

IRSN

INSTITUT
DE RADIOPROTECTION
ET DE SÛRETÉ NUCLÉAIRE

Enhancing nuclear safety

The CT scanner installed base in France and recommendations for radiation protection in medical imaging

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Department

NOTE

The analysis of relationships declared by the IRSN experts involved in carrying out this expertise did not lead IRSN to identify any potential conflicts of interest.

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Résumé

Afin de répondre à une saisine conjointe de la DGS et la DSS [1], l'IRSN a exploité deux des bases de données dont la gestion lui a été confiée par la réglementation : SIGIS, le Système d'Information et de Gestion des Sources (www.irsn.fr/sources), ainsi que l'application de gestion des niveaux de référence diagnostiques (NRD) [5]. L'IRSN a par ailleurs auditionné les associations de professionnels concernés, sur les thématiques en lien avec cette saisine. Cette étude apporte un éclairage sur les évolutions à envisager en se focalisant sur le champ de compétence de l'IRSN qu'est la radioprotection.

L'analyse du parc français des scanners conduit aux observations suivantes :

- le nombre de scanners est de 1175 ;
- l'âge moyen du parc de scanners français est de 3,6 ans.
- l'âge des scanners au moment de leur renouvellement est en moyenne de 6,1 ans ;
- 83 % des 41 scanners de plus de 10 ans sont implantés dans les établissements publics ;
- les indices de dose baissent de l'ordre de 20 à 30 % entre les scanners installés avant 2009 et les scanners installés en 2015

Ainsi, l'IRSN estime que l'âge moyen des scanners au moment de leur renouvellement, entre 5 et 7 ans, est en cohérence avec le cycle des évolutions techniques et n'identifie pas de raisons de modifier le délai de 7 ans au-delà duquel les forfaits techniques sont réduits. Toutefois, une attention particulière doit être portée aux évolutions technologiques ayant un impact positif sur les doses délivrées aux patients afin qu'elles puissent bénéficier à l'ensemble du parc, en veillant à un renouvellement homogène des scanners entre le secteur public et le secteur privé.

A cet effet, l'IRSN recommande de renouveler en priorité les scanners de plus de 10 ans et ceux de plus de 7 ans utilisés en pédiatrie ou, à défaut, de mettre en place un dispositif incitatif à la mise à niveau des scanners lorsque les évolutions proposées ont une influence bénéfique sur leurs performances (dose et qualité image).

L'audition des professionnels de santé et l'analyse réalisée dans le cadre de ce rapport ont mis en avant une augmentation du nombre d'actes et des pratiques pouvant être induites par le système de remboursement ayant un impact sur la radioprotection des patients. Ce rapport souligne également l'importance des outils contribuant à la pertinence des actes dans le domaine de l'imagerie médicale et soulève certaines problématiques en lien avec ces moyens :

- la mise en œuvre, pour le domaine de la radiologie médicale, de l'assurance de la qualité devrait prochainement être réglementaire ;
- la physique médicale, la radioprotection et les équipements associés à ces disciplines sont considérés dans les établissements de santé comme des centres de coûts ;
- le dossier médical partagé et les PACS connectés en réseaux régionaux sont des outils efficaces pour éviter la redondance des examens ;
- la télé-radiologie et les sites internet de prise de rendez-vous pourraient remettre en cause, dans certain cas, la validation de la justification des examens radiologiques s'ils ne sont pas correctement encadrés ;

- l'imagerie médicale en pédiatrie est une activité spécifique nécessitant une organisation particulière qui ne paraît pas correctement prise en compte par le système de remboursement.

L'IRSN estime que la justification des actes d'imagerie doit devenir un enjeu prioritaire des pouvoirs publics. A cette fin, l'IRSN recommande de :

- disposer d'options alternatives à l'imagerie radiologique. Il conviendrait notamment de rendre plus accessibles les examens non irradiants tels que l'échographie et l'IRM tout en restant attentif aux éventuels effets indésirables de ces techniques ;
- de renforcer la sensibilisation des différents acteurs au principe de justification des examens radiologiques.
- de favoriser l'application du principe de justification en faisant évoluer le système de remboursement uniquement basé sur la tarification à l'acte ou à l'activité.

