

## Refereed paper

# Radiological exposure evaluation through the computerised electronic records system as decisional support to X-ray examination justification in family medicine

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## ABSTRACT

**Background** In recent decades, patients' exposure to ionising radiation (IR) during diagnostic examinations has increased a great deal. X-ray requests do not always conform to the principle of 'justification', which emphasises the real utility and necessity of the examination. Databases maintained by general practitioners usually record all requests for radiological examinations of their patients and could be configured to assess the radiological risk for each patient.

**Objective** To show, through the analysis of the data extracted from a database commonly used by Italian general practitioners, whether it is possible to measure patients' exposure to IR in the previous five years, so that doctors are aware of this when they refer patients for examination involving further exposure to radiation.

**Method** Records of 120 patients from an Italian general practice were randomly extracted from the practice database. The patients were a mix of male

and female, aged from 15 to 64 years. All radiological examinations performed in the previous five years were recorded in a special spreadsheet, which had been created for computing the exposure to ionising radiation in milliSivert.

**Results** The calculated cumulative exposure of the 120 patients showed a very different perspective, which could help doctors when applying the principle of justification and allow accurate information to be communicated to the patient concerning their relevant health problem.

**Conclusions** Databases maintained by general practitioners could easily be configured to automatically compute the radiological risk for each patient and to alert the doctor when an X-ray examination is prescribed, giving the doctor crucial decisional support for its justification.

**Keywords:** computerised medical records systems, family practice, radiological exposure

## Introduction

In recent years the exposure of patients to ionising radiation (IR) for diagnostic tests has increased greatly.<sup>1</sup> It has been estimated that 2.4 milliSivert (mSv) of the total dose of about 3 mSv absorbed in the year 2000 as an individual dose may be ascribed to natural irradiation and 0.4–0.6 mSv to diagnostic examinations requiring IR emission.<sup>2</sup>

The progressive modernisation of equipment has largely decreased the IR emission of each examination. However, technological evolution and the availability of new diagnostic instruments, e.g. computerised tomography (CT), positron emission tomography (PET), scintigraphy and interventionist radiology, has increased patients' overall exposure.

The most important units of measurement used to assess IR exposure are the following:

- The Gray (Gy). This is the unit of measurement of the absorbed dose of radiation. One Gray corresponds to a radiation dose which deposits one joule per kilogram of both biological and inert matter. The absorption dose is usually indicated in mSv.
- The Sivert. It measures the equivalent dose of radiation, i.e. the consequences and the damage that the radiation produces on a biological organism. It is the absorbed dose that has the same biological effect of those produced by an amount of X-ray, which deposits one joule per kilogram of the irradiated substance. While the Gray measures the absolute value of a dose absorbed by a mass unit, the Sivert measures the biological effect of IR on the organism.

It is well known that exposure to radiation causes two kind of effects: the deterministic and the stochastic. Radiological diagnostics may produce stochastic effects, causing some diseases, in particular cancers, leukaemia and genetic modifications.<sup>3</sup>

Since exposure to radiation is an incremental risk it is not possible to fix a risk threshold, but any rise in exposure increases the probability of harmful effects. Risk of the onset of harmful effects thus increases with the increase in dose of exposure, but the degree of seriousness is independent from the absorbed dose. For this reason it is important, both for the individual patient and for the whole population, to restrict their exposure to radiation as much as possible.

IR interacts with other carcinogenic factors, such as tobaccos or chemotherapeutics, and with factors connected to the patient, such as age, sex and reproductive history.<sup>4</sup>

Recent improvements in cancer treatments have resulted in increased patient survival rates, but also in an increasing number of new cancers related to IR. The risk is higher for children.

It has been calculated that the chance of developing a form of leukaemia or cancer over the course of a lifetime is five in 100 000 people exposed to a dose of 1 mSv; and that the overall risk of contracting a cancer for each person is about 25 to 30 in 100 000. So an absorbed dose of 5 to 6 mSv in the space of a lifetime doubles the risk of contracting a cancer.<sup>5</sup>

## What are the limitations of exposure to IR?

Directive 96/29/, issued by EURATOM (the European atomic energy authority), states that for members of the public (par. 2, art. 13) the limit for effective dose shall be 1 mSv per year. However, in certain circumstances, a higher effective dose may be authorised in a single year, provided that the average over five consecutive years does not exceed 1 mSv per year.<sup>5</sup>

Dose limits have not been fixed for patients undergoing diagnostic examinations and medical treatments, volunteers collaborating with patients' care and volunteers taking part in research programmes. In addition to the principle of justification, which we will analyse later, other useful parameters have been defined to assess the radiological risk to patients:

- the equivalence of an examination using the standard thorax X-ray
- the equivalence with the natural exposure produced by an examination, calculated in additional years of exposure
- the additional risk of contracting cancer.

The absolute measurement of the absorbed dose can be specified by these parameters, aimed at giving a more immediate and concrete evaluation.<sup>6</sup>

In this way, a thorax CT, with a dose of 7.7 mSv, is equivalent to 385 standard thorax X-rays. This bears an additional risk of 1/2564, and produces an exposure comparable to 3.6 years of natural radiation (see Table 1).

