



Control of health risks in radiodiagnosis: a historic approach

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Abstract

This paper presents the history of the discovery of ionizing radiation, as well as its biological effects and the resulting need to control subsequent health risks. It describes the historic evolution of risk control in radiodiagnosis in Brazil, demonstrating that it may be associated not only to the dose received, but also to errors in diagnosis and to costs to the health system. It is stressed that sanitary regulations have a broad remit of social co-responsibility to involve all the players with a view to safeguarding health.

Keywords: risk control; radiodiagnosis; risks; ionizing radiation; sanitary vigilance.

On December 8, 1895, while experimenting with cathode ray tubes, Wilhelm Conrad Röntgen observed a screen with a fluorescent material – barium platinocyanide – glowing. The glow persisted even when Röntgen placed a book and a sheet of aluminum foil between the tube and the screen. Something left the tube, passed through the barriers and reached the platinocyanide. Since these rays being emitted from the tube were unknown, Röntgen called them X-rays, intending to name the physical phenomena later. However due to the immediate reaction to the discovery, even after describing the phenomena, the rays discovered by Röntgen became known worldwide as X-rays although in some countries such as Germany they were called Röntgen rays (Martins, 1998).

In the following weeks Röntgen remained in his laboratory attempting to uncover the secrets of the new phenomena he had discovered and in December of the same year he achieved the first ever radiograph in history by passing the radiation through his wife Bertha's hand onto a photographic sheet. For the discovery Röntgen received the first Nobel Prize in Physics in 1901 (Martins, 1998).

The medical applications of X-rays followed almost immediately. By January 1896, the use of radiographs for diagnoses had been reported in Germany, the United States, England, France and Russia (Lindenbraten, Kotlyarov, Kotlyarov, 1994; Abrams, 1996; Martins, 1997; Martin, Sutton, 2002). During 1896 more than 100 works on the medical uses of X-rays, including fluoroscopy and cancer treatment were published in several countries (Abrams, 1996; Martin, Sutton, 2002). In the following year the Brazilian doctor Álvaro Alvim carried out the first radiograph of xiphopagus.

Cathode ray tubes had not been designed to produce X-rays and consequently problems of repeatability and beam focusing emerged. Tubes specifically projected for X-rays, similar to those used today, appeared in 1913 with the development of high vacuum tubes by W.D. Coolidge (Ammann, Kutschera, 1997).

In X-ray tubes there is a different electrical potential in the order of 20 to 150kV between the positive (target) and negative (filament) points, depending on the tissue or organ to be radiographed. This high potential difference accelerates the electrons from the filament to the target and on colliding with it the electrons lose energy producing heat and X-rays.

Due to the high generation of heat, the filament and target are made with high melting point elements (Ammann, Kutschera, 1997). X-rays are produced via the transformation of electric energy into X-rays, i.e. the equipment does not have any radioactive elements emitting radiation; consequently the X-ray equipment irradiates without contaminating.

In 1896 the French physicist Antoni Becquerel discovered a uranium compound that produced phenomena similar to X-rays. At first Becquerel thought these were the same X-rays discovered by Röntgen. Later the studies by the couple Marie and Pierre Curie that continued through to the end of 1898, led to the discovery of three new elements (thorium, polonium and radium), leading to the coining of the term 'radioactivity' and the description of the phenomena as a property of the chemical elements. These studies gave the Nobel Prize in Physics to the Curie couple and Becquerel in 1903, and the Nobel Prize in Chemistry to Marie Curie in 1911. In 1935 Irene Curie, daughter of the Curies, received the Nobel Prize in Chemistry for the discovery of artificial radioactivity. The diagnostic and therapeutic uses of these radioactive elements came into medical practice as fast as the X-rays had (Mould, 1995).

These discoveries brought about a revolution in scientific thinking. Up to that time the atom was believed to be impenetrable and immutable. Thanks to the discovery of radioactivity and X-rays, besides the medical applications, the atom could now be studied in greater detail, which contributed significantly to scientific progress in the 20th century (Mould, 1998).

Although the discovery and immediate use of ionized radiation (RI)¹, which includes X-rays and radioactive elements, brought benefits to science and medicine, it also caused injuries to researchers, doctors, patients and other individuals who were exposed to such radiation. As with all technology, X-rays brought with them intrinsic and unknown dangers as they entered the social scene (Beck, 2003).

In January 1897, T.C. Gilchrist, published a report of 23 cases of injuries caused by X-rays and in 1898 the Röntgen Society, which had been founded the previous year, set up a committee to collect data on the harmful effects of X-rays. At that time just the immediate dangers were observed and only 50 years later were the delayed effects of ionized radiation detected.