L'IRSN préconise utiliser la réglementation relative à l'assurance qualité en imagerie médicale et aux audits cliniques, qui est en cours d'élaboration, comme un moyen d'objectiver la pertinence.

Sur les aspects organisationnels, l'IRSN recommande de :

- prendre en compte dans le système de financement les actes de physique médicale et favoriser l'investissement des établissements dans des outils d'archivage et de gestion des doses délivrées ;
- inciter à la mise en place, dans les services d'imagerie, d'équipes pluridisciplinaires dédiées à la radioprotection ;
- encadrer la télé-radiologie et les sites internet de prise de rendez-vous pour s'assurer de l'intégration du processus de validation de la justification dans ces pratiques.

Par ailleurs, la généralisation et le déploiement sur tout le territoire français du DMP et des systèmes de partage d'information tels que les réseaux régionaux de PACS permettront de réduire la redondance des examens. L'IRSN préconise de veiller à leur cohérence au niveau national.

Compte tenu des spécificités de l'imagerie pédiatrique, l'IRSN recommande notamment de valoriser les bonnes pratiques de radioprotection généralement mises en œuvre en pédiatrie.

Abstract

In answer to a joint request from the Directorate General for Health (DGS, Ministry of Health) and the Directorate for Social Security (DSS) [1], IRSN used two databases for which it is responsible by regulations: SIGIS, the information and radioactive sources management system (www.irsn.fr/sources), and the application for the diagnostic reference levels management [5]. IRSN also held hearings with associations of professionals on topics in connection with the request. This study highlights the need for change by focusing on IRSN's field of competence: radiation protection.

The analysis of the French installed base of CT scanners provided the following observations:

- the number of CT scanners is 1,175;
- the average age of the installed base is 3.6 years;
- the average age of CT scanners at the time of renewal is 6.1 years;
- 83% of the 41 CT scanners over 10 years old are installed in public facilities;
- dose indices drop by 20 to 30% between CT scanners installed before 2009 and those installed in 2015.

IRSN considers that the average age of CT scanners at the time of renewal (from 5 to 7 years) is consistent with the current cycle of technical evolutions and does not identify any reason to modify the seven-year deadline after which the technical reimbursement is reduced. Nevertheless particular attention should be paid so that technological advances having a positive impact on doses delivered to patients can benefit the entire installed base, ensuring a homogeneous renewal of CT scanners within public and private sectors.

To do so, IRSN recommends renewing, as a matter of priority, CT scanners over 10 years old and those over seven years old used in paediatrics. Failing that, IRSN recommends establishing an incentive plan for upgrading CT scanners when upgrades are likely to improve their performance in terms of dose and image quality.

The hearings with health professionals and the analysis realised in the scope of this report have pointed out an increase in the number of imaging procedures and some practices potentially encouraged by the reimbursement system impacting the radiation protection of patients. This report also underlines the importance of tools contributing to the relevance of imaging procedures and raises certain issues:

- Implementation of quality assurance in radiology should soon be covered by regulations;
- Medical physics, radiation protection and related equipment are considered in the health establishments as cost centres;
- Shared medical records and picture archiving and communication systems (PACS) available on regional networks are effective tools to avoid the redundant imaging examinations;
- Teleradiology and appointment making via website could call into question the justification for the radiological examination if these practices are not well supervised;
- Paediatric medical imaging requires a specific organisation which does not seem to be correctly taken into account in the reimbursement system.

IRSN thus considers that justification of imaging examinations should become a priority for the health authorities. To do so IRSN recommends:

- making alternative options to X-ray imaging available and making ultrasound and magnetic resonance imaging more accessible;
- improving the awareness of the various participants in the justification process;
- promoting the application of the justification principle by changing the reimbursement system, which is currently based only on the fee schedule for the procedure or activity.