The dose for each test absorbed by an individual patient is very variable and only an approximate value can be given; the absorbed dose depends on patient constitution and on the equipment used. Tables of mean values with an acceptable approximation can be created and can be used to compute the exposure over a certain period of time.

Directive 97/43/EURATOM expressly states the role of 'the Prescriber' in the radiological procedure and recommends a rigorous and steady application of the principle of justification.<sup>7</sup> According to this principle:

Medical exposure referred to in Article 1 (2) shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to

**Table 1** Equivalence of some examinations with the standard thorax X-ray, with natural exposure and additional risk of cancer

X-ray examination	Dose (mSv)	Equivalence to thorax X-ray	Equivalence to natural exposure	Additional risk of cancer
Thorax	0.02	1	3 days	1/million
Cranium	0.07	3.5	11 days	1/300 000
Abdomen	1	50	4 months	1/30 000
Lumbar spine	1.3	65	7 months	1/15 000
Skull	1.7	85	1 year	1/10 000
CT thorax	7.7	385	3.7 years	1/2500
CT abdomen/pelvis	8.8	440	4.5 years	1/2000

society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation.

Moreover:

all individual medical exposures shall be justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved. If a type of practice involving a medical exposure is not justified in general, a specific individual exposure of this type could be justified in special circumstances, to be evaluated on a case-by-case basis.

Therefore the principle of justification expresses the motivation to carry out an X-ray examination, taking into account two crucial factors: the real utility and necessity of the test.

Another fundamental principle is that of 'optimisation', according to which:

All doses due to medical exposure for radiological purposes except radio-therapeutic procedures referred to in Article 1 (2) shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors.

Before prescribing a diagnostic test that implies IR exposure, it is therefore essential to consider whether:

- the test really is useful for the patient (the concept of 'usefulness' should be examined in detail; many tests can be considered useful for a general diagnostic purpose but they do not influence the therapeutic intervention and the disease evolution)
- adequate information cannot be obtained from previous diagnostic investigations on the patient
- it is not possible to carry out an alternative test taking into account the effectiveness, advantages

and risks of the techniques which have the same purpose but do not require IR exposure

- the repetition of the test, to monitor a health problem, is consistent with the progression and the resolution time of the disease, and should not be performed more frequently than necessary.

It is also important to take into account that the risk of cancer is greater for prematurely exposed patients, and this risk seems to persist throughout the lifetime.<sup>8</sup>

### Computerised medical records systems in family practice

In Italy, it is usually the general practitioner who prescribes patient tests, although specialists can prescribe the tests themselves when diagnostic tests are needed to answer a clinical question. Test results are generally sent to the general practitioner and recorded in the practice's computerised medical records system (CMRS). For this reason, the number and the type of tests requiring IR undergone by each patient should be easily obtained from the CMRS. If the database was able to automatically calculate the dose of IR received by patients over the previous five years, it would represent an important means of decisional support to the general practitioner, in relation to the principle of justification.

We carried out this study to assess, through the analysis of data extracted from a CMRS ordinarily used by Italian general practitioners, if it is possible to compute, with a fair degree of accuracy, the cumulative exposure to IR for diagnostic purposes for each patient in the previous five years. This would support the doctor's assessment of the justification, every time a test or a treatment was prescribed that would expose the patient to IR.

## Method

A recent editorial by Michael S Lauer in the *New England Journal of Medicine*<sup>9</sup> suggested that:

the professional ordering a test must consider the degree of the previous radiation exposure of the patient for diagnostic and non-diagnostic aims, at least in the last five years, informing the patient correctly.

As for the patients' point of view, a recent survey<sup>10</sup> carried out in Michigan has shown that, even if they are aware that the CT is a source of radiation, most of the subjects interviewed were not aware of the quantity of the absorbed dose nor the related risks.

More information about the examination prescribed, in addition to the dose of IR likely to have been absorbed in the last five years, would make the patient aware of the related personal radiological risk.

We randomly extracted data on 120 patients from the database of our family practice that includes four doctors with 5200 patients in total. The patients were both male and female, aged from 15 to 64 years and were divided into three age classifications: 15 to 34, 35 to 49 and 50 to 64.

For each of the patients whose data we extracted, all radiological tests prescribed in the previous five years were entered into a special spreadsheet, so that we could calculate the cumulative exposure to IR. The spreadsheet was created using open source software (Open Office); rows of the spreadsheet listed the doses in mSv of the different types of test, and columns showed the tests requiring IR exposure undergone by each patient in the last five years. We were thus able to compute each patient's overall exposure.

Few conditions are necessary to calculate a good approximation of the patient's cumulative dose. First, the patients must have been registered on the general practitioner's list for at least five years, in order to calculate the total dose. Therefore, we excluded and replaced six patients who had been recorded on a list for less than five years.

