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The risks related to iatrogenic radiation from medical imagining are frequently underestimated and rarely explained to patients: findings from a mixed methods investigation (survey and qualitative study).

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Title: The risks related to iatrogenic radiation from medical imagining are frequently underestimated and rarely explained to patients: findings from a mixed methods investigation (cross sectional study and discussion group).

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Abstract

Objective: We use both quantitative and qualitative methodology to assess the current knowledge and practices regarding radiation safety in a sample of clinicians who order imaging tests in their daily practice; explore the challenges they face when addressing the potential risk on the health of their patients and to discuss the best approach to inform patients about the risk of radiation exposure.

Design: A quantitative and qualitative evaluation through a survey and focal groups.

Setting: San Juan Hospital, Alicante and Dr Peset Hospital, Valencia (Southeast Spain) and a sample of clinicians from Spanish scientific societies.

Participants: Radiologists and physicians (both residents and consultants): respiratory medicine, general practitioners, haematology, neurology, urology, accident and emergency, oncology, cardiology, orthopaedics and surgery.

Primary and secondary outcome measures: Physicians' knowledge and practices regarding radiation safety and the best approach to inform patients about benefits and risks.

Results: Nearly 80% of the clinicians surveyed had never heard of the European recommendations on Radiation Protection and Safety. Less than 10% of the clinicians surveyed identified correctly the risk associated with abdominal X-ray, intravenous urography or barium enema. 31.7% of the clinicians surveyed reported that they inform the patients about the risks associated with medical imaging and this proportion was significantly higher among GPs (Adjusted OR 4.32; CI 95% 1.75 to10.77; p=0.002). All of the participants agreed that the most appropriate way to present information was a table with a list of imaging tests and their corresponding radiation equivalence in terms of chest X-rays and environmental radiation exposure, as well as cancer risk associated with each imaging test.

Conclusions: The risks related to iatrogenic radiation from medical imagining are frequently underestimated and rarely explained to patients. With a clear understanding of the risk and proper communication tools, clinicians will be able to accurately inform patients about that risk.

Article summary section: Strengths and limitations of this study.

- This is the first study to investigate about the best information to improve patient–clinician discussions regarding risks and benefits of imaging, showing that clinicians preferred communicating risks verbally and helped by a table showing the radiation equivalence.
- The strength of this study lays on the application of the qualitative methodology together with the analysis of quantitative method to detail those barriers related with the communication with patient in the clinical practice.
- Those clinicians who answered the survey electronically could be more interested in radiation safety than those who did not;
- We designed our own survey for evaluating medical doctor knowledge and awareness on radiation safety and cannot rule out any issues with validity.

Introduction

An increase in the use of medical imaging in clinical practice[1] fuels concern about radiation exposure and cumulative risk of cancer[2]. The European Union (EU) legislation sets out a series of directives regarding radiation protection and now includes the safe use of ionizing radiation in medical practice. The revised 'Basic Safety Standards Directive' was adopted in 2013 by all member states[3], who must bring into force laws, regulations and other administrative provisions to comply with this directive by 6th of February 2018.

One key innovation in the revised directive was the need to record the radiation dose received by each patient undergoing a medical imaging test, with particular attention to computerized tomography (CT) or procedures involving interventional radiology[3]. The transposition of the directive into national law will require the participation of all stakeholders involved, but clinicians themselves have a key role. For example, if they are to discuss the risks and benefits of carrying out a new imaging test with their patients, they will need a clear understanding of the effective dose received by each test, and the health risk associated with each particular dose of radiation exposure. Previous studies have reported sub-optimal knowledge about radiation among clinicians[4-6], which explains in part why they tend not to undertake this discussion with their patients[7].

In the last few years, several initiatives have strived to increase clinician awareness of radiation exposure and protection[8-10]. One such example is the European Union Guidelines on radiation protection, education, and the training of medical professionals[11]. Unfortunately, there is no data about the impact of these initiatives.

Hence, it is essential to establish the current level of clinicians' awareness of the data currently available regarding iatrogenic radiation exposure and the main barriers that they experienced when translating it in terms of the benefits and risks to their patients. Moreover, exploring variation in their awareness and practices regarding radiation safety, according to factors such as medical specialty or professional category, will be useful in order to design targeted strategies to reduce unnecessary radiation exposure and to improve compliance with the EU's Basic Safety Standards Directive.

Most of the studies carried out in this area have centred on quantitative evaluations of clinicians' knowledge about excess radiation exposure associated with imaging, using surveys[4-6, 13]. Although useful, such studies can miss important aspects, such as perceived difficulties in discussing the risks and benefits of imaging with patients. Moreover, other potential challenges faced when trying to integrate questions of radiation safety into their daily practice are more appropriately addressed using qualitative methodology. For example, radiologists and clinicians can easily reflect on whether their conduct and attitudes contribute positively to patients' perceptions of benefits and safety of imaging tests and, thus, toward patient cooperation[14]. A previous qualitative study showed that displaying clinically relevant radiation exposure information may improve the discussion with patients when ordering a new test[15]. However, although some authors detailed the different strategies to improve communication about medical radiation benefits and risk[7], there is no data about the best information to inform patients.

In this study we use both quantitative and qualitative methodology to assess the current knowledge and practices regarding radiation safety in a sample of clinicians who order imaging tests in their daily practice; explore the challenges they face when addressing the potential risk on the health of their patients and to discuss the best approach to inform patients about the risk of radiation exposure.

2. Material and methods

2.1 Design

We carried out a quantitative and qualitative evaluation through a survey and focal groups in order to achieve a comprehensive picture of physicians' knowledge and attitudes towards the health risk associated with medical imaging.

2.2 Quantitative study

Participants

We selected radiologists and physicians (both residents and consultants) from a selection of the medical specialities which tend to request a substantial number of imaging tests[16] such as respiratory medicine, urologists, surgeons, general practitioners and haematologists.

Procedure

Radiologists and the other physicians participating were contacted and invited to take part in the study using different sources: in person or through scientific societies, or scientific meetings.

To collect the information of interest we designed a survey to be administered either through a google spread sheet, for those contacted through their respective scientific societies or in person. Below, we present in detail the procedure used by each medical specialty:

- Radiologists: All the radiologists working at San Juan Hospital, Alicante (N = 14) and Dr Peset Hospital, Valencia (N =16), and a sample of radiologists attending the 32nd Spanish National Meeting in Radiology in 2014 were contacted and surveyed in person (N = 60).
- The rest of the radiologists (N =45), pneumologists (N=123) and hematologists (N=75) answered the survey using the google spread sheets.

- All urologists working at both participating hospitals (San Juan Hospital, Alicante and Dr Peset Hospital, Valencia) were contacted and answered the survey in person (N=14).
- Surgeons were surveyed either in person (N=44) (working at both participating hospitals (San Juan Hospital, Alicante and Dr Peset Hospital, Valencia) or using the google spread sheets (N=40).
- General practitioners: The majority of general practice medical doctors working in primary care centers associated with Dr Peset Hospital answered the survey in person (N=45).

In order to assess the possibility of selection bias due to the different procedures when answering the survey, we compared the characteristics and results between those physicians who answered the questionnaire electronically with those who completed it in person and there were not differences. All the surveys were completed between April 2014 and April 2015.

Survey design

We developed a survey *ad hoc* that included the following items grouped into three different categories: 1) personal data, such as sociodemographic characteristics, number of years in practice and professional category (consultant or resident); 2) data related with doctors' knowledge, such as previous formal training in radiation safety, awareness of current European recommendations[8], knowledge about radiation exposure associated with diagnostic examinations and the belief that there is a link between lifetime risk for cancer and imaging tests, and 3) attitudes towards informing patients about risks associated with medical imaging and their responsibility in the education of patients (annex I). The survey was piloted by a number of medical staff prior to use, and adaptations were made to improve clarity before use.

Statistical analysis

All information that identified the survey participants was removed before analysis. Basic descriptive statistics were obtained for each question using SPSS 22.0 (IBM). Cumulative frequency and percentage values for all responses were estimated. Associations between groups were analysed using the Pearson Chi^2 test, with $P<0.05$ considered statistically significant. The effect of diverse explicative variables was considered by means of a stratified analysis and unconditional logistic regression was used (95% confidence intervals). A multivariate logistic regression model was built applying a stepwise procedure to enter variables in the model.

2.3 Qualitative study

Participants

Two focus groups were conducted separately in two hospitals in the Autonomous Community of Valencia, Spain, (San Juan de Alicante Hospital and Doctor Peset Hospital in Valencia) in May 2015. The focal group in San Juan de Alicante Hospital was composed of clinicians from the following specialties: radiology, haematology, neurology, urology, respiratory medicine, accident and emergency, and surgery. In the Doctor Peset Hospital, the focal group included clinicians from the specialties of radiology, neurology, oncology, cardiology, respiratory medicine and orthopedics.

Procedure

The participating clinicians represented a convenience sample from the two centres. The group was not intended to be a representative sample, but rather, the purpose was to get a general sense of their knowledge regarding radiation exposure and what is, in their opinion, the most important information to be communicated to the patient when they order an imaging test. To do this they were informally invited to join the focus group by the researchers of the study. The two groups used an identical protocol and procedure, which began with a short presentation by the head of the radiology department in each hospital and with a presentation of the results previously obtained in the quantitative surveys. Physicians were asked to describe their specialty and the care setting in which they worked (in-patient, out-patient, accident and emergency). The focus group discussions lasted between 45-60 minutes and were audio recorded.

Focus group guides

The research team developed a semi-structured focus group protocol to guide the discussion based on a literature review of exposure radiation topics and on the main results obtained in the quantitative survey. The protocol was divided into two main themes: a) the information that the patients should receive before undergoing an imaging test, for instance, the specific information about risks associated with medical imaging, information on alternative tests and participation of the patients in decisions, and b) the participants assessed three potential information sheets to be given to patients detailing the radiation exposure risk associated with imaging to determine which they felt would be easiest for the patients to understand.

These information sheets (annex II) were: a) the official information given in current clinical practice in these hospitals; b) an adapted radiation equivalence table[7], showing the effective radiation dose received by the different imaging tests under study expressed as radiation exposure units (u) equivalent to one chest X-ray. The table also showed the radiation equivalence of each test corresponding with one year's natural environmental radiation exposure in different geographical locations, as well as the cancer risk associated with each test, and c) a figure showing a visual representation of the cancer risk associated with radiation of each imaging test (compared to environmental radiation exposure), this last one designed by the authors.

Data analysis

Demographic data were summarized for all study participants using descriptive statistics. Audio-recordings were transcribed literally and notes from the interviewers were used for later analysis. All personal identifiers were removed.

First, a careful transcription reading was made and the text then split up into meaningful information units. These units were coded following a mixed strategy (emerging and predefined codes according to the study objectives), and categories were developed on the basis of grouping codes with the same theme.

Finally, the points of agreement and disagreement were analysed and triangulation (cross validation) of the results was performed to qualitatively analyse the degree of agreement.

Results

1. Quantitative study

A total of 515 medical doctors completed the survey (table 1); 299 (58.1%) submitted the questionnaire electronically and 216 (41.9%) in person. Just over one quarter of the respondents were radiologists (135, 26.2%), nearly one in ten were general practitioners (GPs) and the rest were from other hospital-based clinical specialties such as respiratory medicine (123, 23.9%), surgery (84, 16.3%), haematology (75, 14.6%), or urology (14, 2.7%). Overall, the clinicians were experienced, with a median of 15 years of clinical practice. Nearly three-quarters of the respondents had finished their residency and were classified as consultants or higher. The majority worked in health facilities pertaining to the National Health Service. There were significant differences in the characteristics of the radiologists, general practitioners and other clinical specialties. Generally speaking the non-radiology hospital specialists tended to be older, more experienced and there was a lower proportion of residents (table 1). Moreover, they were more likely to have completed the questionnaire on-line compared to the radiologists and the general practitioners.

Over half of the survey participants reported that they had received training regarding the radiation exposure associated with medical imaging (63.5%) table 2. This varied greatly according to medical specialty given than nearly all radiologists (92.6%) had received the training, in contrast with the other hospital based clinical services (50.0%) and GPs (76.1%).