IRSN recommends using the new regulation on quality assurance in medical imaging and on clinical audit to check the suitability of imaging procedures.

On organisational aspects, IRSN recommends:

- supporting, in the reimbursement system, medical physics and encouraging investment in dose management systems;
- promoting the creation of multidisciplinary teams dedicated to radiation protection in imaging departments;
- supervising teleradiology and appointment making via website to ensure justification of the examinations.

Moreover, the generalisation and adoption in France of shared medical records and PACS will reduce the redundancy of medical imaging examinations. IRSN recommends their coherence is ensured at the national level.

Due to the specific nature of paediatric imaging, IRSN recommends promoting and highlighting good practices in radiation protection commonly implemented in this field.

Glossary

- AFIB: Association Française des Ingénieurs Biomédicaux [French Association of Biomedical Engineers]
- AFPPE: Association Française du Personnel Paramédical d'Electroradiologie [French Association of Radiographers]
- ASN: Autorité de sûreté nucléaire (French nuclear safety authority)
- CLCC: Centre de Lutte Contre le Cancer [Comprehensive Cancer Centre]
- COCIR: European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
- DACS: Dose archiving and communication system
- DGOS: Direction Générale de l'Offre de Soins [Directorate General for Healthcare Services, Ministry of Health]
- DGS: Direction Générale de la Santé [Directorate General for Health, Ministry of Health].
- DMP: Dossier Médical Partagé [Shared Medical Record]
- DREES: Directorate for Research, Studies, Assessment and Statistics
- DSND: Representative in charge of Nuclear Safety and Radiation Protection for Defense-related Activities and Facilities
- DSS: Directorate of Social Security
- FHP: Fédération des cliniques et hôpitaux privés de France [Federation of private clinics and hospitals in France]
- FNMR: Fédération Nationale des Médecins Radiologues [French National Federation of Radiologists]
- HERCA: Heads of the European Radiological protection Competent Authorities
- ICRP: International Commission on Radiological Protection
- ONDAM: Objectif National de Dépenses d'Assurance Maladie [National Healthcare Insurance Expenditure Target]
- PACS: Picture archiving and communication system
- SAE: Statistique annuelle des établissements de santé [Annual statistics on health facilities]
- SFIPP: Société Francophone d'Imagerie Pédiatrique et Prenatale [French Society for Paediatric and Prenatal Imaging]
- SFPM: Société Française de Physique Médicale [French Medical Physics Society]
- SFR: Société Française de Radiologie [French Society of Radiology]

1 INTRODUCTION

By letter dated 4 August 2017, the DGS and the DSS jointly asked IRSN to establish:

- an inventory of the French computed tomography (CT) scanner installed base specifying the number of facilities, their distribution by age category and/or according to the available dose reduction technologies, as well as an estimate of the frequency of CT scanner replacement;
- an analysis of the impact of the year of manufacture on patient doses.

More generally, IRSN was requested to transmit recommendations on good practices taking into account the needs of radiation protection in medical imaging, including the use and replacement of equipment, in particular in the field of paediatrics.

In order to respond to this request, IRSN used two databases for which it is responsible according to regulations:

- SIGIS, Information and Source Management System: this database centralises the authorisations issued by the various authorities responsible for sources of ionising radiation (ASN, prefectures, DSND, etc.) and the movement of sources in France (acquisition, transfer, export, import, takeover, replacement, etc.) (www.irsn.fr/sources). A retrieval of data from this database on 15 September 2017 was used to establish the inventory of the French CT scanner installed base. These data confirmed with a review of the data available in the literature [1-4];
- NRD, an application to manage diagnostic reference levels: using this database IRSN can analyse the annual dose assessments transmitted by health facilities in accordance with the decree of 24 October 2011 [5]. Dose assessments submitted between 1 January 2013 and 31 December 2015 were analysed to assess the impact of the year of CT scanner manufacture on doses delivered to patients.