Another important limitation on the calculation of the patient's overall exposure is admission to hospital in the previous five years. X-ray tests are often carried out during hospitalisation, and they are not recorded in the general practitioner's database (and sometimes not mentioned in the hospital discharge letter), even though the CMRS generally includes the patient's referral for hospital admission. Furthermore, it is not easy to calculate the doses absorbed during hospitalisation.

Finally, it is necessary to underline that the exposure to radiation for each test depends on the characteristics of the radiological equipment and the constitution of the patient; for this reason it is not possible to know the exact absorbed dose, but it is possible to use

updatable tables that express mid-values, obtained from national and international literature.

## Results

Some problems occurred during the input of the data extracted from the CMRS. Sometimes two recorded requests for the same test, within a short interval of time, were found for the same patient. We generally considered these to be a repetition, caused by the loss of the X-ray request form due to bureaucratic reasons; in this case one of the two items usually did not include a report. Therefore, we omitted from the spreadsheet any X-ray request without a report (e.g. two mammographies within three months), considering multiple entries only in cases where the reports were present (e.g. two X-rays of the ankle in two months for a fracture of the tibial malleolus).

Sometimes single X-ray requests without reports were found. In this case it was not possible to know if the patient had ever undergone the test or if they really underwent it without bringing the report to their general practitioner. In our study, radiological investigations without reports were not entered into the spreadsheet.

The resulting spreadsheet listed the IR exposure of the previous five years for each of the 120 patients extracted from the CMRS. The cumulative results are reported in Table 2. There are no significant differences among the three age groups.

Of the 120 patients, 69 (57.5%) had undergone at least one radiological test in the previous five years, without taking into account those carried out during possible hospitalisations.

The most prescribed radiological test was the teeth panoramic radiography: 24 patients, 1 in 5 of the total number, had undergone this test. The ratio was higher for the patients in the age group 15–34 (1 in 4).

## Discussion

If CMRS automatically computes the exposure to radiation over the previous five years for each patient, and displays this value in a window at the moment the clinician orders a test that involves IR, the general practitioner can better enforce the principle of justification on the basis of such data, and would be able to inform the patient about the possible risk related to the new test.

Even if it is not possible to define a risk threshold, the recommendation of the 96/23/EURATOM directive

**Table 2** Exposure (in mSv) radiation in the last five years of 120 patients randomly extracted out of 5200 in a family practice of the Lecce health district

	$\geq 2.5$ mSv/5 years	$\geq 5$ mSv/5 years	$\geq 10$ mSv/5 years
Total ( $n=120$ )	35.83% (43)	26.67% (32)	6.7% (8)
Age			
15–34 ( $n=40$ )	35.00% (14)	27.50% (11)	2.50% (1)
35–49 ( $n=40$ )	30.50% (13)	30.00% (12)	7.50% (3)
50–64 ( $n=40$ )	40.00% (16)	22.50% (9)	10.00% (4)

**Table 3** Problems noticed during the extraction of the radiological tests from the database and possible solutions for manual and automatic calculation

Problem	Solution for manual calculation	Suggested solution for automatic calculation
Two requests for the same test within a short time period	X-ray request without report removed from the calculation	Remove the most recent request without report
Radiological test result without report	Requests without report removed from the calculation	Removed, but listed in a box for confirmation with the patient
Absorbed dose depending on the equipment used	Use of tables with mid-values	Annual update of internal tables used for automatic calculation
Exposure during hospitalisation not computable		Point out in a box possible hospitalisations in the past five years

for subjects exposed to IR (not to exceed a dose of 5 mSv every five years) could be taken as the level above which the patient should be informed about the increasing radiological risk produced by the new test.

The problems that arose during the data analysis, the way they were solved when data was input manually into the spreadsheet and the way these could be solved by a programmed automatic calculation, are entered in Table 3.

The routine used in the CMRS for automatic calculation could be programmed to automatically remove those X-ray requests without a report that are repeated within a six-month period. These requests without reports could be highlighted within a box so that, for example, when the doctor orders a new X-ray test he/she is prompted to check with the patient whether the test requested earlier was actually carried out or not.

As hospital admission is usually recorded in the CMRS, a database could also highlight a possible hospital admission within the previous five years.

Finally, in order to compute each exposure with acceptable approximation, internal tables of the CMRS

concerning the adsorbed dose for each examination should be updated every year.

## Conclusions

Using the databases maintained by general practitioners, it is possible to obtain a good approximation of the exposure to radiation over the previous five years for each patient, in order to support the doctor in the application of the principle of justification and to allow the patient to be more informed when agreeing to X-ray investigations.

CMRS could automatically compute the dose absorbed in the previous five years, highlighting it in a box when the doctor is prescribing a radiological test. Therefore, it would be appropriate for software firms to equip the databases used by general practitioners with a suitable program. Future research could test this scenario to assess whether the implementation of the automatic calculation of the IR exposure by CMRS increases the appropriateness of X-ray examinations.

The database, in family medicine, may represent an important decisional support for the doctor in caring for his/her own patients.

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#### CONFLICTS OF INTEREST

None.

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