authorities and the Argentine organism of normalization (IRAM)
- A fourth stage consisting of the formal issuing of the Guide by the normalization organism and the health authorities.

The systems of quality are necessary but not enough to prevent human error arising from lack of motivation and from attitudes of those who have an incorrect perception of the risks, which is why the implementation of the Safety Culture is absolutely necessary. The use of the analytical approach in the design of the system of quality together with the participation of personnel allows the Safety Culture to be encouraged and developed effectively.

4) Some foreseen complementary activities to be carried out within the RPP program:

The effective participation of professionals and technicians in the development of the RPP of the patient is a key aspect for its success, which is why the initial awareness work is very important. It should be pointed out that the Guide of prescription criteria does not cover high complex clinical profiles, which should be resolved appropriately by the prescribing doctor and the doctor responsible for the test.

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