Nearly 80% of the clinicians surveyed had never heard of the European recommendations on Radiation Protection and Safety, and accordingly only 26.8% of them were aware of the regulation regarding the need to justify all radiological tests

(Table 2). Even among radiologists, only 42.2% claimed to have heard of the European recommendations, although more of them knew of the requirement to justify the use of all radiological tests (60%), table 2. Among the 138 hospital clinicians surveyed who reported that they were aware of the regulation regarding the need to justify all radiological tests, only 42 (30.4%) of them said they actually adhered to this regulation in their daily clinical practice. The proportion of GPs that followed this regulation was higher than for the hospital-based specialties (p=0.006). When asked about any difficulty regarding justifying all radiological tests they ordered in their daily practice, only 43 clinicians responded. The most common challenge faced was conflicts between the radiologists and the clinician ordering the test (19, 43%), while 8 clinicians expressed that sometimes they felt pressured to order the test by the patients (18%), and 6 (14%) mentioned avoiding legal problems. Overall, the differences observed about receiving training on radiation safety or being aware of the European guidelines was highest among radiologists compared to other clinical services or general practitioners, and these differences remained significant after adjusting for age, years of clinical practice, professional category and method for responding to the questionnaire (table 3).

The clinicians were asked to consider the amount of radiation absorbed by patients undergoing different medical imaging tests and to judge it in terms of 1) cancer risk and 2) equivalence to the number of chest x-rays; using a multiple choice tick-box method. Generally speaking, the clinicians tended to underestimate the cancer risk associated with medical imaging (figure 1). Less than 10% of the clinicians surveyed responded correctly for abdominal X-ray, intravenous urography or barium enema; all estimating that the risk involved was significantly lower than available estimates. Among imaging tests with virtually no radiation risk, the clinicians were much more likely to select the correct risk level, although surprisingly some of the hospital specialists and GPs believed that magnetic resonance imaging (MRI) was associated with radiation risk, especially if it involved contrast. Abdominal computerized tomography (CT) and pulmonary ventilation/perfusion scan generated a much more varied response from the clinicians, and there was clearly some awareness among them that these tests have an increased cancer risk. Nevertheless, only 57 (15.0%) and 65 (17.1%) of the clinicians selected the correct cancer risk estimate for each of the tests, and there was a general tendency to underestimate. Information regarding equivalence to chest X-rays showed a similar picture and can be found in supplementary data, figure S1. There were no significant differences between the medical specialties, generally speaking all clinicians tended to underestimate the cancer risk involved with imaging tests.

Overall, 31.7% clinicians surveyed reported that they always inform the patients about the risks associated with medical imaging (table 4); although this proportion was significantly higher among GPs (56.6%). This favourable practice by GPs remained after adjusting for sex, age, years of clinical practice, professional level, and questionnaire response method (Adjusted OR 4.32; CI 95% 1.75 to10.77; p=0.002). Clinicians who had received training on radiation exposure associated with medical imaging, were more likely to inform the patient about potential risks (Adjusted OR 1.94; CI 95% 1.13 to 3.33; p=0.016; adjusted for sex, age, years of clinical practice, professional level, questionnaire response method and medical specialty), as were those who were aware of the European recommendations on Radiation Protection and Safety (data not shown). The information provided tended to be oral, although 47 (25%) clinicians said they provided both oral and written information to their patients regarding cancer risk. Nearly half of those that gave information to their patients judged it to be “not much” and “easy to understand”; and among the 105 (63%) who commented on impact of the information on the patient, half felt if had no effect (51, 49%), some felt it made patients feel calm or safe (17.16%), while others felt discussing radiation risk leads to fear (24, 23%) or mistrust (13, 8%).

2. Qualitative study

Overall, 22 radiologists and other clinical specialists participated in the two focal groups, 12 of whom were female (55%). Most of the clinicians admitted to ordering unnecessary imaging tests because patients requested them. With regard to why patient's request medical imaging, the clinicians stated:

'Patients tend to be more reassured by the number of imaging tests they receive rather than the doctor's medical opinion'

'They think that imaging tests are beneficial because they have always been used'.

Overall, the clinicians considered that is was important for patients to be informed about the benefits from tests but recognised the difficulty of talking about risks without creating undue concern. Although this point generated intense discussion, all finally agreed that it is first necessary to explain the benefits of the test:

'First of all, the patient should know that the image test improves his/her health, and after, patients should be informed about whether the imaging test they are going to have involves radiation exposure'

'If we talk with patients about test benefits and risks, this can even help avoid unnecessary tests'

Although it was not a universally accepted topic, there was significant concern among the participants regarding whether health professionals themselves know that radiation exposure accumulates throughout an individual's life.

'Neither the doctors nor the patients know that radiation accumulates'.

All participants agreed on the importance of giving information to patients to allow them to participate in the final decision when ordering an imaging test. Providing different clinical management alternatives was seen as an important component in the process:

'I think that alternatives are important. The patients must be given alternative options'

Informing the patients on the life-time accumulation of radiation was also judged as relevant:

'Both patients and doctors should consider how much radiation patients have received during their lives in order to take responsible decisions.

It was agreed that the explanation should be simple in order to avoid confusion and given the clinicians' limited time.

'If we give them too much information, it takes too much time'.

Finally, the focal groups discussed the best approach to explain the radiation dose to patients. Equivalence to X-rays and natural radiation was considered the most appropriate although they agreed that showing the patients the low individual risk of cancer associated with each test is also appropriate.

'I think it is very difficult, but the best way could be through a comparison with the equivalent in chest X-rays'.

'An X-ray can be compared with the natural environmental dose of radiation, in other words, the dose is similar to 3 or 4 days of exposure to natural radiation'.

'It is best to show patients that the risk of cancer related to each radiation exposure is minimal'

All of the participants agreed that the most appropriate way to present information was a table showing a number of imaging tests and their corresponding radiation equivalence in terms of chest X-rays and environmental radiation exposure, as well as cancer risk associated with each imaging test.

While all the participants considered that although the written information is essential, they agreed it should be accompanied by patient-doctor discussion and stressed that this does not always occur in practice:

'What is happening in many hospitals is that they ask the patients to sign the informed consent without any type of explanation about potential risks'.

Discussion

This study highlights the difficulties in translating the new European Directive 2013/59/Euratom[3] into clinical practice, particularly the new requirements concerning the need to consider radiation exposure when ordering imaging tests and the requirement to inform the patient about the risk of radiation exposure. The Member States had 4 years to transpose this Directive into national legislation, including relevant aspects as radiation protection education, training and provision of information. However, two years later in 2015, improvements in knowledge on the risk of radiation exposure among practicing clinicians remains insufficient to manage constructive discussions with patients about the benefits and risks of medical imaging tests in light of the accumulative radiation exposure. The use of quantitative and qualitative methods to address this problem shows the low clinicians' awareness of radiation exposure and protection and the lack of effective patient–clinician discussions about the risk of radiation exposure. To our knowledge, this is the first study that analyse which is the best approach for clinicians to discuss the potential risks with patients. Our results show that the preferred method by clinicians is using a table which shows the radiation equivalence in terms of x-rays, environmental exposure or associated cancer risk is.

The results of the survey confirm that clinicians are in general unaware of radiation exposure associated with imaging tests. While a high percentage of clinicians (63.3%) indicated they had received formal training on radiation safety, it was alarming they did not know about current European regulations related with radiation exposure. Furthermore, proportion of clinicians that correctly identified the radiation dose estimates and risk cancer associated with imaging tests was worryingly low. Less than one in five of the clinicians surveyed knew the cancer risk of an abdominal CT and very few were aware of the risk associated with the performance of a barium enema or urography.

Our results are similar to those of previous studies[6, 13, 17, 18] carried out before 2013, when the new Directive was approved. The value of this study is that it shows that the surveyed participants still underestimated the radiation exposure from a CT examination compared to an x-ray, and a large proportion of providers are unaware of the lifetime risk of carcinogenesis associated with imaging tests. Lee et al[6] showed that only 13% of the radiologists estimated the dose from the CT correctly. In other studies [12, 13], assessing the knowledge of non-radiologic physicians, around 34% of them correctly estimated the effective dose from a thoracic CT scan. In contrast, another study [19] showed an inadequate knowledge among radiologists, but particularly in non-radiologists. In our study, radiologists showed the highest percentage of correct dose estimates in all the imaging tests, although their knowledge was not as good as expected.

This better result for radiologists reflects the formal training that they received during their residence period at the hospital. Physicians from other specialties should, therefore, receive a special training in radiation safety. Nevertheless, this better result was not reflected in the level of knowledge regarding increased cancer risk, and this was similar for all specialties.

Most previous studies have focused on the clinicians' knowledge about radiation exposure from CT. However, according to our study, clinicians have less knowledge on radiation exposure associated with other imaging diagnostic tests such as urography or barium enema, which are also associated with significant radiation exposure.

Awareness of radiation exposure is crucial when ordering an imaging test: if clinicians underestimate the health risk, patients could be exposed to unjustifiable ionizing radiation; if he/she overestimates the risk and avoids medical imaging, patients may not receive pertinent tests thereby delaying timely diagnosis with potentially serious consequences[20].

In accordance with previous studies [4], our results suggest that clinicians do not regularly discuss the potential risks with patients. Nevertheless, given that according to the qualitative study clinicians explained that the general population think that all the imaging tests are beneficial, it is essential to explain the potential risk and benefits associated to the test. In this sense, and according to the qualitative study, clinicians preferred communicating risks verbally helped by a table showing the radiation equivalence (referring to exposure in terms of x-rays, environmental exposure or associated cancer risk) rather than by a figure or text. However, clinicians stated a significant concern regarding whether health professionals themselves know that radiation exposure accumulates throughout an individual's life, which could limit the communication with the patient. Moreover, patients should be given alternative options detailing the risks and benefices associated with each option, especially where the potential risk of radiation-induced malignancy is high,

This study had some limitations. In light of any validated tool for evaluating medical doctor knowledge and awareness on radiation safety, we designed our own and cannot rule out any issues with validity. Yet it reflects the opinions and attitudes of doctors that perform or prescribe imaging studies with ionising radiation.

As with all surveys, the results are limited by the diligence of the individuals filling out the survey. Clinicians were not aleatory selected to be included in the study. We selected all the radiologists, urologists and surgeons working at both participating hospitals (San Juan Hospital, Alicante and Dr Peset Hospital, Valencia) and the GPs working in all primary care centers associated with Dr Peset Hospital (including residents and attending) to answer the survey in person. However, those clinicians who answered the survey electronically could be more interested in radiation safety than those who did not; in this case, the results could be even worse.

The generalisability of the results could be affected by having only two recruitment centres for some of the specialists included in the study. However, there were general hospital centres including physicians of different levels of clinical hierarchy.

Qualitative methods often rely on smaller sample sizes to allow for participant account to be analysed in sufficient detail for the results to be meaningful. However, the participants in this study were a mix of medical specialities from different two health centres.

There are many situations where the quantitative analysis does not cover the entire reality, lacking some relevant information[10]. By applying the qualitative methodology together with the analysis of quantitative method, the study was able to detail those barriers related with the communication with patient in the clinical practice.

In conclusion, given the key role of clinicians to comply with the European legislation before 2018, there is an urgent need to educate them about radiation exposure and associated risks. Increased clinicians' awareness will allow them to make informed decisions when ordering imaging tests and to limit the amount of radiation that patients receive. Communication between patients and medical staff about radiation risk is currently lacking. Without a clear understanding of the risk, clinicians will never be able to accurately inform patients about that risk, even though they cite it as an important part of the imaging test ordering process in clinical practice.

Contributors: BL, IHA, JV and IGA conceived of the study, designed the study and obtained funding. BL, LAP, MAP, JV, IGA, MLD, MFL and MG acquired the data. BL prepared the data and BL, LAP and MG interpreted statistical analyses. BL coordinated the data management. BL, LAP and MG did the statistical analyses and drafted the data tables. All authors co-wrote the manuscript. All authors critically revised the paper for important intellectual content and approved the final version.