Only in 1915, 20 years after the discovery of X-rays, did the Röntgen Society publish the first recommendations for the protection of workers. It was the beginning of radioprotection or radiological protection as a field of study into the harmful effects of ionized radiation (Martin, Sutton, 2002).

During first 30 years of X-ray usage, professionals using this technology suffered many injuries. In Brazil, Dr. Álvaro Alvim died in 1928 after both his hands were amputated due to injuries caused by exposure to radiation. In homage to the deaths caused by ionized radiation exposure and to call attention to the harmful effects to health, in 1936 the Röntgen Society built the Monument to the Martyrs of X-rays and Radium listing the names of 169 people from 15 different nations. In 1959 the list already had 360 names, including that of Marie Curie.

Risks in X-ray diagnostic

Risk is a polysemic term that in some fields can be understood as a synonym of probability and in others as a mathematical expectation or even as an inherently indefinable concept. It may also be understood as a concept created to mediate the relation between man and the source of danger, which proves helpful in the decision making process. Thus being a value judgment, it is not independent of political, economic and social factors (Fischhoff, Bostrom, Quadrel, 2005; Romerio, 2002; Beck, 2003; Slovic, 2004).

X-rays as well as the radiation coming from radioactive elements have sufficient energy to ionize atoms. Consequently they are called ionizing radiation. These are of nuclear origin, as the α , β and γ (alpha, beta and gamma) radiations or of an atomic source, that is to say that they are produced by interactions with atoms, as in the case of X-rays.

X-rays are electromagnetic waves like light, radio and mobile phone waves. What is different is the frequency of the wave and consequently its energy. And so X-rays are electromagnetic waves with sufficient energy to ionize atoms. This doesn't mean that mechanical or electromagnetic non-ionizing radiation is not harmful to human health.

Ionizing radiation arises from natural or artificial sources. The natural sources include cosmic rays, soil radiation and the radionuclides, which are naturally present in the human

body. Radon, for instance is a radioactive gas produced by the natural decay of uranium. Construction materials, such as concrete and brick contain radon, namely an element that emits alpha particles that mainly lodge themselves in lung tissue and are potentially harmful to human health.

In the years following the discovery of ionizing radiation many technological advances were made in optimizing its use and production², as well as its effects on man. The response of an individual's organism to radiation depends on factors such as the dose received, individual organic characteristics, the area irradiated and the level of the dose, among others.

Ionizing radiation can affect cells either in a direct manner, damaging a macromolecule (DNA, proteins and enzymes among others), or in an indirect form, by interacting with the surroundings and producing free radicals (Nias, 1998). These cellular modifications can be repaired by enzymes. However, if this does not occur biochemical damage can follow and cause premature death, changes in the process of cell division and genetic mutations.

The biological effects of ionizing radiation can be of two types: deterministic and stochastic. The deterministic effects occur when generalized or localized irradiation in the body causes more cell death than the organism can compensate for (threshold of clinical effects). Beyond this threshold the severity of injury increases with the dose. Despite these effects have a deterministic character they can be reversible or not (ICRP, 1991). Also they can be understood as effects that require a threshold of absorbed dose to occur and the seriousness of which increases with the dosage increase.

On the other hand, the stochastic effects occur when generalized or localized irradiation in the body produces less cell death than can be compensated for by the body. The death of some cells may not cause any injury at all whereas modification of a single cell could result in cancer. This type of effect is of a probabilistic nature. In this case the increase in dose provokes an increase in the probability of injury and not in the severity of the injury (ICRP, 1991). There is no type of dose threshold for these effects to occur. The probability that these effects may occur is a function of the dose, however the seriousness of effects is independent of the dose.

Radioprotection studies are related to protection of human health and to the harmful effects of ionizing radiation. Their theoretical base should include social and technical judgments, since the reasons that justify the beneficial use of the radiation must be established. Thus it cannot be guided by scientific considerations alone. Radioprotection should prevent the occurrence of deterministic effects and reduce the stochastic effects.

The release of ICRP 60 (ICRP, 1991) consolidated the three principles of radioprotection: justification, optimization and limitation of dosage. The principle of justification states that no practice can be carried out that does not produce sufficient benefits to compensate the corresponding damage to individuals exposed or to society, taking into account social, economic and the other pertinent factors. The principle of optimization establishes that the radiological protection should be optimized in such a way that the magnitude of the individual doses, the number of people exposed and the probability of occurrence of exposure are maintained as low as can be reasonably feasible taking into account the economic and social factors involved. The limitation of dosage principle states that the normal exposure of individuals should be restricted to such a point that it doesn't exceed the limits of the doses specified (ICRP, 1991; Brasil, 14 nov. 2005).