The professional associations concerned, AFIB, AFPPE, FHP, FNMR, SFIPP, SFPM, SFR, were also heard on several topics:

- the policy of purchasing or replacing CT scanners;
- the justification of medical imaging procedures;
- good practices and regulations for radiation protection of medical imaging patients.

The inventory of the current CT scanner installed base, the analysis of the impact of the year of manufacture on doses delivered and the recommendations associated with this aspect are presented in Chapter 2 of this document.

Hearings with professionals made it possible to identify certain weaknesses that led IRSN to issue recommendations regarding the radiation protection of medical imaging patients. These are presented in the third chapter of this report.

This study sheds light on the developments to be considered, particularly in the reimbursement system, by focusing on IRSN's field of competence, namely radiation protection. The authorities could take other points of view into consideration to confirm or modify these recommendations.

2 INVENTORY OF THE CURRENT CT SCANNER INSTALLED BASE AND ANALYSIS OF THE IMPACT OF THE YEAR OF MANUFACTURE ON DOSES DELIVERED

2.1 Inventory of the current CT scanner installed base

2.1.1 Evolution over time of the of the number of CT scanners

According to the data recorded in the SIGIS database, the number of CT scanners authorised by the ASN as of December 2017 was 1,175. This figure excludes CT scanners for radiotherapy. The actual number of CT scanners may differ by a few units due to delays in the transmission of data for new authorisations or equipment no longer in use.

Figure 1 shows the evolution over time of the number of CT scanners authorised by ASN. The number of licensed CT scanners has increased by 145 in 6 years. The number of authorisations increased more between 2015 and 2016 (+3.4%) than in previous years (around +1.4% per year).