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Ethical approval: Institutional Review Board approval for the study was obtained from Miguel Hernández University, Hospital San Juan Alicante and Hospital Dr Peset, Valencia. Informed consent was sought from all study participants for qualitative study.

Transparency declaration: The authors affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Tables:

Table 1: Clinical and demographic characteristics of the 515 clinicians included in the survey according to medical specialty:

Variable	Total N=515	Radiology N=135	Clinical services[1] N = 334	GP N = 46	p-value
Sex (n, %)					<0.001
Men	238 (46.4)	64 (47.4)	168 (50.3)	6 (13.0)	
Women	275 (53.6)	71 (52.6)	164 (49.1)	40 (87.0)	
NA[2]	2 (0.4)		2 (0.6)		
Age (median, IQR[3])	42.0 (32.0-52.75)	35 (29-51)	45 (34-53)	31 (26-42)	<0.001
Professional level (n, %)					<0.001
Resident	113 (21.9)	51 (37.8)	35 (10.5)	27 (58.7)	
Consultant	380 (73.8)	78 (57.8)	292 (87.4)	10 (21.7)	
NA[2]	22 (4.3)	6 (4.4)	7 (2.1)	9 (19.6)	
Years of practice (median, IQR[3])	15.0 (6.0-25.0)	9 (4-24)	18 (8-26)	4 (2-15)	<0.001
Type of health facility (n, %)					0.247

Public	405 (78.6)	100 (74.1)	265 (79.3)	40 (87.0)	
Private	32 (6.2)	11 (8.1)	19 (5.7)	2 (4.3)	
Both public and private	71 (13.8)	21 (15.6)	48 (14.4)	2 (4.3)	
NA[2]	7 (1.4)	3 (2.2)	2 (0.6)	2 (4.3)	
Questionnaire response method (n, %)					<0.001
Electronically	299 (58.1)	45 (33.3)	253 (75.7)	1 (2.2)	
In person	216 (41.9)	90 (66.7)	81 (24.3)	45 (97.8)	

[1] including respiratory medicine, surgery, haematology, urology or other (cardiology, neurology, oncology, otolaryngologist, digestive, internal medicine); [2] information not available; [3] Inter-quartile range.

Table 2. Training, awareness and practices regarding radiation safety according to medical specialty

Variable	Total Frequency N = 515	Radiology N =135	Clinical services N=334	General practice N=46	p-value
Ever received training on radiation exposure associated with medical imaging					<0.001
Yes	327 (63.5)	125 (92.6)	167 (50.0)	35 (76.1)	
No	187 (36.3)	9 (6.7)	167 (50.0)	11 (23.9)	
NA	1 (0.2)	1 (0.7)			
Context of training (if received)					<0.001
During undergraduate training	82 (25.1)	10 (8.0)	64 (38.3)	8 (22.9)	
During hospital residence	96 (29.4)	59 (47.2)	30 (18.0)	7 (20.0)	
At work	45 (13.8)	15 (12.0)	26 (15.6)	4 (11.4)	
Multiple courses in more than one context	104 (20.2)	41 (32.8)	47 (28.1)	16 (45.7)	
Awareness of the European					<0.001

recommendations on radiation protection and safety					
Yes	105 (20.4)	57 (42.2)	41 (12.3)	7 (15.2)	
No	405 (78.6)	75 (55.6)	292 (87.4)	38 (82.6)	
NA	5 (1.0)	3 (2.2)	1 (0.3)	1 (2.2)	
Awareness of the regulation regarding the need to justify all radiological tests					<0.001
Yes	138 (26.8)	81 (60.0)	44 (13.2)	13 (28.3)	
No	374 (72.6)	53 (39.3)	289 (86.5)	32 (69.6)	
NA	3 (0.6)	1 (0.7)	1 (0.3)	1 (2.2)	
If yes, adherence of this regulation in daily practice					0.577
Yes	98 (71.0)	56 (69.1)	33 (75.0)	9 (69.2)	
No	37 (26.8)	24 (29.6)	9 (20.5)	4 (30.8)	
NA	3 (2.2)	1 (1.2)	2 (4.5)	0	

Table 3: Multi-variable model relating medical speciality with training, awareness and practices regarding radiation safety.

	Radiology	Clinical services				General practice			
	OR	**OR (95%CI)**	**p-value**	**AdjOR[1] (95%CI)**	**p-value**	**OR (95%CI)**	**p-value**	**AdjOR[1] (95%CI)**	**p-value**
Ever received training on radiation exposure associated with medical imaging	1	0.07 (0.03-0.15)	<0.001	0.09 (0.04-0.19)	<0.001	0.23 (0.09-0.607)	0.003	0.21 (0.06-0.77)	0.018
Awareness of the European recommendations on radiation protection and safety	1	0.18(0.10-0.29)	<0.001	0.19(0.11-0.33)	<0.001	0.24 (0.10-0.58)	0.002	0.31 (0.12-0.80)	0.015
Awareness of the regulation regarding the need to justify all radiological tests	1	0.10 (0.06-0.16)	<0.001	0.14 (0.08-0.23)	<0.001	0.27 (0.139-0.55)	<0.001	0.22 (0.09-0.53)	0.001

[1] Adjusted for sex, age, years of clinical practice and professional level.

Table 4: Practices and opinions regarding shared decision making and discussing the risks of medical imagings with patients

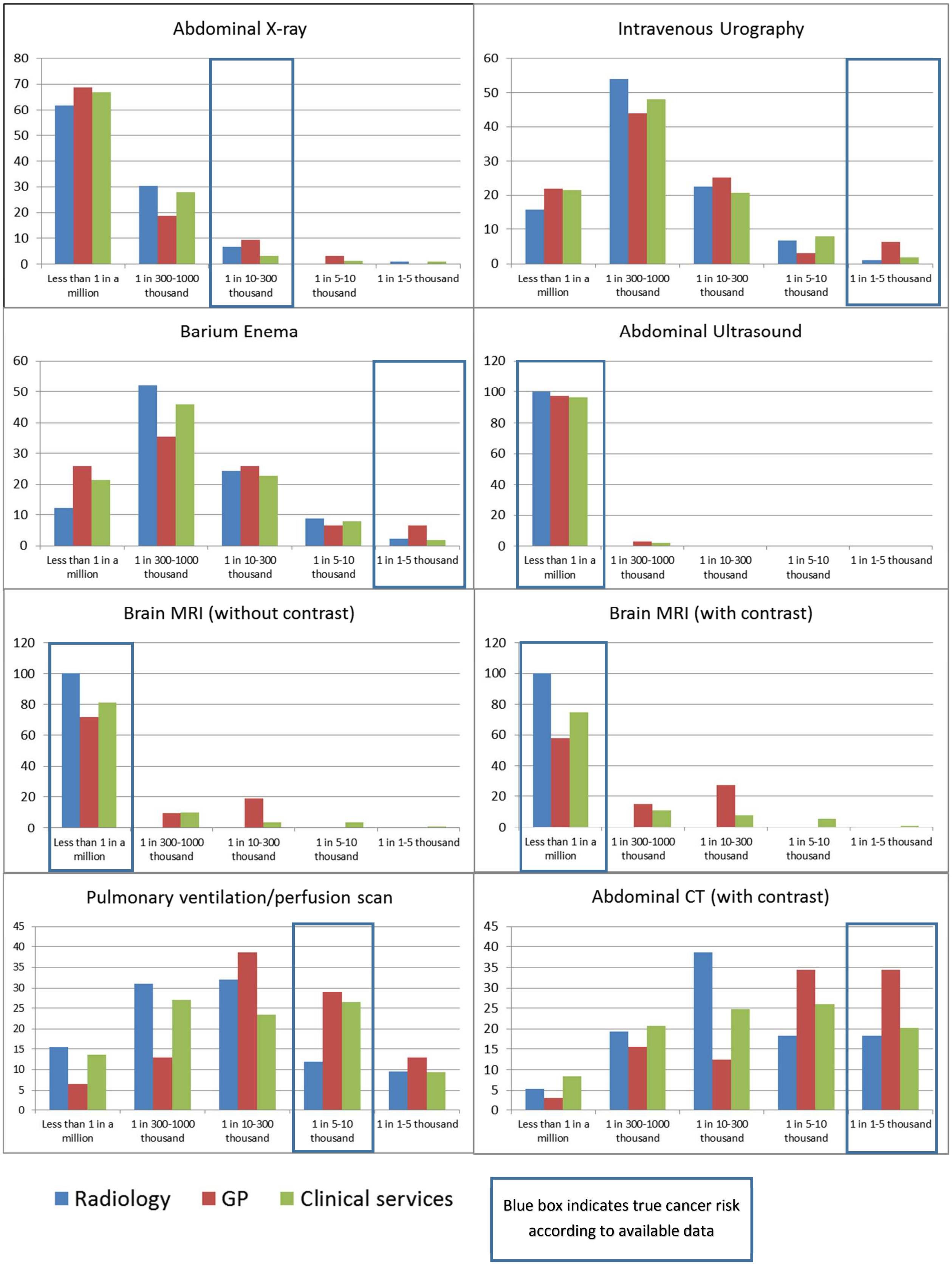
Variable	Total (515)	Radiology (135)	Clinical services (334)	GP (46)	*p-valor*
Do you inform patients about the radiation risks associated with medical imaging?					*0.002*
No	337 (65.4)	89 (65.9)	230 (68.9)	18 (39.1)	
Yes, always	163 (31.7)	41 (30.4)	96 (28.7)	26 (56.5)	
Yes, sometimes	4 (0.8)	1 (0.7)	2 (0.60)	1 (2.2)	
NA	11 (2.1)	4 (3.0)	6 (1.8)	1 (2.2)	
If yes, type of information given					*0.001*
Oral	94 (56.3)	13 (31.0)	60 (61.2)	21 (77.8)	

Written	28 (16.8)	12 (28.6)	15 (15.3)	1 (3.7)	
Both oral and written	43 (25.7)	17 (40.5)	22 (22.4)	4 (14.8)	
NA	2 (1.2)	0	1 (1.0)	1 (3.7)	
Amount of information given					*0.422*
Very little	18 (3.5)	4 (9.5)	11 (11.2)	3 (11.1)	
Not much	75 (14.6)	15 (35.7)	45 (15.9)	15 (55.6)	
Just enough	69 (13.4)	22 (52.4)	39 (39.8)	8 (29.6)	
A lot	1 (0.2)	1 (2.4)	0	0	
Too much	2 (0.4)	0	2 (2.0)	0	
NA	2	0	1 (1.0)	1 (3.7)	
Opinion regarding patients' understanding					*0.287*
Very difficult to understand	4 (2.4)	2 (4.8)	2 (2.0)	0	
Difficult to understand	24 (14.4)	8 (19.0)	15 (15.3)	1 (3.7)	
Can be understood without too much difficulty	56 (33.5)	17 (40.5)	28 (28.6)	11	

				(40.7)	
Easy to understand	78 (46.7)	15 (35.7)	50 (51.0)	13 (48.1)	
Very easy to understand	2 (1.2)	0	1 (1.0)	1 (3.7)	
NA	3 (1.8)	0	2 (2.0)	1 (3.7)	
Do you share the decision to order an imaging test with the patient?					*<0.001*
No	120 (23.3)	52 (38.5)	58 (17.4)	10 (21.7)	
Yes	108 (21.0)	16 (11.9)	67 (20.1)	25 (54.3)	
Sometimes	4 (0.8)	2 (1.5)	0	2 (4.3)	
NA	283 (55.0)	65 (48.1)	209 (62.6)	9 (19.6)	

Figure 1: Clinicians' responses to a question regarding the cancer risk associated with different medical imaging tests

- Proportion of clinicians selecting each response (%)



Annex I: Survey

The following survey aims to assess the health professionals' knowledge about the radiation risk associated with imaging tests, as well as knowledge of the available recommendations. Please complete the sections of the entire survey and if you have any comment, you can fill in the comments section at the end of it.

Identification data:

- Sex:
- Age:
- Specialty:
- Professional level (resident or consultant):
- Years of practice (including specialty):
- Type of health facility (public, private or both):

1- Have you received training on radiation exposure associated with medical imaging?

