REVIEW ARTICLE

Article received on November 20, 2016 and accepted for publishing on January 12, 2017.

Towards an integrated medical system for radiological medical imaging investigations

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Abstract: *The continuously increasing number of medical investigations using radiological methods imposes the strong necessity of informing patients about benefits and risks regarding radiation absorbed doses. Tracking the radiation doses absorbed by patients must be a future challenge of any medical system. The effective doses received by patients in many types of medical investigations must be calculated, transformed, recorded and cumulated. Doctors and patients must be very responsible in prescribing or demanding new radiological medical investigations. Radiological standards, legislation, guidelines, programmers and practice supervised by international commissions on radiology protection must include new specific measures for patients' cumulated doses. A pilot Romanian project had tried to accomplish some of these tasks.*

INTRODUCTION

Radiation is commonly associated with nuclear accidents or modern irradiative artificial sources such as: mobile phones, great antennas, satellites, food irradiation, and radioactive building materials.

Generally, radiation is associated with all kind of human activities.

As a huge surprise, in fact, radiation is quite a natural phenomenon in our lives. There are many radioactive substances in air, water and soil that are called natural background radiation. During a long airplane flight one can also receive an important radiation dose. Typically doses from natural sources are measured in mSv. The Sievert (Sv) is the International System of Units (SI) derived unit for radiation dose.

There are many other different units for absorbed radiation and transformations can be made in order to compare them.

A recent United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) publication [1] estimates worldwide distribution of radiation exposure:

- 13% from cosmic sources
- 16% from soil
- 9% from food
- 20% from medical investigations
- 42% from radon sources

Radon-222 is a radionuclide in the form of a gas that normally emanates from the soil. Radon is a colorless,

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odorless, radioactive gas. Most exposure to radon comes from being indoors in buildings. A strong interaction between smoking and radon has been proven, so radon is considered as a primary cause of lung cancer, smokers being more vulnerable [2]. There are no widely available medical tests to measure radon exposure. So radon belongs to natural sources of radiation.

The increased doses of radiation in our climate and habitat is surveyed by national or international organizations, there are standards, policies and strategies for general radiation protection.

International commissions on radiology protection are worldwide active for radiological standards, legislation, guidelines, programmers, and practice.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) highlights the levels and effects of exposure to ionizing radiation [1].

The International Commission on Radiological Protection (ICRP) has published a lot of reports on generally human protection and the specific protection of patients exposed to ionizing radiation [3].

In Romania, CNCAN is the national competent authority in nuclear field "having responsibilities of regulation, authorization and control stipulated in this Law is the National Commission for Nuclear Activities Control, public institution of national interest, legal entity, with the head office in Bucharest, being headed by a President having the rank of State Secretary, coordinated by the Prime Minister [4].

RADIOLOGICAL MEDICAL INVESTIGATIONS

Medical imaging is a complex process of visualization of the interior of a human body. A lot of techniques and engineering tools are used in order to obtain a visual representation:

- Radiology using X-rays;
- Computed Tomography (CT scan) using also uses special X-ray equipment;
- Nuclear medicine, using internal radioactive substances including scintigraphy that uses radio-isotopes travelling to organs, positron emission tomography (PET) or Single-photon emission computed tomography (SPECT) ;
- Mammography as a specific type of breast imaging that uses low-dose x-rays;
- Magnetic resonance imaging using the property of hydrogen atoms from human body to absorb or emit radiofrequency energy when placed in an external magnetic field;
- Medical ultrasonography or ultrasound, a diagnostic imaging technique based on the application of ultrasound;
- Endoscopy using an instrument inserted in the human organ;
- Thermography, using thermographic cameras and infrared imaging techniques;
- Elastography;
- Tactile imaging or mechanical imaging.

Only the first four investigations imply radiological methods in medical investigations. The last ones do not imply radiological risks, even there are scientific debates on SAR (specific absorption rate) as a dosimetric quantity for Electromagnetic Fields bio effects [5].