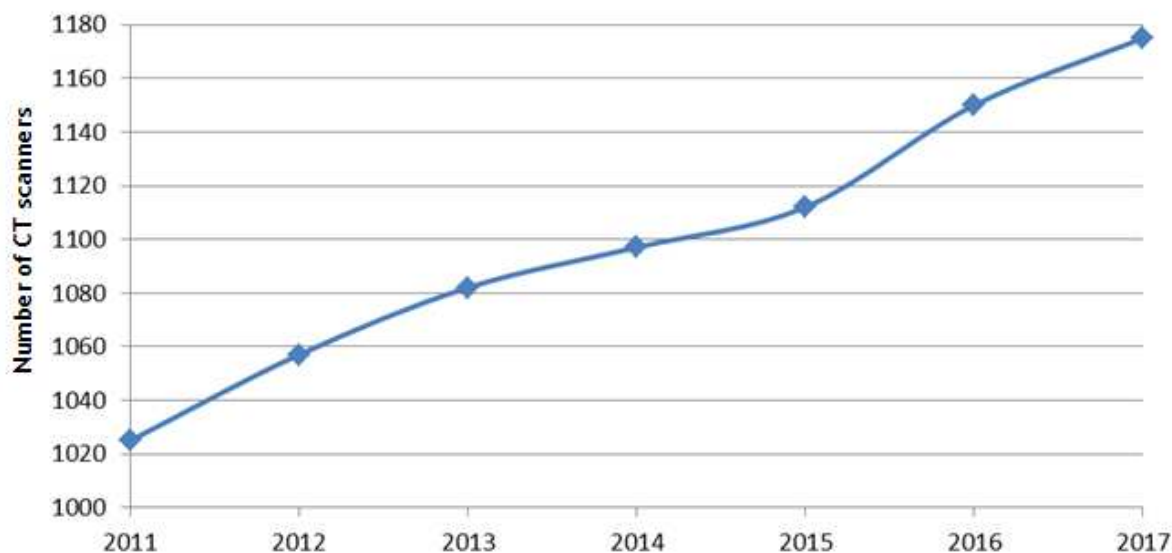


Figure 1: Change in the number of CT scanners authorised since 2011

The increase in the number of CT scanners in recent years must be viewed in light of the increase in the number of procedures. For example, according to the DREES data [3.4], the number of CT scans among inpatients and outpatients (excluding private practice) in public and private non-profit facilities increased by 4.5% between 2014 and 2015. In its 2016 report [2] on medical imaging, the Cour des Comptes mentions an average annual growth rate of +4.1% between 2007 and 2014 in the number of CT scan procedures in the private sector and the high productivity of the French installed base. According to OECD data, France ranks fifth in terms of the average annual number of CT scan examinations per inhabitant (see Figure 2). On the basis of data from DREES and SAE, the Cour des Comptes estimated that the average number of CT scan procedures performed in 2014 was between 173 and 226 per week, depending on the type of facility concerned.

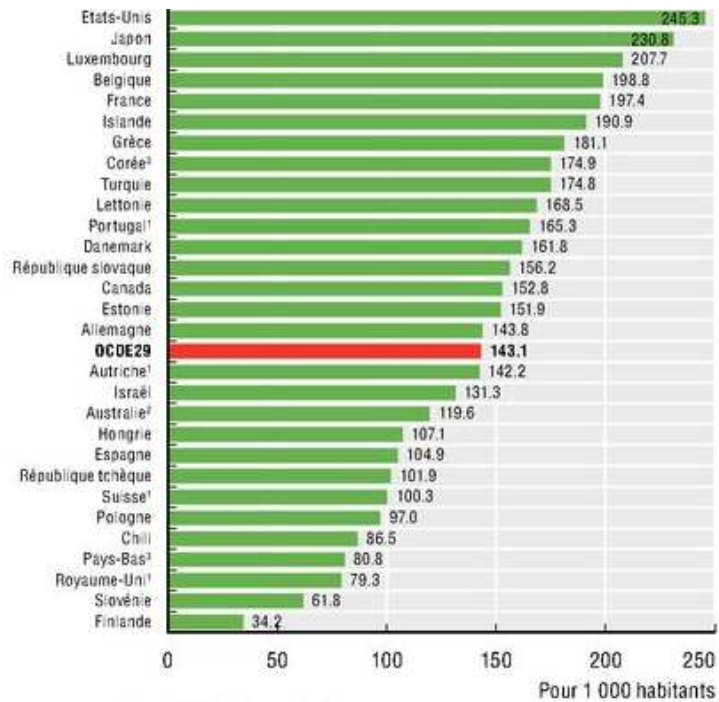


Figure 2: Annual number of CT scan exams per 1,000 inhabitants according to the OECD (2015 or nearest year) [6]

2.1.2 Age of the CT scanner installed base

The average age of France’s CT scanner installed base, based on SIGIS data as of 15 September 2017, is 3.6 years. The maximum age is 14.6 years.

Figure 3 shows the distribution of CT scanners by age group, based on SIGIS data. These figures are consistent with COCIR European data from 2016 [1] (see Figure 4).

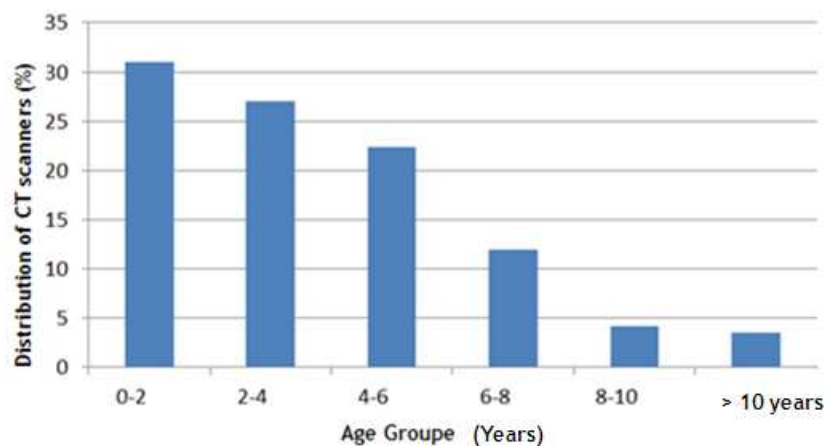


Figure 3: Distribution of the number of CT scanners by age group (SIGIS 2017 data)