Yes ( ) No ( )

If yes, context of training

During undergraduate training () During hospital residence () At work () Other (explain)

2- Awareness of the European recommendations on radiation protection and safety?

Yes ( ) No ( )

If yes, which aspects do you know?

____

3- Awareness of the regulation regarding the need to justify all radiological tests?

Yes ( ) No ( )

If yes, adherence of this regulation in daily practice

Yes ( ) No ( )

Which dificulties do you find when applying them?

____

4- What is the relation between the radiation doses of a chest x-ray compared with the annual dose received by a person related environmental radiation?

1/100 ( ) 1/10 ( ) Igual ( ) 10 times more ( ) 100 times more ( ) I do not know ( )

5- How much radiation is absorbed by the patient when having a chest x-ray? (MSv - milliSieverts - derived unit of effective dose of radiation) (mSv - milliSieverts)

0.02 mSv ( ) 0.2 mSv ( ) 2 mSv ( ) 20 mSv ( ) 200 mSv ( ) I do not know ( )

6- If a chest x-ray is assigned one unit, how many units would absorb a patient in the following tests?

IMAGING TEST	0-1 u	1-10 u	10-50 u	50-100 u	100-500 u
Abdomen x-ray					
IVU					
Barium enema					
Abdominal ultrasound					
Brain MRI (with contrast)					
Brain MRI (without contrast)					
Scanner ventilation / perfusion lung					
Abdominal CT (contrast)					

7- What is the risk of cancer associated with radiation absorbed in each of the following tests?

Imaging test	< 1/1.000.000	1/1.000.000-1/300.000	1/300.000-1/10.000	1/10.000-1/5.000	1/5.000-1/1.000
Abdomen x-ray					
IVU					
Barium enema					
Abdominal ultrasound					
Brain MRI (with contrast)					
Brain MRI (without contrast)					
Scanner ventilation / perfusion lung					
Abdominal CT (contrast)					

8- Do you inform patients about the radiation risks associated with medical imaging? Yes, always ( ) Yes, sometimes ( ) No ( )

If yes:

8.1 Type of information given:

Oral () Written (informed consent () Both ()

8.2 Amount of information given:

Very little ( ) Not much ( ) Just enough ( ) A lot ( ) Too much ( )

8.3. La *información* que les suministra le parece:
Very difficult to understand ( ) Difficult to understand ( ) Can be understood without too much difficulty ( ) Easy to understand ( ) Very easy to understand ( )

8.4. Do you share the decision to order an imaging test with the patient?

Yes ( ) No ( )

Which are the main limitations to do it?

8.7 What information should be provided to the patient?

Observations:

Annex II: Information sheets to be given to patients detailing the radiation exposure risk associated with imaging, which were evaluated by the clinician participants.

a) The official information given in current clinical practice in these hospitals.

Most frequently associated risks

Irradiation:

A CT is associated with ionizing radiation (x-rays) so it should be avoided in the case of pregnant women. In the rest of the population, the CT is only carry out when there is a precise indication to do it, because it has associated a high amount of radiation exposure.

As a guideline it should be noted that the dose received by the patient with the practice of a Skull CT scan radiation (2.3 mSv) is equivalent to 115 chest X-rays and is similar to 3 years of background radiation. Spiral CT (8mSv) radiation is equivalent to 400 chest X-rays and 3.5 years of background radiation. Abdominal CT scan is equivalent to 500 chest X-rays and 4.5 years of background radiation.

The potential risk of radiation includes a slightly elevated risk of cancer within a few years. This risk is less than 0.5%, so it can be considered very low compared to the normal incidence of cancer in the population, which is 33% for women and 50% for men, according to the American Society of Cancer.

b) An adapted radiation equivalence table[7], showing the effective radiation dose received by the different imaging tests under study expressed as radiation exposure units (u) equivalent to one chest X-ray.

Most frequently associated risks

Irradiation:

A CT is associated with ionizing radiation (x-rays) so it should be avoided in the case of pregnant women. In the rest of the population, the CT is only carry out when there is a precise indication to do it, because it has associated a high amount of radiation exposure.

As a guideline, the following table shows the equivalence between different imaging tests. For instance, the skull CT, with a radiation dose associated of 2.3 mSv, is equivalent to 115 chest x-rays and 1 year of background radiation (a person is exposed to 2.4 mSv of background radiation by year). The risk of cancer associated is from 1/ 100.000 to 1/10.000 (which is 33% for women and 50% for men, according to the American Society of Cancer)

Imaging test	**Effective dose (mSv)**	**Chest x-rays equivalent**	**Background Equivalent Radiation Time**	**Probability of Cancer from Imaging (%)**
Chest x-rays	0.02		3 days	1/1.000.000
Skull CT	2.3	115	1 year	1/100.000 to 1/10.000
Chest CT	8	400	3.6 years	1/10.000 to 1/1.000
Abdomen CT	10	500	4.5 years	1/1.000

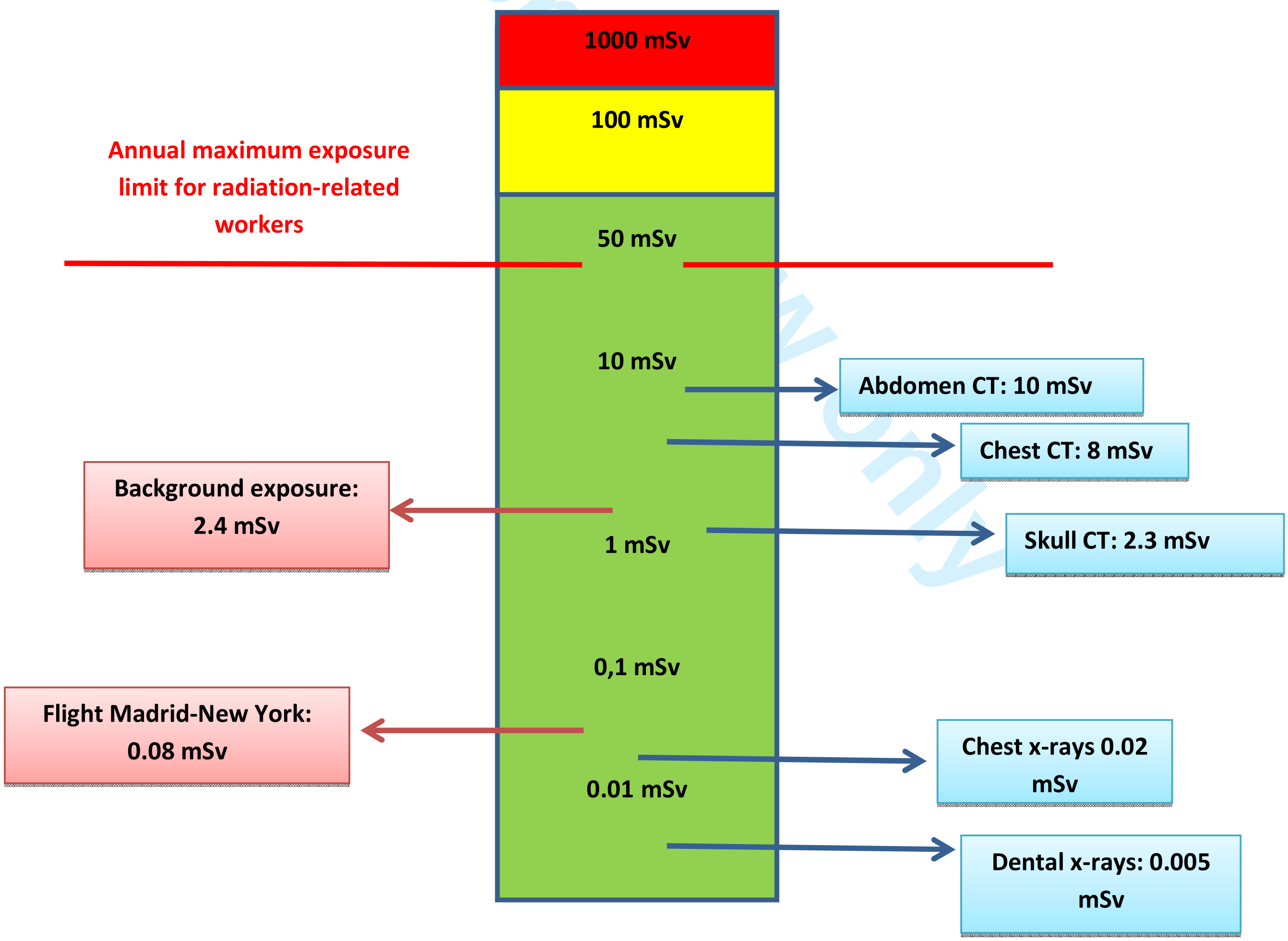
c) A figure showing a visual representation of the cancer risk associated with radiation of each imaging test (compared to environmental radiation exposure.

Most frequently associated risks

Irradiation:

A CT is associated with ionizing radiation (x-rays) so it should be avoided in the case of pregnant women. In the rest of the population, the CT is only carry out when there is a precise indication to do it, because it has associated a high amount of radiation exposure.

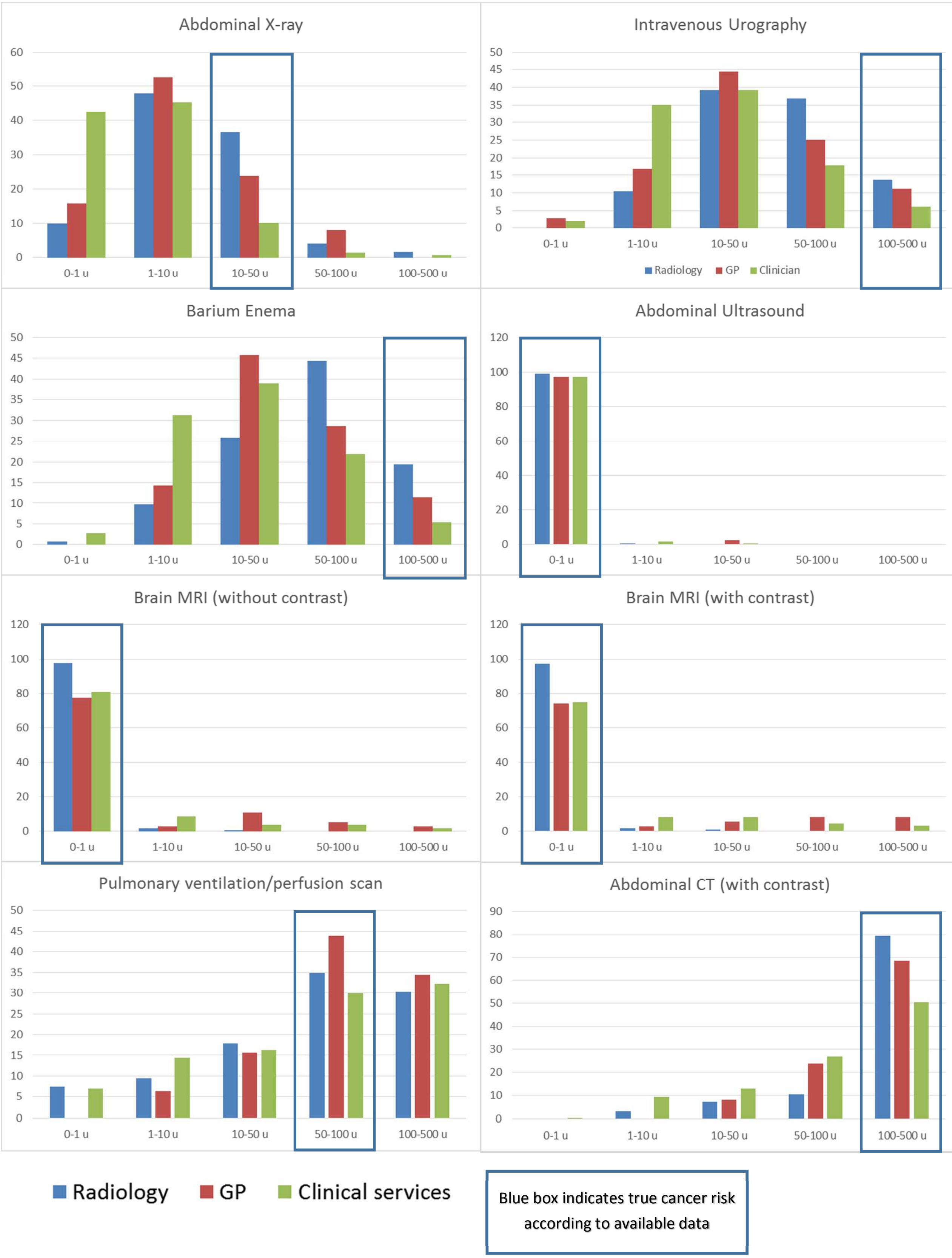
As a guidelines, the following graphs shows the equivalences between the radiation absorbed by each imaging test and other radiation sources, according to the risk: low (green), medium (yellow) and high (red):