Patient exposure to ionizing radiation can be made externally, internally nor both. CTs doses are usually externally absorbed, while in angiography, fluoroscopy or scintigraphy investigations, a radioactive substance is ingested. Contrast media are also used on radiography and CT to visualize vessels or tissues. Iodine is a modern intravenous contrast agent, but barium is also used. Usually iodine contrast media is used intravenously, it can also be used intra arterially. Barium sulfate is usually swallowed. Magnetic Resonance Imaging or CTs also use contrast agents.

Differences between exposure and contamination can also be debated [6]. Exposure to a radiation source does not imply that this person becomes a new radioactive source. Contamination incorporates the radioactive agent in the body, such as in thyroid gland.

Exposure to X- rays increases the future incidence of cancer, but quantitative models predicting the level of risk are still not worldwide accepted. Different methods for radiation risk calculus are available. The linear no-threshold (LNT) model assumes the proportionality between cancer risks versus absorbed dose. The relationship between dose and DNA damage is considered linear. The International Commission on Radiological Protection (ICRP) recommends the use of the LNT model [7].

Significant uncertainties are related to dose assessment, low dose and low dose-rate extrapolation approaches, transfer of risks from a population for which health effects data are available to one for which such data are not available [8]. Adaptive responses of human cells have also been observed at low doses [9].

Classical radiographies, computed tomographies (CTs) and scintigraphies are worldwide used medical radiological investigations that expose the patients to significant doses of radiation.

The actual volume of medical prescription, the contrast substances used in order to increase their accuracy, the overlapped investigations are general causes for a strong increasing of the cumulative radiation dose absorbed by patients. Patients and doctors usually excess in demanding, using and prescribing medical investigations in spite of harmful effects associated with radiation delivery.

The prescribed medical investigations total volume, starting from dental radiographies and ending at multiple regions CT scans prove a gap in monitoring and tracking of the cumulative radiation doses in many health services all over the world. The received radiation doses by patients are quit impossible to be cumulated in spite of the fact that in our modern world, 20 % of absorbed radiation dose is due to medical investigation.

The patients travel from one hospital to another, all over the country or all over the world.

An integrated system must be implemented. In order to cumulate all the absorbed doses by a patient in different types of radiological investigations, the doses measurement units must be the same and the recorded doses must be kept together in a single patient monitoring unit.

RADIATION DOSE RISK AND DIAGNOSTIC BENEFIT [10]

The treating physician and the radiologist can prescribe and carry out radiological imaging procedures. Several objectives and subjective elements are implied in a prescription:

- Medical request
- Imaging investigation algorithm
- The personal experience of the examiner
- Patient history
- The results of any other previous investigations

All the time a correct judgment concerning the benefit/risk ratio must be performed. Medicine and the radiation risks knowledge must be well handled. The aim of managing radiation exposure is to minimize the irradiative risk without sacrificing, or unduly limiting, the obvious benefits in the prevention, diagnosis and also in effective cure of diseases (optimization).

When too little radiation is used for diagnosis or therapy there is an increase in risk. Too low an amount of radiation in diagnosis will result in an image that does not have enough information to make a correct diagnosis. There are several ways that will minimize the risk without sacrificing the valuable information that can be obtained for patients' benefit. A possible measure is to carefully justify the examination before sending a patient to the radiologist or nuclear medicine physician. Repetition should be avoided in recently investigations performed into another clinic or hospital. An investigation may be seen as a useful one if its outcome – positive or negative – influences management of the patient. Another factor, which potentially adds to usefulness of the investigation, is strengthening confidence in the diagnosis. Most common examples of unjustified examinations include: routine chest radiography at admission to a hospital or before surgery in absence of symptoms indicating cardiac or pulmonary involvement (or insufficiency); skull radiography in asymptomatic subjects of accidents; lower sacrolumbal radiography in stable degenerative condition of the spine in the 5th or later decade of life, but there are of course many others [11]. From medical experience, the diagnosis benefit is a priority. For a lung Rx examination any suspected image is repeated or supplementary investigated in a Computed Tomography.

Many times, the personal experience of the radiologist is the dominant factor in high radiation doses investigations:

• urgent exam such as trauma and polytrauma, fractured skull or spine where CT exams are a real benefit for the patient and an economic benefit for the hospital. They can shorten the patient's hospital stay.