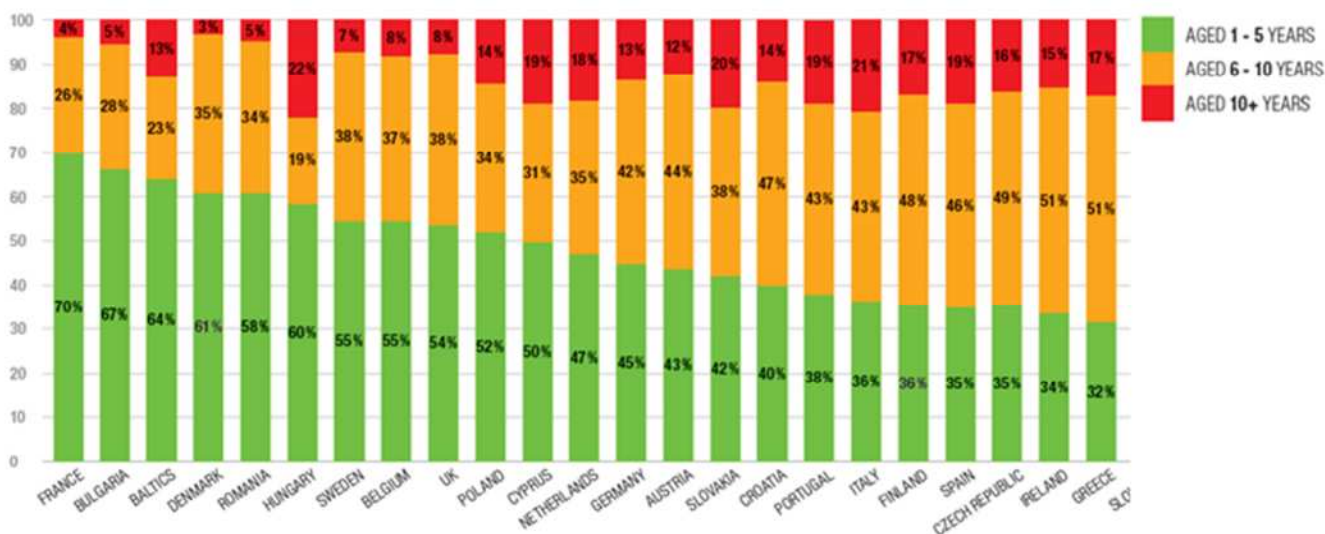


Figure 4: Distribution of the percentage of CT scanners by age group in Europe (COCIR 2016 data [1])

These data show that France complies with COCIR's recommendations regarding the distribution of the installed base by age group, namely:

- at least 60% of the installed base shall be less than 5 years old;
- less than 30% of the installed base shall be between 6 and 10 years old;
- less than 10% of the installed base shall be more than 10 years old.

France has a recent installed base and is, according to COCIR, in first place among European countries [1].

It was not possible for IRSN to determine, from the SIGIS data, the average age of CT scanners in the years prior to 2017. COCIR data [1] however show that there is a slight ageing of the French CT scanner installed base between 2008 and 2015 (see Table 1). This aspect should be kept under review, although the increase in the number of new authorised CT scanners, which has increased since 2016, will certainly help to reduce the ageing of the installed base.

Year	2015			2008		
	1-5	6-10	10+	1-5	6-10	10+
Distribution (%)	70%	26%	4%	73%	25%	2%

Table 1: Distribution of percentage of CT scanners by age group in 2008 and 2015 for France (COCIR 2016 data [1])

2.1.3 Installed base replacement rate

Figure 5 shows the distribution of the percentage of CT scanners replaced by age at replacement. The age of the CT scanners at replacement is 6.1 years on average. This average was determined by identifying all the replacements identified in SIGIS during 2006-2017.