Supplementary figure 1

Clinicians' responses to questions regarding radiation equivalence to chest X-ray of different medical imaging tests

- 1 chest X-ray = 1 unit (u)
- Proportion of clinicians selecting each response (%)



STROBE Statement—checklist of items that should be included in reports of observational studies

		Item No	Recommendation
YES Page 1	**Title and abstract**	**1**	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
			(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
	Introduction		
YES Page 6	Background/rationale	**2**	Explain the scientific background and rationale for the investigation being reported
YES Page 7	Objectives	**3**	State specific objectives, including any prespecified hypotheses
	Methods		
YES Page 8	Study design	**4**	Present key elements of study design early in the paper
YES Pages 8 (Quantitative) and 10 (Qualitative)	Setting	**5**	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
YES Pages 8 (Quantitative) and 10 (Qualitative)	Participants	**6**	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
			(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
YES Pages 9 (Quantitative) and 10 (Qualitative)	Variables	**7**	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
YES Pages 9 (Quantitative) and 10 (Qualitative)	Data sources/ measurement	**8***	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
YES Page 9	Bias	**9**	Describe any efforts to address potential sources of bias
NO	Study size	**10**	Explain how the study size was arrived at
YES Pages 10 (Quantitative) and 12 (Qualitative)	Quantitative variables	**11**	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
YES Pages 10 (Quantitative) and 12	Statistical methods	**12**	(*a*) Describe all statistical methods, including those used to control for confounding
			(*b*) Describe any methods used to examine subgroups and

(Qualitative)			interactions
			(*c*) Explain how missing data were addressed
			(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
			(*e*) Describe any sensitivity analyses

Continued on next page

	Results		
NA	Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
			(b) Give reasons for non-participation at each stage
			(c) Consider use of a flow diagram
YES Pages 13 (Quantitative) and 16 (Qualitative)	Descriptive data	**14***	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
			(b) Indicate number of participants with missing data for each variable of interest
			(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
YES Pages 13-15 (Quantitative)	Outcome data	**15***	*Cohort study*—Report numbers of outcome events or summary measures over time
			Case-control study—Report numbers in each exposure category, or summary measures of exposure
			Cross-sectional study—Report numbers of outcome events or summary measures
YES Pages 13-15 (Quantitative) and 16-18 (Qualitative)	Main results	**16**	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
			(*b*) Report category boundaries when continuous variables were categorized
			(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
NA	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
	Discussion		
YES Page 19	Key results	**18**	Summarise key results with reference to study objectives
YES Pages 21-22	Limitations	**19**	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
YES Pages 20-21	Interpretation	**20**	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
YES Page 22	Generalisability	**21**	Discuss the generalisability (external validity) of the study results
	Other information		
YES page 23	Funding	**22**	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Evaluation of clinicians' knowledge and practices regarding medical radiological exposure: findings from a mixed methods investigation (survey and qualitative study)

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Primary Subject Heading:	Radiology and imaging
Secondary Subject Heading:	Medical education and training
Keywords:	radiation exposure, quantitative methods, qualitative methods., imaging test

SCHOLARONE™
Manuscripts

Title: Evaluation of clinicians' knowledge and practices regarding medical radiological exposure: findings from a mixed methods investigation (survey and qualitative study)

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Key words: radiation exposure, imaging test, clinicians, qualitative methods, quantitative methods.

Abstract

Objective: To assess the impact of initiatives aiming to increase clinician awareness of radiation exposure; to explore the challenges they face when communicating with patients; and, to study what they think is the most appropriate way of communicating medical radiological exposure to patients.

Design: A quantitative and qualitative evaluation through a survey and focal groups.

Setting: San Juan Hospital and Dr Peset Hospital (Southeast Spain) and clinicians from Spanish scientific societies.

Participants: The surveys were answered: a) in person (216): all the radiologists (30), urologists (14) and surgeons (44) working at both participant hospitals; a sample of GPs from the catchment area of one hospital (45), and a consecutive sample of radiologists attending a scientific meeting (60); and b) electronically through Spanish scientific societies (299): radiologists (45), pneumologists (123), haematologists (75), and surgeons (40). Clinicians were not randomly selected and thus, the results are limited by the diligence of the individuals filling out the survey.

Primary and secondary outcome measures: Clinicians' knowledge and practices regarding medical radiological exposure, and what they considered is the most appropriate for communicating.

Results: Nearly 80% of the clinicians surveyed had never heard of the European recommendations. Less than 20% of the clinicians surveyed identified correctly the radiation equivalence dose of intravenous urography or barium enema. 31.7% of them reported that they inform the patients about the long-term potential risks of ionizing radiation. All participants agreed that the most appropriate way to present information

was a table with a list of imaging tests and their corresponding radiation equivalence dose in terms of chest X-rays and background radiation exposure.

Conclusions: Medical radiological exposure is frequently underestimated and rarely explained to patients. With a clear understanding of the medical radiological exposure and proper communication tools, clinicians will be able to accurately inform patients.

Article summary section: Strengths and limitations of this study.

- This is the first study to investigate what clinicians who participated in this study thought to be the most appropriate tool for communicating medical radiological exposure to patients. Results showed that clinicians preferred to communicate this information verbally supported by a table showing the radiation equivalence dose.
- The strength of this study lies in the application of qualitative methodology together with the analysis of quantitative information to understand the barriers clinicians face when communicating medical radiological exposure to patients in their daily clinical practice.
- The clinicians who answered the survey electronically could be more interested in medical radiological exposure than those who did not;
- We designed our own survey for evaluating medical doctor knowledge and awareness on medical radiological exposure and cannot rule out any issues with validity.

Introduction

An increase in the use of medical imaging in clinical practice[1] fuels concern about radiation exposure and long-term potential risks of ionizing radiation from medical imaging [2]. The European Union (EU) legislation sets out a series of directives regarding radiation protection and now includes the safe use of ionizing radiation in medical practice. The revised 'Basic Safety Standards Directive' was adopted in 2013 by all member states[3], who must bring into force laws, regulations and other administrative provisions to comply with this directive by 6th of February 2018.

One key innovation in the revised directive is the need to record the radiation dose received by each patient undergoing a medical imaging test, with particular attention to computerized tomography (CT) or procedures involving interventional radiology[3]. The transposition of the directive into national law will require the participation of all stakeholders involved, but clinicians themselves have a key role. For example, if they are to discuss the potential risks and benefits of carrying out a new imaging test with their patients, they will need a clear understanding of the effective dose received by each test. Previous studies have reported sub-optimal knowledge about radiation among clinicians[4-6], which explains in part why they tend not to undertake this discussion with their patients[7].

In the last few years, several initiatives have strived to increase clinician awareness of radiation exposure and protection[8-11]. One such example is the European Union Guidelines on radiation protection, education, and the training of medical professionals[12]. Unfortunately, there is no data about the impact of these initiatives.

Hence, it is essential to assess the impact of these proposals in the level of clinicians' awareness of the data currently available on radiation exposure and the main barriers that they experienced when translating it in terms of the benefits and potential risks to their patients. Moreover, exploring variation in their awareness and practices regarding medical radiological exposure, according to factors such as medical specialty or professional category, will be useful in order to design targeted strategies to reduce unnecessary radiation exposure and to improve compliance with the EU's Basic Safety Standards Directive.

Most of the studies carried out in this area have centred on quantitative evaluations of clinicians' knowledge about excess radiation exposure associated with imaging, using surveys[4-6, 13]. Although useful, such studies can miss important aspects, such as perceived difficulties in discussing the risks and benefits of imaging with patients. Moreover, other potential challenges faced when trying to integrate questions of medical radiological exposure into their daily practice are more appropriately addressed using qualitative methodology. For example, radiologists and clinicians can easily reflect on whether their conduct and attitudes contribute positively to patients' perceptions of benefits and medical radiological exposure of imaging tests and, thus, toward patient cooperation[14]. A previous qualitative study showed that displaying clinically relevant radiation exposure information may improve the discussion with patients when ordering a new test[15]. However, although some authors detailed the different strategies to improve communication about medical radiation benefits and potential risk[7], there is no data about what the clinicians think is the most appropriate way to communicate this potential risk to patients.

In this study we use both quantitative and qualitative methodology to assess the impact of several initiatives aiming to increase clinician awareness of radiation exposure. We assess the current knowledge and practices regarding medical radiological exposure in a sample of clinicians who order imaging tests in their daily practice; explore the challenges they face when addressing the potential risk on the health of their patients, and to study what they think is the most appropriate way to communicate medical radiological exposure to patients.

2. Material and methods

2.1 Design

We carried out a quantitative and qualitative evaluation through a survey and focal groups in order to achieve a comprehensive picture of clinicians' knowledge and attitudes towards medical radiological exposure.

2.2 Quantitative study

Participants

We selected radiologists and clinicians (both residents and consultants) from a selection of the medical specialities that tend to request a substantial number of imaging tests[16] such as respiratory medicine, urologists, surgeons, general practitioners and haematologists.

Procedure

Radiologists and the other physicians participating were contacted and invited to take part in the study using different sources: in person or through scientific societies, or scientific meetings.

To collect the information of interest we designed a survey to be administered either through a google spread sheet, for those contacted through their respective scientific societies, or in person. Below, we present in detail the procedure used by each medical specialty:

- Radiologists: All the radiologists working at San Juan Hospital, Alicante (14/14, 100%) and Dr Peset Hospital, Valencia (16/16, 100%), and a consecutive sample of radiologists attending the 32nd Spanish National Meeting in Radiology in 2014 were contacted and surveyed in person (60/2000, 3%). (We included in parenthesis the total number of radiologists working in each hospital and radiologists attending the national meeting).

- The rest of the radiologists (45/3000, 1.5%), pneumologists (123/2010, 6.2%) and hematologists (75/2000, 3.8%) answered the survey using the google spread sheets. (We included in parenthesis the total number of clinicians belonging to each scientific society)
- All urologists working at both participating hospitals (San Juan Hospital, Alicante and Dr Peset Hospital, Valencia) were contacted and answered the survey in person (14/14, 100%) (We included in parenthesis the total number of urologists working in each hospital).
- Surgeons were surveyed either in person (44/44, 100%) (working at both participating hospitals (San Juan Hospital, Alicante and Dr Peset Hospital, Valencia) or using the google spread sheets (40/5000, 0.8%). (We included in parenthesis the total number of surgeons working in both hospital and the total number of surgeons belonging to their scientific society
- General practitioners: General practice medical doctors working in primary care centers associated with Dr Peset Hospital answered the survey in person (45/150, 30%).

In order to assess the possibility of selection bias due to the different procedures when answering the survey, we compared the characteristics and results between those physicians who answered the questionnaire electronically with those who completed it in person and there were not statistically significant differences. We compared the clinical and demographic characteristics (table 1), the training, awareness and practise regarding medical radiological exposure (table 2), practices and opinions regarding shared decision making with patients (table 3) and clinicians' responses regarding radiation equivalence to chest X-ray of different medical imaging tests (figure 1) using the Pearson Chi^2 test for categorical variables and Mann–Whitney U test for continuous variables, with P<0.05 considered statistically significant. All the surveys were completed between April 2014 and April 2015.