• scintigraphic investigation in thyroid diseases

• repeated mammography

• bone disease with seemingly benign tumors requiring an examination for differential diagnosis.

RADIATION MEASUREMENT UNITS

„The International Commission on Radiological Protection (ICRP) recommends that the public limit of artificial irradiation should not exceed an average of 1 mSv effective dose per year, not including medical and occupational exposures. ICRP limits for occupational workers are 20 mSv per year, averaged over defined periods of five years, with the further provision that the dose should not exceed 50 mSv in any single year" [12].

The Sievert (Sv) is a derived unit in the International System of Units (SI) used for equivalent absorbed radiation dose measurement. This must be the central unit of a tracking medical system.

There are many different units for absorbed radiation used on a large scale. Becquerel (Bq) and Curie (Ci) as SI units are used for released radioactivity, while Coulomb/Kilogram (C/kg) and Roentgen (R) are used for the dose travelling through the air, Gray (Gy) and Rad, used with quantities of absorbed dose. A lot of Internet sites provide convertors between them.

The biological effects of the absorbed amount of radiation can be described with Roentgen equivalent man (rem) and Sievert (Sv). They are specific measurement units.

The Sievert can better describe the effective equivalent dose absorbed by biological tissues while the Gray can describe the absorbed dose of any material.

Table 1: Radiation Measurement Units

Type	Measurement unit		
Released radioactivity	Curie (Ci)	Non-SI	**1 curie = 3.7x10^{10} radioactive decays per second**
	Becquerels (Bq)	SI unit Derived	One becquerel represents the activity of a quantity of radioactive material in which one nucleus decays per second – **1 Bq = 1 s^{-1}**
Dose travelling through air (Exposure)	Coulomb/Kilogram (C/kg)	SI unit	**1 C/kg = 3876 R**
	Roentgen (R)	Non-SI	**1 C/kg = 3876 R**
Absorbed Radiation dose	Gray (Gy)	SI unit Derived	It is defined as the absorption of one joule of radiation energy per kilogram of matter **1Gy=1J/Kg=1m^2/s^2**
	Rad	Deprecated, replaced by the Gray	**1 rad = 0.01 Gy = 0.01 J/kg**
Dose equivalent (the biological effects of the absorbed amount of radiation)	Röntgen equivalent man (rem)	Non-SI	**1 rem=0,01Sv** **1 mrem/h = 8766 mrem/yr**
	Sievert (Sv)	SI unit Derived	represents the equivalent biological effect of the deposit of a joule of radiation energy in a kilogram of human tissue

Modern radiological apparatus for computerized tomographies or scintigraphies can provide the radiation doses during a particular investigation, but the recorded doses' types and the radiation measurement units in different types of investigations are not the same.

In the classic radiological investigation an important topic for data management is the measurement and the calculation of radiation dose expressed in Dose area product (DAP), expressed in (Gy*cm2). The dose length product (DLP) was chosen as input data for the system in CTs investigations and it is expressed in mGy*cm. The DLP must be converted to mSv in order to unify the results.

REQUIREMENTS OF A DESIGNED TRACKING SYSTEM

A tracking proposed system must include computers, smartcards for storing data and suitable software applications for recording, retrieving and alert. The effective doses received by patients must be unified and cumulated.

The system provides the replication of the information stored in central databases, local databases and patient cards to cover all the following possible situations:

- The patient goes to the doctor without the patient card. In this case, the system provides the data corresponding to the patient based on the local database, if the patient has been investigated in that hospital unit; if the patient is new, the system must provide the data from the central database to the local database, so as to take the optimal decision in recommending the type of investigation. After the investigation, the system must store the new local database accumulated radiation dose to the patient, the information arriving in the central database. Later, when the patient goes to the doctor for further investigations with the card, the system must ensure synchronization between the information stored on the card and information stored in the local and central database.
- The patient goes to the doctor with no card and the hospital unit's information system does not have access to the central database (ex: for mobile laboratories). If the local database contains the information corresponding to the patient, the doctor must be able to use them for recommending a particular type of investigation. After the investigation, the system must store in the local database the new radiation doses accumulated by the patient. Later, when the local system can access the central system, the information corresponding to the patient must be synchronized between the two databases.
- The patient presents the card to the doctor but the doctor does not have access to any database (local or central). In this case the doctor, using a computer with a card reader can access the history of investigations and the doses received by the patient, as the current cumulative dose calculated and can recommend the most appropriate investigation. After investigation, the appropriate dose must be recorded on the patient's card and next time when the patient goes to the doctor with the card, this information must be stored in both in the local and the central database.