Nevertheless, a seminar of radiology experts established a X-ray diagnostic risk concept in Neuherberg (Germany) in 1979. This event inferred that an important step in the development of studies on the efficiency/efficacy would be the adoption, by all countries, of programs to guarantee the quality of X-ray diagnostic in order to improve the quality of the image and reduce the doses and operating costs. There was a consensus that the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA) should play a catalyzing role in the process of such programs. The fact that only a limited number of countries had begun national programs to guarantee quality in X-ray diagnostic was also discussed. However, a large number of them already had local initiatives that depended on the specific interest of the specialists (radiologists, physicists, doctors and technicians) (WHO, 1982).

As a result of this seminar, in 1982 the WHO published recommendations on the setting up of quality control and guarantee programs entitled "Quality assurance in diagnostic radiology". This document, a milestone in the process of establishing new concepts concerning risks associated with radiodiagnostic services, proposed that the quality of the diagnosis, the doses administered to the patients and the costs of the services should serve as the main parameters. This threesome that became known as the 3 D rule (Diagnosis, Doses and Dollars), expressing the need to provide a correct diagnosis in order to be able to make a suitable decision concerning treatment. That is to say that in the first place there is a concern related to the risk of a diagnostic error or to obtaining incomplete information; in the second place the concern is with the doses (in patients, workers and individuals in general); and in third place operational costs. To achieve these goals it is necessary to control the radiodiagnostic services in terms of equipment calibration, personnel training and the setting up of quality guarantee programs (WHO, 1982; Gray et al., 1983; Opas, 1997, Stevens, 2001; BIR, 2001; Aichinger et al., 2004).

Risk control in X-ray diagnostic

X-ray diagnostic is important for public health, whether it be for its supportive role in diagnosis and follow-up in several medical areas or because it is the main source of exposure to artificial radiation. Thus, in order to be able to use ionized radiations to maximum benefit with minimum harm, the setting up of national systems for radiological protection is required, which should be coordinated by a regulatory body with specific legislation for the area³ (WHO, 1972, 1982; ICRP, 1991, 1996; IAEA 1996, 2004, 2006).

In Brazil, as in other countries, the first state interventions in the field of ionized radiation were related to occupational exposure regulations. On December 14, 1950 Law 1,234 was passed that "granted rights and advantages to public servants who work with X-rays and radioactive substances". The following year, Law 29,155 of January 17 regulated the aforementioned law and laid down the first control measures concerning public health services using ionized radiation. It also defined the first radioprotection standards, such as for example the requirement for protective plating on the equipment, in the wards and in the control rooms, the use of protective gloves for fluoroscopy and the carrying out of periodical exams on professionals exposed to radiation.

In 1962, Law 4,118 set up the National Commission of Nuclear Energy (CNEN) and regulated national nuclear energy policy. Today CNEN is still responsible for the peaceful uses of nuclear energy. It establishes the *Basic Standards of Radioprotection* and controls the medical uses of nuclear medicine, radiotherapy and individual monitoring. The *Basic Standards of Radioprotection* published by CNEN cover X-ray diagnostic, setting up public and occupational exposure limits, units of measurement and individual monitoring of workers. However, licensing or inspecting X-ray diagnostic services has never been an attribution of CNEN (NN 3.01/2005) (CNEN, Nov. 14th 2005).

The control of the use and sale of X-ray equipment began with Law 5,991 of December 17, 1973, that “deals with the sanitary control of the sale of drugs, medicines, pharmaceutical raw materials and the like and regulates other matters”.⁴ Although not referred to explicitly in the law, the definition of other matters encompasses equipment for X-ray diagnostic.

Law 6,360, published in 1976 and later regulated by decree 79,094 of 1977 that “deals with sanitary vigilance to which medicines, drugs, pharmaceutical raw materials and the like, cosmetics, disinfectants and other products are subject ...”, stated that none of the projects submitted to sanitary vigilance control could be industrialized, displayed for sale or delivered to the consumer before being registered with the sanitary vigilance agency.

Still in 1977, with the aim of regulating sanitary violations, Law 6437/77 was published including, among other sanitary violations, the following: “III – to install medical consultation rooms,cabinets or services that use apparatus and equipment that generate X-rays,without a license from the competent sanitary agency or contrary to the regulations of other legal rules and pertinent regulations”. The National Sanitary Vigilance Secretariat was set up in the same period and has for the past thirty years been explicitly and legally responsible for radiodiagnostic equipment and services

After the tragedy in Goiânia in 1986 involving the disposal and consequent incorrect use of a radioactive source of cesium from radiotherapy equipment, the National Council of Health published Resolution 6 of December 21, 1988, establishing general requirements for radiological protection including X-ray diagnostic. However, it was a resolution of a broad ranging character without any specific implications for the actions of the sanitary vigilance agency.