Survey design

We developed a survey *ad hoc* that included the following items grouped into three different categories: 1) personal data, such as sociodemographic characteristics, number of years in practice and professional category (consultant or resident); 2) data related with doctors' knowledge, such as previous formal training in medical radiological exposure, awareness of current European recommendations[8], knowledge about radiation exposure associated with different diagnostic examinations, and 3) attitudes towards informing patients about medical radiological exposureand their responsibility in the education of patients (annex I). The survey was piloted by a number of medical staff prior to use, and adaptations were made to improve clarity before use. The pre-piloted survey was answered by 4 radiologists and 1 clinician working at San Juan Hospital. After the pilot, a question related with the clinician's context of training on radiation exposure was included ('*If yes, context of training: During undergraduate training () During hospital residence () At work () Other (explain)*, and questions 4-7, which ask about doses associated with diagnostic examinations, were transformed into multiple choice to facilitate answering and analysis of the questionnaire.

This modified questionnaire was piloted in a different sample of 3 radiologists and 1 clinician working at the same hospital.

Statistical analysis

All information that identified the survey participants was removed before analysis. Basic descriptive statistics were obtained for each question using SPSS 22.0 (IBM). Cumulative frequency and percentage values for all responses were estimated. Associations between groups were analysed using the Pearson Chi^2 test, with P<0.05

considered statistically significant. The effect of diverse explicative variables was considered by means of a stratified analysis and unconditional logistic regression was used (95% confidence intervals). A multivariate logistic regression model was built applying a stepwise procedure to enter variables in the model.

2.3 Qualitative study

Participants

Two focus groups were conducted separately in two hospitals in the Autonomous Community of Valencia, Spain, (San Juan de Alicante Hospital and Doctor Peset Hospital in Valencia) in May 2015. The focal group in San Juan de Alicante Hospital was composed of clinicians from the following specialties: radiology, haematology, neurology, urology, respiratory medicine, accident and emergency, and surgery. In the Doctor Peset Hospital, the focal group included clinicians from the specialties of radiology, neurology, oncology, cardiology, respiratory medicine and orthopedics.

Procedure

The participating clinicians represented a convenience sample from the two centres. The group was not intended to be a representative sample, but rather, the purpose was to get a general sense of their knowledge regarding radiation exposure and what is, in their opinion, the most important information clinicians thought to be communicated to the patient when they order an imaging test. To do this they were informally invited to join the focus group by the researchers of the study. The two groups used an identical protocol and procedure, which began with a short presentation by the head of the radiology department in each hospital and with a presentation of the results previously obtained in the quantitative surveys. Physicians were asked to describe their specialty and the care setting in which they worked (in-patient, out-patient, accident and emergency). The focus group discussions lasted between 45-60 minutes and were audio recorded.

Focus group guides

The research team developed a semi-structured focus group protocol to guide the discussion based on a literature review of exposure radiation topics and on the main results obtained in the quantitative survey. The protocol was divided into two main themes: a) the information that clinicians thought patients should receive before undergoing an imaging test, for instance, the specific information about medical radiation exposure, information on alternative tests and participation of the patients in decisions, and b) the participants assessed three potential information sheets to be given to patients detailing the radiation exposure associated with imaging to determine which they felt would be easiest for the patients to understand.

These information sheets (annex II) were: a) the official information given in current clinical practice in these hospitals; b) an adapted radiation equivalence table[7], showing the effective radiation dose received by the different imaging tests under study expressed as radiation exposure units (u) equivalent to one chest X-ray. The table also showed the radiation equivalence of each test corresponding with one year's natural background radiation exposure in different geographical locations, and c) a figure showing a visual representation of medical radiation exposure of each imaging test (compared to background radiation exposure), this last one designed by the authors.

Data analysis

Demographic data were summarized for all study participants using descriptive statistics. Audio-recordings were transcribed literally and notes from the interviewers were used for later analysis. All personal identifiers were removed.

First, a careful transcription reading was made and the text then split up into meaningful information units. These units were coded following a mixed strategy (emerging and predefined codes according to the study objectives), and categories were developed on the basis of grouping codes with the same theme.

Finally, the points of agreement and disagreement were analysed and triangulation (cross validation) of the results was performed to qualitatively analyse the degree of agreement.

Results

1. Quantitative study

A total of 515 medical doctors completed the survey (table 1); 299 (58.1%) submitted the questionnaire electronically and 216 (41.9%) in person. Just over one quarter of the respondents were radiologists (135, 26.2%), nearly one in ten were general practitioners (GPs) and the rest were from other hospital-based clinical specialties such as respiratory medicine (123, 23.9%), surgery (84, 16.3%), haematology (75, 14.6%), or urology (14, 2.7%). Overall, the clinicians were experienced, with a median of 15 years of clinical practice. Nearly three-quarters of the respondents had finished their residency and were classified as consultants or higher. The majority worked in health facilities pertaining to the National Health Service. There were significant differences in the characteristics of the radiologists, general practitioners and other clinical specialties. Generally speaking the non-radiology hospital specialists tended to be older, more experienced and there was a lower proportion of residents (table 1). Moreover, they were more likely to have completed the questionnaire on-line compared to the radiologists and the general practitioners.

Over half of the survey participants reported that they had received training regarding the radiation exposure associated with medical imaging (63.5%) (table 2). This varied greatly according to medical specialty given than nearly all radiologists (92.6%) had received the training, in contrast with the other hospital based clinical services (50.0%) and GPs (76.1%).

Nearly 80% of the clinicians surveyed had never heard of the European recommendations on Radiation Protection and Safety, and accordingly only 26.8% of them were aware of the regulation regarding the need to justify all radiological tests

(Table 2). Even among radiologists, only 42.2% claimed to have heard of the European recommendations, although more of them knew of the requirement to justify the use of all radiological tests (60%), table 2. Among the 138 hospital clinicians surveyed who reported that they were aware of the regulation regarding the need to justify all radiological tests, only 42 (30.4%) of them said they actually adhered to this regulation in their daily clinical practice. The proportion of GPs that followed this regulation was higher than for the hospital-based specialties (p=0.006). When asked about any difficulty regarding justifying all radiological tests they ordered in their daily practice, only 43 clinicians responded. The most common challenge faced was conflicts between the radiologists and the clinician ordering the test (19, 43%), while 8 clinicians expressed that sometimes they felt pressured to order the test by the patients (18%), and 6 (14%) mentioned avoiding legal problems. Overall, the differences observed about receiving training on medical radiological exposure or being aware of the European guidelines was highest among radiologists compared to other clinical services or general practitioners, and these differences remained significant after adjusting for age, years of clinical practice, professional category and method for responding to the questionnaire (table 4).

The clinicians were asked to consider the amount of radiation absorbed by patients undergoing different medical imaging tests and to judge it in terms of equivalence to the number of chest x-rays, using a multiple choice tick-box method. Figure 1 summarizes the results. In most cases, clinicians underestimated radiation doses. Less than 20% of the clinicians surveyed responded correctly for intravenous urography or barium enema; all estimating that the radiation dose involved was significantly lower than available estimates. Among imaging tests with no radiation dose, the clinicians were much more likely to select the correct level, although surprisingly some of the hospital specialists and GPs believed that magnetic resonance imaging (MRI) was associated with radiation, especially if it involved contrast. Abdominal computerized tomography (CT) and pulmonary ventilation/perfusion scan generated a much more varied response from the clinicians, and there was clearly some awareness among them that these tests involved a considerable amount of radiation.

There were no significant differences between the medical specialties, generally speaking, all clinicians tended to underestimate the radiation dose involved with imaging tests.

Overall, 31.7% clinicians surveyed reported that they always inform the patients about the medical radiation exposure (table 3); although this proportion was significantly higher among GPs (56.6%). This favourable practice by GPs remained after adjusting for sex, age, years of clinical practice, professional level, and questionnaire response method (Adjusted OR 4.32; CI 95% 1.75 to10.77; p=0.002). Clinicians who had received training on radiation exposure associated with medical imaging, were more likely to inform the patient about medical radiation exposure (Adjusted OR 1.94; CI 95% 1.13 to 3.33; p=0.016; adjusted for sex, age, years of clinical practice, professional level, questionnaire response method and medical specialty), as were those who were aware of the European recommendations on Radiation Protection and Safety (data not shown). The information provided tended to be oral, although 47 (25%) clinicians said they provided both oral and written information to their patients regarding medical exposure. Nearly half of those that gave information to their patients judged it to be "not much" and "easy to understand"; and among the 105 (63%) who commented on impact of the information on the patient, half felt if had no effect (51, 49%), some felt it made patients feel calm or safe (17.16%), while others felt discussing radiation long-term potential risk leads to fear (24, 23%) or mistrust (13, 8%).

2. Qualitative study

Overall, 22 radiologists and other clinical specialists participated in the two focal groups, 12 of whom were female (55%). Most of the clinicians admitted to ordering unnecessary imaging tests because patients requested them. With regard to why patient's request medical imaging, the clinicians stated:

'Patients tend to be more reassured by the number of imaging tests they receive rather than the doctor's medical opinion'

'They think that imaging tests are beneficial because they have always been used'.

Overall, the clinicians considered that is was important for patients to be informed about the benefits from tests but recognised the difficulty of talking about medical radiation exposure without creating undue concern. Although this point generated intense discussion, all finally agreed that it is first necessary to explain the benefits of the test:

'First of all, the patient should know that the image test improves his/her health, and after, patients should be informed about whether the imaging test they are going to have involves radiation exposure'

'If we talk with patients about test benefits and risks, this can even help avoid unnecessary tests'

Although it was not a universally accepted topic, there was significant concern among the participants regarding whether health professionals themselves know that the combined exposures (background exposure and medical imaging) add up throughout our lifetime and increase our risk of cancer over time[17]. *'Neither the doctors nor the patients know that each exposure to radiation builds up in our body'.*

All participants agreed on the importance of giving information to patients to allow them to participate in the final decision when ordering an imaging test. Providing different clinical management alternatives was seen as an important component in the process:

'I think that alternatives are important. The patients must be given alternative options'

Informing the patients on that combined exposures add up throughout our lifetime was also judged as relevant:

'Both patients and doctors should consider how much radiation patients have received during their lives in order to take responsible decisions.

It was agreed that the explanation should be simple in order to avoid confusion and given the clinicians' limited time.

'If we give them too much information, it takes too much time'.

Finally, the focal groups discussed what the clinicians thought was most appropriate for communicating the radiation dose to patients. Equivalence to X-rays and natural radiation was considered the most appropriate.

'I think it is very difficult, but the best way could be through a comparison with the equivalent in chest X-rays'.

'An X-ray can be compared with the natural background dose of radiation, in other words, the dose is similar to 3 or 4 days of exposure to natural radiation'.

All of the participants agreed that the most appropriate way to present information was a table showing a number of imaging tests and their corresponding radiation equivalence in terms of chest X-rays and background radiation exposure

While all the participants considered that although the written information is essential, they agreed it should be accompanied by patient-doctor discussion and stressed that this does not always occur in practice:

'What is happening in many hospitals is that they ask the patients to sign the informed consent without any type of explanation about medical radiation exposure'.

Discussion

This study highlights the difficulties in translating the new European Directive 2013/59/Euratom[3] into clinical practice, particularly the new requirements concerning the need to consider radiation exposure when ordering imaging tests and the requirement to inform the patient about the medical radiation exposure. The Member States had 4 years to transpose this Directive into national legislation, including relevant aspects as radiation protection education, training and provision of information. However, two years later in 2015, improvements in knowledge on the medical radiation exposure among practicing clinicians remains insufficient to manage constructive discussions with patients about the benefits and potential risks of medical imaging tests. The use of quantitative and qualitative methods to address this problem shows the low clinicians' awareness of radiation exposure and protection and the lack of effective patient–clinician discussions about it. To our knowledge, this is the first study that analyse what clinicians think is most appropriate for communicating the medical radiation exposure to patients. Our results show that the clinicians' preferred method is using a table, which shows the radiation equivalence in terms of x-rays and background exposure.

The results of the survey confirm that clinicians are in general unaware of radiation exposure associated with imaging tests. While a high percentage of clinicians (63.3%) indicated they had received formal training on medical radiological exposure, it was alarming they did not know about current European regulations related with radiation exposure. Furthermore, proportion of clinicians that correctly identified the radiation dose estimates was worryingly low. Less than one in four of the clinicians surveyed knew the radiation dose associated with a barium enema or urography.