Additionally the system provides applications for:

- Viewing in real time the history of investigations, of the doses delivered to the patient and of the current cumulative calculated dose expressed in mSv.
- Aiding the medical staff in taking the adequate decisions regarding the indication of investigations according to the current calculated cumulative doses and the maximum doses allowed for the risk and age groups.
- Performing of various periodic reports in order to take different types of decisions related with the existing radioprotection rules.

The proposed system includes the following modules:

a) Applications running on smart cards, called on card applications.

b) Off-card applications that are running on medical stations. They include smart card readers and writers in order to record and retrieve the information about the type of investigations and the specific emitted doses

c) A data base records all the necessary information in order to replicate a lost or destroyed card but also this database must provide the possibility of collecting data about the patients on several criteria, it must provide the possibility of standard or customized reports' creation.

d) The security solutions such as public key infrastructure PKI in order to achieve a high level of security of recording and retrieving data. A public-key infrastructure (PKI) is a set of hardware, software, people, policies, and procedures needed to create, manage, distribute, use, store, and revoke digital certificates. A PKI establishes and maintains a trustworthy networking environment by providing key and certificate management services that enable encryption and digital signature capabilities across applications — all in a manner that is transparent and easy to use. Digital certificates are electronic credentials that are used to assert the online identities of individuals, computers and other entities on a network. They are issued by certification authorities (CAs) that must validate the identity of the certificate-holder both before the certificate is issued and when the certificate is used.

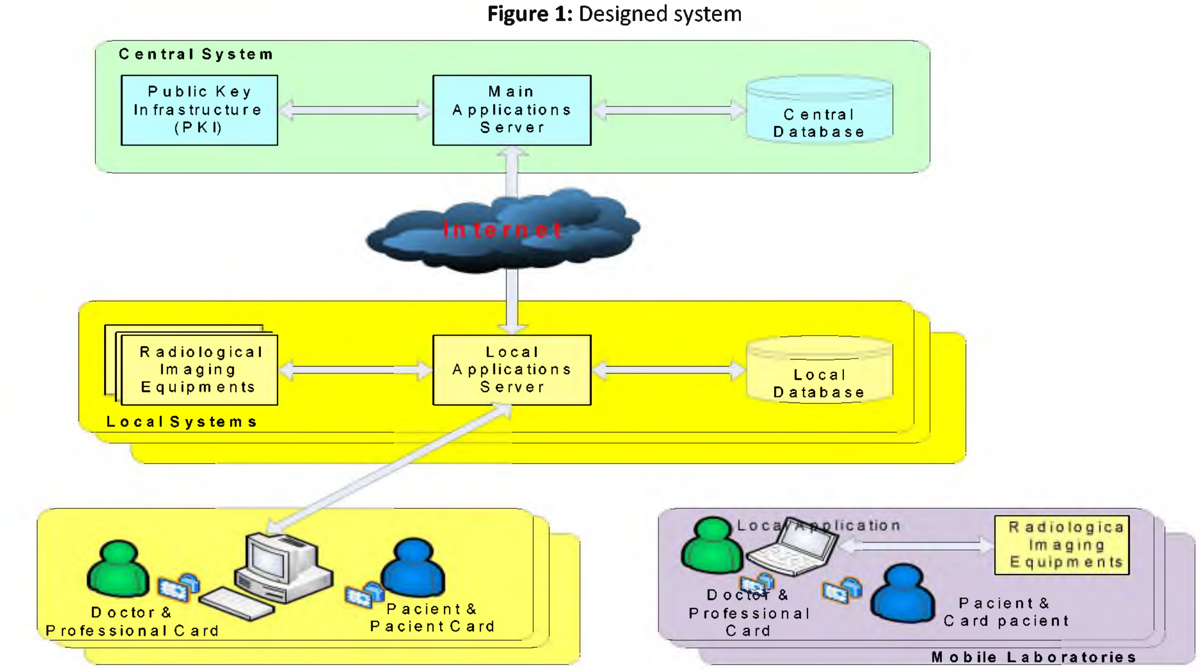
The entire system must be designed around the two types of cards: the patients' cards and the medical cards and it ensure many requirements ensuring secured communications.