At that time the Brazilian health system including the sanitary vigilance agency was embarking on a complete restructuring process due to the publication of the 1988 Constitution that defined the framework of the National Health System (SUS - Sistema Único de Saúde). Paragraph 200 reads as follows:

- The national health system is responsible, among other duties, according to the law:
- I – to control and inspect procedures, products and compounds of interest to health and to participate in the production of medicines, equipment, immuno-biological products, hemoderivatives and other raw materials;
 - II – to carry out sanitary and epidemiological actions, as well as actions related to work safety;
 - ...
 - VII – to participate in the control and inspection of the production, transport, storage and use of psychoactive, toxic and radioactive substances and products.
 - ...

Another two years passed before Law 8,080 of September 19, 1990 regulated and structured the National Health System (SUS – Sistema Único de Saúde) and defined the role of sanitary vigilance:

Art. 6 Also included under the responsibility of the National Health System (SUS –Sistema Único de Saúde):

I– to carry out the following actions:

a) sanitary vigilance;...

§ 1 Sanitary vigilance is understood to be a set of actions capable of eliminating, reducing or preventing risks to health and intervene in sanitary problems arising from the environment, production and circulation of goods and services of interest to health, covering:

I– the control of consumer goods that are directly or indirectly related to health, including all the stages and processes from production to consumption; and

II - the control of services that are directly or indirectly related to health.

Nevertheless the definition established for sanitary vigilance was very far from the reality of Brazilian practices. The tragedy in Goiânia was unfortunately the first of many others in the 1990s exposing the consequences of an inefficient risk control system for health. The cases of the Santa Genoveva Clinic, in Rio de Janeiro, of the Caruaru Institute of Renal Diseases, of Schering, and the crisis of the adulterated medicines led the Brazilian government to restructure sanitary vigilance (Costa, 2004).

At the peak of the crisis that sanitary vigilance was experiencing and one year before the publication of Law 9,782/99 (that defined the National System of Sanitary Vigilance and set up the National Agency of Sanitary Vigilance – Anvisa), the National Secretariat of Sanitary Vigilance, ex-SNVS, published edict 453/98⁵ that embodied the main recommendations of multilateral organizations (WHO, OPAS, ICRP and IAEA) and established a regulatory benchmark for X-ray diagnostic in Brazil.

Conclusion

The wider concept of risk in the process of X-ray diagnostic, established globally in the 1980s, sheds light on the current regulation process of these services. Understanding that the control of the exposure dose alone is not enough and that diagnostic and costing errors are fundamental for risk control, highlights the need to recheck the aforementioned sanitary regulation process.

Currently the responsibility for sanitary regulation in Brazil lies only in the State via the sanitary vigilance services, while other agents involved such as manufacturers, professional bodies, professional consultants and those responsible for radiodiagnostic services have little or no commitment from a sanitary regulation standpoint. And the existence of non-compliant services and diagnostic errors caused by negatoscopes or malfunctioning processors result in a serious increase in untimely diagnoses, as well as costs and doses in patients and workers.

NOTES

¹ Ionized radiation can be considered as any particle or electromagnetic radiation that on interacting with a material removes electrons from the atoms transforming them into ions. Consequently, the alpha particles, the beta particles and gamma radiation emitted by radioactive sources as well as X-rays are forms of ionized radiation.

² Among various forms of technology, the setting up and control of the parameters (tension, currents and time) to take a radiograph so that the radiographic technique is reproducible is one of the more important examples. Other components of radiodiagnostic procedures such as intensifying screens, additional filtration, anti-scatter X-ray grids and illuminators were developed and incorporated as medical practices in the first three decades of the last century.

³ Brazil is a signatory of the recommendations of the International Atomic Energy Agency (IAEA), the International Electrotechnical Commission (IEC) and the International Standards Organization (ISO). Therefore the national norms should reflect the recommendations of these organizations and in the absence of a national norm for a determined area they should be adopted.

⁴ "A substance, product, apparatus or accessory not covered in the previous concepts, the standard application of which is connected to safeguarding and protecting individual or collective health, personal or environmental hygiene, or for diagnostic and analytical purposes.....".

⁵ The "Guidelines for radiological protection in medical and odontological X-ray diagnostic" established by this edict is divided in the following manner: I – General considerations; II – Radiological protection system; III – Operational requirements; IV – Requirements for medical X-ray diagnostic; V – Requirements for odontological radiology; VI – Temporary provisions; Schedule A – Reference levels; Schedule B – Registration form; Schedule C – Glossary.

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