Our results are similar to those of previous studies[6, 13, 18, 19] carried out before 2013, when the new Directive was approved. The value of this study is that it shows that the surveyed participants still underestimated the radiation exposure from a CT examination compared to an x-ray after several initiatives aiming to increase clinician awareness of radiation exposure were carried out. Lee et al[6] showed that only 13% of the radiologists estimated the dose from the CT correctly. In other studies [12, 13], assessing the knowledge of non-radiologic physicians, around 34% of them correctly estimated the effective dose from a thoracic CT scan. In contrast, another study [20] showed an inadequate knowledge among radiologists, but particularly in non-radiologists. In our study, radiologists showed the highest percentage of correct dose estimates in all the imaging tests, although their knowledge was not as good as expected.

This better result for radiologists reflects the formal training that they received during their residence period at the hospital. Physicians from other specialties should, therefore, receive a special training in medical radiological exposure. Most previous studies have focused on the clinicians' knowledge about radiation exposure from CT. However, according to our study, clinicians have less knowledge on radiation exposure associated with other imaging diagnostic tests such as urography or barium enema, which are also associated with significant radiation exposure.

Awareness of radiation exposure is crucial when ordering an imaging test: if clinicians underestimate the radiation dose, patients could be exposed to unjustifiable ionizing radiation. Moreover, clinicians should take into account patient's age, since the red bone marrow and brain are highly radiosensitive tissues, especially in childhood[21]. However, if he/she overestimates the radiation dose and avoids medical imaging, patients may not receive pertinent tests thereby delaying timely diagnosis with potentially serious consequences[22].

In accordance with previous studies [4], our results suggest that clinicians do not regularly discuss the medical radiation exposure with patients. The qualitative study showed, however, that clinicians think that the general population believes that all tests are beneficial. Therefore, empowering clinicians to discuss the risks as well as the benefits of the imaging tests is essential.

In this sense, and according to the qualitative study, clinicians preferred communicating medical radiation exposure verbally with the support of a table showing the radiation equivalence (referring to exposure in terms of x-rays, or background exposure) rather than by a figure or text. However, clinicians stated a significant concern regarding whether health professionals themselves know the combined radiation exposures add up throughout our lifetime, which could limit the communication with the patient.

Moreover, patients should be given alternative options detailing the potential risks and benefices associated with each option.

This study had some limitations. In light of any validated tool for evaluating medical doctor knowledge and awareness on medical radiological exposure, we designed our own and cannot rule out any issues with validity. Yet it reflects the opinions and attitudes of doctors that perform or prescribe imaging studies with ionising radiation. As with all surveys, the results are limited by the diligence of the individuals filling out the survey. Clinicians were not randomly selected to be included in the study. We selected all the radiologists, urologists and surgeons working at both participating hospitals (San Juan Hospital, Alicante and Dr Peset Hospital, Valencia) and the GPs working in all primary care centers associated with Dr Peset Hospital (including residents and attending) to answer the survey in person. However, those clinicians who answered the survey electronically could be more interested in medical radiological exposure than those who did not; in this case, the results could be even worse.

We assessed physician's knowledge of the medical radiation exposure, but we did not consider the evaluation of their awareness of the benefits of diagnostic imaging. As previous authors stated[23], we need to describe the risk in the context of the clinical benefit of imaging tests. Moreover, according to evidence[24], in many cases the numerical benefits of medical radiation exposures may outweigh the risks.

The generalisability of the results could be affected by having only two recruitment centres for some of the specialists included in the study. However, there were general hospital centres including physicians of different levels of clinical hierarchy.

Qualitative methods often rely on smaller sample sizes to allow participant account to be analysed in sufficient detail for the results to be meaningful. However, the participants in this study were a mix of medical specialities from different two health centres.

There are many situations where the quantitative analysis does not cover the entire reality, lacking some relevant information[10]. The analysis of the clinician-patient discussions may be limited if we only apply quantitative methods. Qualitative methods can give us an overview of clinicians' point of view when ordering medical imaging examinations involving ionizing radiation allowing us to detail those barriers related with the communication with patient in the clinical practice.

In conclusion, given the key role of clinicians to comply with the European legislation before 2018, there is an urgent need to educate them about medical radiation exposure. Increased clinicians' awareness will allow them to make informed decisions when ordering imaging tests and to limit the amount of radiation that patients receive. Communication between patients and medical staff about radiation exposure is currently lacking. Without a clear understanding of the medical radiation exposure, clinicians will never be able to accurately inform patients about benefits/long-term potential risk, even though they cite it as an important part of the imaging test ordering process in clinical practice.

Contributors: BL, IHA, JV and IGA conceived of the study, designed the study and obtained funding. BL, LAP, MAP, JV, IGA, MLD, MFL and MG acquired the data. BL prepared the data and BL, LAP and MG interpreted statistical analyses. BL coordinated the data management. BL, LAP and MG did the statistical analyses and drafted the data tables. All authors co-wrote the manuscript. All authors critically revised the paper for important intellectual content and approved the final version.

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Ethical approval: Institutional Review Board approval for the study was obtained from Miguel Hernández University, Hospital San Juan Alicante and Hospital Dr Peset, Valencia. Informed consent was sought from all study participants for qualitative study.

Transparency declaration: The authors affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Tables:

Table 1: Clinical and demographic characteristics of the 515 clinicians included in the survey according to medical specialty:

Variable	Total N=515	Radiology N=135	Clinical services[1] N = 334	GP N = 46	p-value
Sex (n, %)					<0.001
Men	238 (46.4)	64 (47.4)	168 (50.3)	6 (13.0)	
Women	275 (53.6)	71 (52.6)	164 (49.1)	40 (87.0)	
NA[2]	2 (0.4)		2 (0.6)		
Age (median, IQR[3])	42.0 (32.0-52.75)	35 (29-51)	45 (34-53)	31 (26-42)	<0.001
Professional level (n, %)					<0.001
Resident	113 (21.9)	51 (37.8)	35 (10.5)	27 (58.7)	
Consultant	380 (73.8)	78 (57.8)	292 (87.4)	10 (21.7)	
NA[2]	22 (4.3)	6 (4.4)	7 (2.1)	9 (19.6)	
Years of practice (median, IQR[3])	15.0 (6.0-25.0)	9 (4-24)	18 (8-26)	4 (2-15)	<0.001
Type of health facility (n, %)					0.247

Public	405 (78.6)	100 (74.1)	265 (79.3)	40 (87.0)	
Private	32 (6.2)	11 (8.1)	19 (5.7)	2 (4.3)	
Both public and private	71 (13.8)	21 (15.6)	48 (14.4)	2 (4.3)	
NA[2]	7 (1.4)	3 (2.2)	2 (0.6)	2 (4.3)	
Questionnaire response method (n, %)					<0.001
Electronically	299 (58.1)	45 (33.3)	253 (75.7)	1 (2.2)	
In person	216 (41.9)	90 (66.7)	81 (24.3)	45 (97.8)	

1 [1] including respiratory medicine, surgery, haematology, urology or other (cardiology,
2 neurology, oncology, otolaryngologist, digestive, internal medicine); [2] information not
3 available; [3] Inter-quartile range.

Table 2. Training, awareness and practices regarding medical radiological exposure according to medical specialty

Variable	Total Frequency N = 515	Radiology N =135	Clinical services N=334	General practice N=46	p-value
Ever received training on radiation exposure associated with medical imaging					<0.001
Yes	327 (63.5)	125 (92.6)	167 (50.0)	35 (76.1)	
No	187 (36.3)	9 (6.7)	167 (50.0)	11 (23.9)	
NA	1 (0.2)	1 (0.7)			
Context of training (if received)					<0.001
During undergraduate training	82 (25.1)	10 (8.0)	64 (38.3)	8 (22.9)	
During hospital residence	96 (29.4)	59 (47.2)	30 (18.0)	7 (20.0)	
At work	45 (13.8)	15 (12.0)	26 (15.6)	4 (11.4)	
Multiple courses in more than one context	104 (20.2)	41 (32.8)	47 (28.1)	16 (45.7)	

Awareness of the European recommendations on radiation protection and safety					<0.001
Yes	105 (20.4)	57 (42.2)	41 (12.3)	7 (15.2)	
No	405 (78.6)	75 (55.6)	292 (87.4)	38 (82.6)	
NA	5 (1.0)	3 (2.2)	1 (0.3)	1 (2.2)	
Awareness of the regulation regarding the need to justify all radiological tests					<0.001
Yes	138 (26.8)	81 (60.0)	44 (13.2)	13 (28.3)	
No	374 (72.6)	53 (39.3)	289 (86.5)	32 (69.6)	
NA	3 (0.6)	1 (0.7)	1 (0.3)	1 (2.2)	
If yes, adherence of this regulation in daily practice					0.577
Yes	98 (71.0)	56 (69.1)	33 (75.0)	9 (69.2)	
No	37 (26.8)	24 (29.6)	9 (20.5)	4 (30.8)	
NA	3 (2.2)	1 (1.2)	2 (4.5)	0	

Table 3: Practices and opinions regarding shared decision making and discussing the medical radiation exposure with patients.

Variable	**Total (515)**	**Radiology (135)**	**Clinical services (334)**	**GP (46)**	***p-valor***
Do you inform patients about medical radiation exposure?					*0.002*
No	337 (65.4)	89 (65.9)	230 (68.9)	18 (39.1)	
Yes, always	163 (31.7)	41 (30.4)	96 (28.7)	26 (56.5)	
Yes, sometimes	4 (0.8)	1 (0.7)	2 (0.60)	1 (2.2)	
NA	11 (2.1)	4 (3.0)	6 (1.8)	1 (2.2)	
If yes, type of information given					*0.001*
Oral	94 (56.3)	13 (31.0)	60 (61.2)	21 (77.8)	
Written	28 (16.8)	12 (28.6)	15 (15.3)	1 (3.7)	

Both oral and written	43 (25.7)	17 (40.5)	22 (22.4)	4 (14.8)	
NA	2 (1.2)	0	1 (1.0)	1 (3.7)	
Amount of information given					*0.422*
Very little	18 (3.5)	4 (9.5)	11 (11.2)	3 (11.1)	
Not much	75 (14.6)	15 (35.7)	45 (15.9)	15 (55.6)	
Just enough	69 (13.4)	22 (52.4)	39 (39.8)	8 (29.6)	
A lot	1 (0.2)	1 (2.4)	0	0	
Too much	2 (0.4)	0	2 (2.0)	0	
NA	2	0	1 (1.0)	1 (3.7)	
Opinion regarding patients' understanding					*0.287*
Very difficult to understand	4 (2.4)	2 (4.8)	2 (2.0)	0	
Difficult to understand	24 (14.4)	8 (19.0)	15 (15.3)	1 (3.7)	
Can be understood without too much difficulty	56 (33.5)	17 (40.5)	28 (28.6)	11 (40.7)	