Two different data flows must be implemented:

• Electronic cards flow management that includes: smart cards issuance, their renewal in case of loss, damage or theft.

• Operational cards flow management including: patients and doctors authentication using unique PINs.

Figure 1: Designed system



DESIGNED SYSTEM

A Romanian pilot study has been implemented the International System of Units uses the Sievert (Sv) as a derived unit in order to estimate the effective dose.

The new Romanian system is based on smart cards and Public Key Infrastructure and its structure is represented in figure 1. The system was implemented in Dr. Carol Davila Central Military Universitary Emergency Hospital, Bucharest, Romania.

The whole designed system and software application was the main result of the 187/2012 SRSPIRIM project in a Romanian National Partnerships Program, Collaborative Applied Research Projects – PCCA 2.

The system includes the following components:

• smart cards dedicated to patients: Citizen Radiation Safety Card (CRSC) and

• professional Radiation Safety Card (PRSC), designed for medical and investigation laboratories personnel. Among the last ones, one or more Administrator Radiation Cards are also designed and used in order to enroll patients in the application.

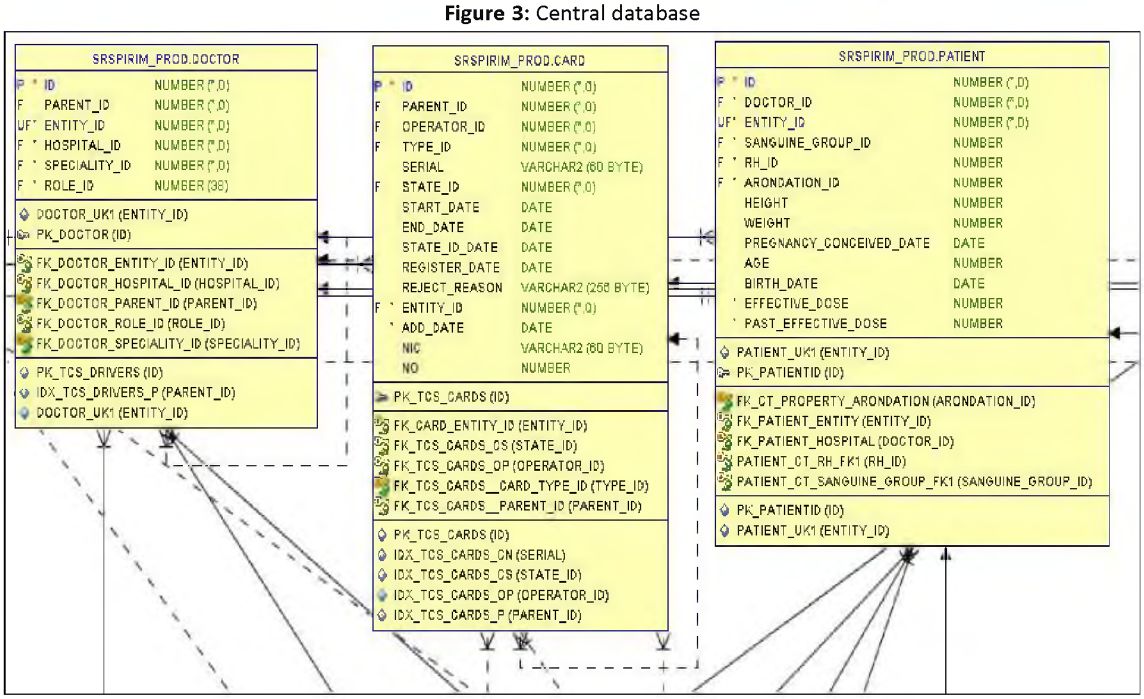
A common patient card and a doctor card are shown in Figure 2.

Figure 2: Types of cards

The hardware part of the system consists in computers, smart cards and card readers in order to record and retrieve the information about the type of investigations and the specific emitted doses.

The software includes a data base that records the commonly information on doctors, patients, types of medical procedures but also designed applications in order to replicate a lost or destroyed card.

Figure 3: Central database

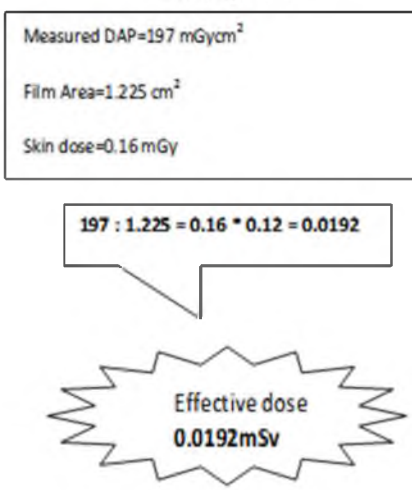


This database provides the possibility of collecting data about the patients on designed criteria and future designed reports. Central database diagram, containing the recorded medical information are stored in many tables. A part of the design of the complex relationships between these tables is presented in Figure 3.

The security solutions include a Public Key

Infrastructure base (PKI), in order to achieve a high level of security of recording and retrieving data. A public-key infrastructure (PKI) is a set of hardware, software, people, policies, and procedures needed to create, manage, distribute, use, store, and revoke digital certificates. A PKI establishes and maintains a trustworthy networking environment by providing key and certificate management services that enable encryption and digital signature capabilities across applications — all in a manner that is transparent and easy to use. The application ensures a secured authentication of doctors and patients using digital certificates and cryptographic hardware. The whole logic application is stored in the central server. The clients use the minimum functional software. The applications users have access through a web browser. The system uses cryptographic libraries FIPS 140-2 or CC EAL4. The keys are RSA 1024 bits minimum length. The cryptographic hardware must support PKCS#11, PKCS#15 and Microsoft CryptoAPI. The cryptographic hardware must ensure the recovery of the cryptographic context. The certification system ensures roll–over facilities. The PKI system has an own relational database storing all the emitted certificates.

Figure 4: Effective dose calculus in radiological investigations



EXPERIMENTAL IMPLEMENTING

In the classic radiological investigation the calculus for radiation dose uses Dose Area Product (DAP), expressed in (Gy*cm^2) as an indicator of the total risk of inducing cancer. It also has the advantages of being easily measured, with a DAP meter on the X-ray set. In order to obtain the effective dose measured in Sv, the DAP is divided by the film area and then it is multiplied by the tissue factor [13] as shown in Figure 4. A sensible situation was determined by CT-s registered dose. More related CT radiation doses are available on CT consoles. Dose length Product DLP was chosen as input data for the system in CTs investigations but the required reported data is the effective dose. Conversion factors were used. The conversion factors can slightly vary from different manufacturers. Conversion factors for normalized effective dose per DLP depend only on the region of the body being scanned. All CT manufacturers provide tables with such conversion factors.

Conversion factors are also available for children of various ages, but this project does not include children [14]. Conversion problems were detected for multiple CT scans in one single examination, because more DLP are measured in the same examination and recording them becomes a long procedure.

EXPERIMENTAL RESULTS

Different studies were performed.

During a starting one month study in the hospital, the maximum cumulative dose has been overpass The CT exams are the most concerning prescribed imaging investigations that can lead to high cumulative doses.

The initially Figure 5 reveals some aspects from the initial study at the beginning of the project. The initial proposed threshold radiation dose of 20 mSv was frequently over passed and maybe a higher dose may be accepted for medical investigations in the future.

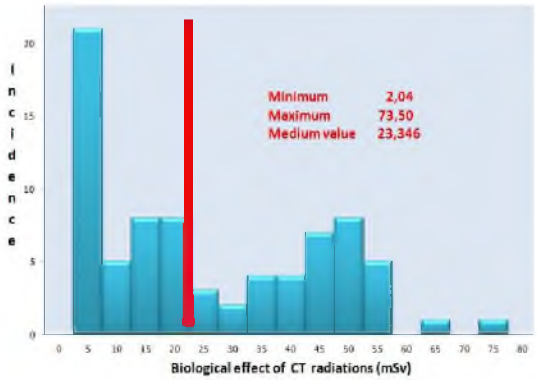
During a three years study in the hospital, different studies were performed.