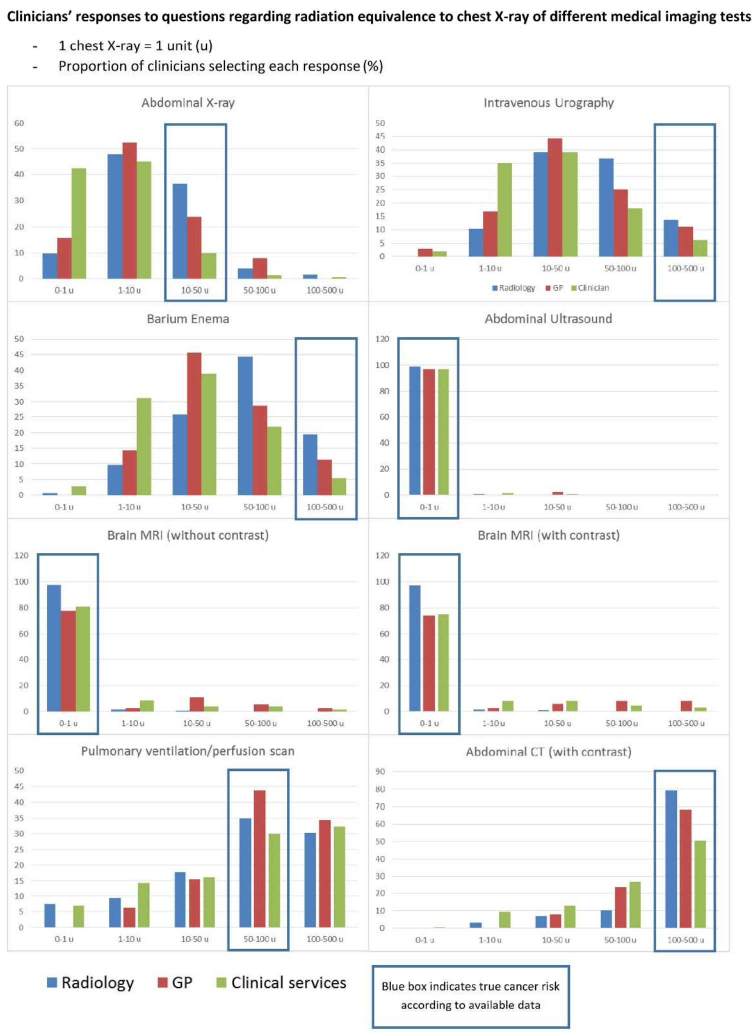
Easy to understand	78 (46.7)	15 (35.7)	50 (51.0)	13 (48.1)	
Very easy to understand	2 (1.2)	0	1 (1.0)	1 (3.7)	
NA	3 (1.8)	0	2 (2.0)	1 (3.7)	
Do you share the decision to order an imaging test with the patient?					*<0.001*
No	120 (23.3)	52 (38.5)	58 (17.4)	10 (21.7)	
Yes	108 (21.0)	16 (11.9)	67 (20.1)	25 (54.3)	
Sometimes	4 (0.8)	2 (1.5)	0	2 (4.3)	
NA	283 (55.0)	65 (48.1)	209 (62.6)	9 (19.6)	

Table 4: Multi-variable model relating medical speciality with training, awareness and practices regarding medical radiological exposure.

	Radiology	Clinical services				General practice			
	OR	OR (95%CI)	p-value	AdjOR[1] (95%CI)	p-value	OR (95%CI)	p-value	AdjOR[1] (95%CI)	p-value
Ever received training on radiation exposure associated with medical imaging	1	0.07 (0.03-0.15)	<0.001	0.09 (0.04-0.19)	<0.001	0.23 (0.09-0.607)	0.003	0.21 (0.06-0.77)	0.018
Awareness of the European recommendations on radiation protection and safety	1	0.18(0.10-0.29)	<0.001	0.19(0.11-0.33)	<0.001	0.24 (0.10-0.58)	0.002	0.31 (0.12-0.80)	0.015
Awareness of the regulation regarding the need to justify all radiological tests	1	0.10 (0.06-0.16)	<0.001	0.14 (0.08-0.23)	<0.001	0.27 (0.139-0.55)	<0.001	0.22 (0.09-0.53)	0.001

[1] Adjusted for sex, age, years of clinical practice and professional level.

40



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Annex I: Survey:

The following survey aims to assess the health professionals' knowledge about the radiation risk associated with imaging tests, as well as knowledge of the available recommendations. Please complete the sections of the entire survey and if you have any comment, you can fill in the comments section at the end of it.

Identification data:

- Sex:
- Age:
- Specialty:
- Professional level (resident or consultant):
- Years of practice (including specialty):
- Type of health facility (public, private or both):

1- Have you received training on radiation exposure associated with medical imaging?

Yes ( ) No ( )

If yes, context of training

During undergraduate training () During hospital residence () At work () Other (explain)

2- Awareness of the European recommendations on radiation protection and safety?

Yes ( ) No ( )

If yes, which aspects do you know?

____

3- Awareness of the regulation regarding the need to justify all radiological tests?

Yes ( ) No ( )

If yes, adherence of this regulation in daily practice

Yes ( ) No ( )

Which dificulties do you find when applying them?

____

4- What is the relation between the radiation doses of a chest x-ray compared with the annual dose received by a person related environmental radiation?

1/100 ( ) 1/10 ( ) The same ( ) 10 times more ( ) 100 times more ( ) I do not know ( )

5- How much radiation is absorbed by the patient when having a chest x-ray? (MSv - milliSieverts - derived unit of effective dose of radiation) (mSv - milliSieverts)

0.02 mSv ( ) 0.2 mSv ( ) 2 mSv ( ) 20 mSv ( ) 200 mSv ( ) I do not know ( )

6- If a chest x-ray is assigned one unit, how many units would absorb a patient in the following tests?

IMAGING TEST	0-1 u	1-10 u	10-50 u	50-100 u	100-500 u
Abdomen x-ray					
IVU					
Barium enema					
Abdominal ultrasound					
Brain MRI (with contrast)					
Brain MRI (without contrast)					
Scanner ventilation / perfusion lung					
Abdominal CT (contrast)					

7- Do you inform patients about the medical radiation exposure?

Yes, always ( ) Yes, sometimes ( ) No ( )

If yes:

7.1 Type of information given:

Oral () Written (informed consent () Both ()

7.2 Amount of information given:

Very little ( ) Not much ( ) Just enough ( ) A lot ( ) Too much ( )

7.3. Opinion regarding patients' understanding:

Very difficult to understand ( ) Difficult to understand ( ) Can be understood without too much difficulty ( ) Easy to understand ( ) Very easy to understand ( )

7.4. Do you share the decision to order an imaging test with the patient?

Yes ( ) No ( )

Which are the main limitations to do it?

7.5 What information should be provided to the patient?

Observations:

Annex II: Information sheets to be given to patients detailing the radiation exposure associated with imaging, which were evaluated by the clinician participants.

a) The official information given in current clinical practice in these hospitals.

Most frequently associated risks

Irradiation:

A CT is associated with ionizing radiation (x-rays) so it should be avoided in the case of pregnant women. In the rest of the population, the CT is only carry out when there is a precise indication to do it, because it has associated a high amount of radiation exposure.

As a guideline it should be noted that the dose received by the patient with the practice of a Skull CT scan radiation (2.3 mSv) is equivalent to 115 chest X-rays and is similar to 1 year of background radiation. Spiral CT (8mSv) radiation is equivalent to 400 chest X-rays and 3.5 years of background radiation. Abdominal CT scan is equivalent to 500 chest X-rays and 4.5 years of background radiation.

The potential risk of radiation includes a slightly elevated risk of cancer within a few years. This risk is less than 0.5%, so it can be considered very low compared to the normal incidence of cancer in the population, which is 33% for women and 50% for men, according to the American Society of Cancer.

b) An adapted radiation equivalence table[7], showing the effective radiation dose received by the different imaging tests under study expressed as radiation exposure units (u) equivalent to one chest X-ray.

Most frequently associated risks

Irradiation:

A CT is associated with ionizing radiation (x-rays) so it should be avoided in the case of pregnant women. In the rest of the population, the CT is only carry out when there is a precise indication to do it, because it has associated a high amount of radiation exposure.

As a guideline, the following table shows the equivalence between different imaging tests. For instance, the skull CT, with a radiation dose associated of 2.3 mSv, is equivalent to 115 chest x-rays and 1 year of background radiation (a person is exposed to 2.4 mSv of background radiation by year). The risk of cancer associated is from 1/ 100.000 to 1/10.000 (which is 33% for women and 50% for men, according to the American Society of Cancer)

Imaging test	**Effective dose (mSv)**	**Chest x-rays equivalent**	**Background Equivalent Radiation Time**
Chest x-rays	0.02		3 days
Skull CT	2.3	115	1 year
Chest CT	8	400	3.6 years
Abdomen CT	10	500	4.5 years

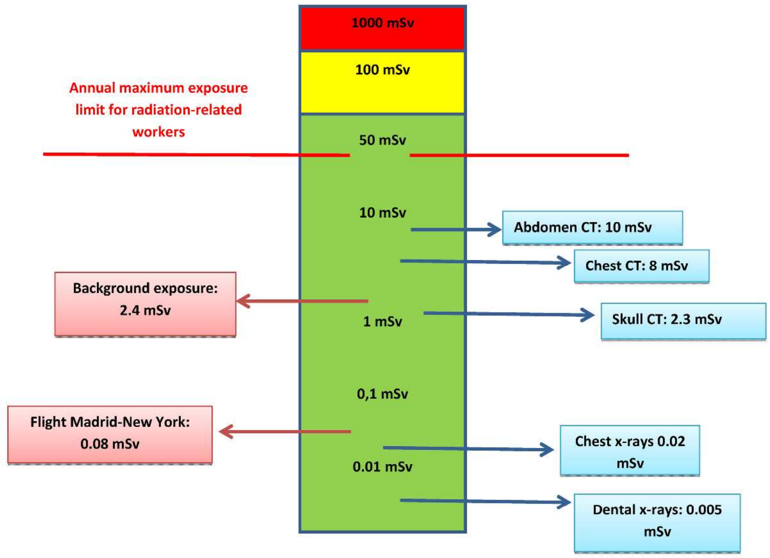
c) A figure showing a visual representation of the medical radiation exposure (compared to background radiation exposure).

Most frequently associated risks

Irradiation:

A CT is associated with ionizing radiation (x-rays) so it should be avoided in the case of pregnant women. In the rest of the population, the CT is only carry out when there is a precise indication to do it, because it has associated a high amount of radiation exposure.

As a guidelines, the following graphs shows the equivalences between the radiation absorbed by each imaging test and other radiation sources, according to the long-term potential risk: low (green), medium (yellow) and high (red):



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STROBE Statement—checklist of items that should be included in reports of observational studies

		Item No	Recommendation
YES Page 1	**Title and abstract**	**1**	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
			(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
	Introduction		
YES Page 6	Background/rationale	**2**	Explain the scientific background and rationale for the investigation being reported
YES Page 7	Objectives	**3**	State specific objectives, including any prespecified hypotheses
	Methods		
YES Page 8	Study design	**4**	Present key elements of study design early in the paper
YES Pages 8 (Quantitative) and 10 (Qualitative)	Setting	**5**	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
YES Pages 8 (Quantitative) and 10 (Qualitative)	Participants	**6**	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
			(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
YES Pages 9 (Quantitative) and 10 (Qualitative)	Variables	**7**	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
YES Pages 9 (Quantitative) and 10 (Qualitative)	Data sources/ measurement	**8***	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
YES Page 9	Bias	**9**	Describe any efforts to address potential sources of bias
NO	Study size	**10**	Explain how the study size was arrived at
YES Pages 10 (Quantitative) and 12 (Qualitative)	Quantitative variables	**11**	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
YES Pages 10 (Quantitative) and 12	Statistical methods	**12**	(*a*) Describe all statistical methods, including those used to control for confounding
			(*b*) Describe any methods used to examine subgroups and

(Qualitative)			interactions
			(*c*) Explain how missing data were addressed
			(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
			(*e*) Describe any sensitivity analyses

Continued on next page

	Results		
NA	Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
			(b) Give reasons for non-participation at each stage
			(c) Consider use of a flow diagram
YES Pages 13 (Quantitative) and 16 (Qualitative)	Descriptive data	**14***	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
			(b) Indicate number of participants with missing data for each variable of interest
			(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
YES Pages 13-15 (Quantitative)	Outcome data	**15***	*Cohort study*—Report numbers of outcome events or summary measures over time
			Case-control study—Report numbers in each exposure category, or summary measures of exposure
			Cross-sectional study—Report numbers of outcome events or summary measures
YES Pages 13-15 (Quantitative) and 16-18 (Qualitative)	Main results	**16**	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
			(*b*) Report category boundaries when continuous variables were categorized
			(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
NA	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
	Discussion		
YES Page 19	Key results	**18**	Summarise key results with reference to study objectives
YES Pages 21-22	Limitations	**19**	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
YES Pages 20-21	Interpretation	**20**	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
YES Page 22	Generalisability	**21**	Discuss the generalisability (external validity) of the study results
	Other information		
YES page 23	Funding	**22**	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.