The database contains 1125 records with 333 patients. From these records 42 patients were rejected in the final analysis because incomplete data.

These records contain all the investigations performed and all patients.

A lot of patients were examined in more than one investigation, so the system enrolled only 291 unique patients.

Figure 5: Cumulative radiation doses received by patients in the initial study



The recorded cumulated effective doses are shown in figure 6 and their distribution on decades is shown in figure 7.

Figure 6: Recorded doses in the project

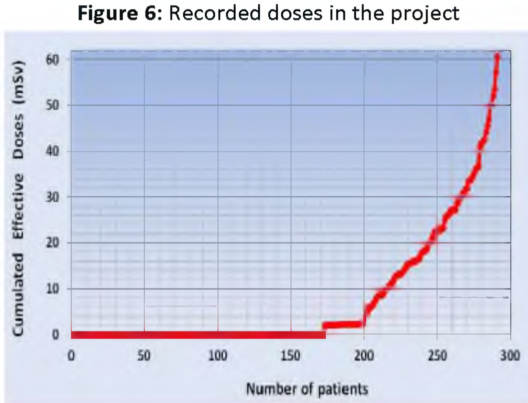
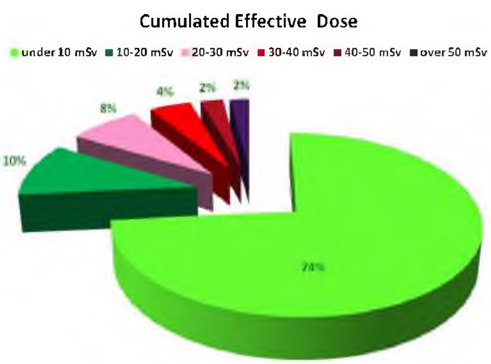


Figure 7: Recorded doses on decades



From these 291 patients, shown in figure 8 by gender, many of them have performed multiple investigations as in figure 9 and from them, in 47 cases, the received cumulated dose exceed the 20 mSv threshold dose, meaning 16,5% of cases.

Figure 8: Patients recorded in the project

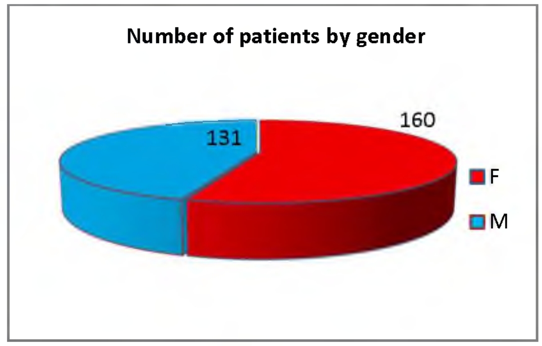
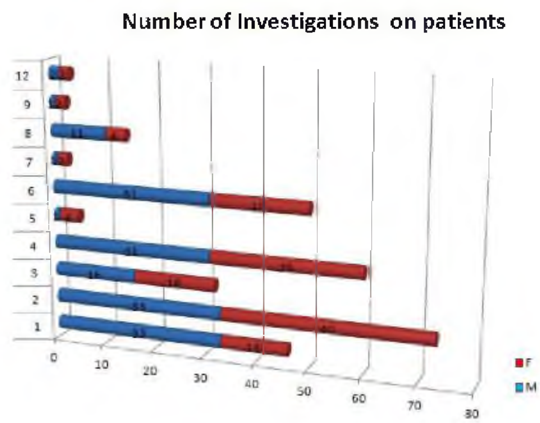


Figure 9: Patients recorded in the project



ACKNOWLEDGMENT

The results were obtained from the SRSPIRIM project 187/2012, in Romanian Partnerships Program, Collaborative Applied Research Projects Subprogram. The authors wish to address thanks to all the persons involved in this project for their support, work and ideas.

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