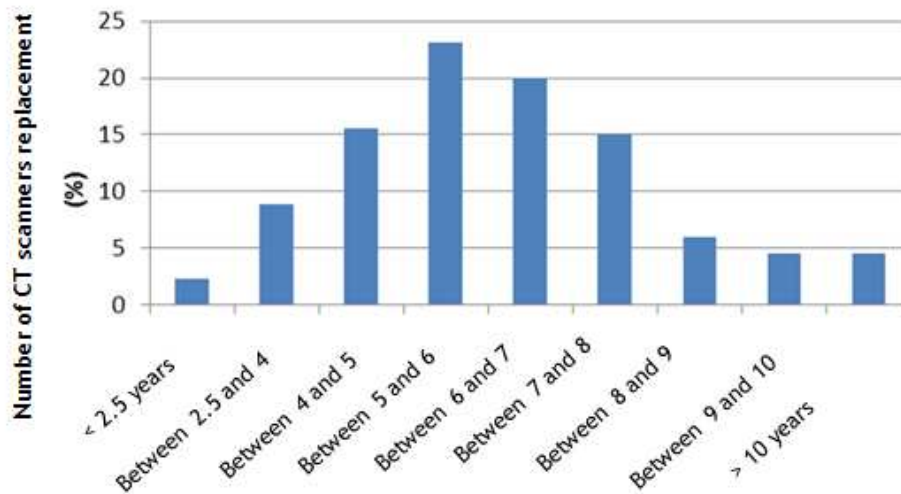


Figure 5: Age distribution of CT scanners at the time of their replacement (2006-2017 data)

Table 2 shows that the rate of CT scanner replacement decreases steadily from 2013 to 2017. The average age at replacement increased from 5.7 years in 2013 to 6.8 years in 2016, an increase of 20% in four years. This trend, confirmed in 2017, is consistent with the slight ageing of France’s CT scanner installed base identified using COCIR data between 2008 and 2015[1] (see Table 1).

Year	Average age of CT scanners at replacement (years)
2013	5.7
2014	6.2
2015	6.6
2016	6.8
2017	6.9

Table 2: Average age of CT scanners at replacement by year

Two reasons were given by health professionals to explain the slower replacement rate of CT scanners:

- successive price adjustments in recent years may have made it difficult for some facilities to invest in new machines. Olivier Veran [7] also raises this issue: “The constraints on the overall budget are such that a reduction in prices is applied each year to remain within the framework of the national healthcare insurance expenditure target. In addition evoking incomprehension for professionals, such a situation makes any long-term strategy (hiring, purchasing, etc.) difficult”;
- the second-hand market is less attractive today than it was a few years ago. The trade-in value of CT scanners is no longer an incentive for their early replacement.

It should be noted that, while it is increasing, the average age of CT scanners at the time of replacement remains under seven years. This is due to the fact that the flat fees paid to private CT scanner operators to cover depreciation and operating costs are reduced after seven years of operation. The decrease in flat fees thus constitutes an incentive for the replacement of CT scanners before seven years.

It should also be noted that the SIGIS data do not provide quantifiable information on any upgrades to the CT scanner installed base. The technical improvements are such that there are many upgrade possibilities during the life of a CT scanner. These upgrades improve CT scanner performance, particularly in terms of dose delivered. According to the professional societies interviewed, these upgrades are rarely carried out during operation because they are costly and are not taken into account in the current system of reimbursement of procedures. Facilities would thus be forced to wait for the replacement of CT scanners to benefit from performance improvements.

2.1.4 Differences between public and private sectors

From the 2015 DGOS data contained in the report by the Cour des Comptes [1], the proportion of CT scanners installed in the public sector can be estimated at around 47%. The distribution of CT scanners between the public and private sectors therefore appears balanced.

According to the data from SIGIS, 83% of the 41 CT scanners over 10 years old are located in public facilities (see Figure 6). It should be noted that the SIGIS data do not distinguish between the proportion of procedures performed on hospitalised patients and that performed on “outpatient” patients with CT scanners in public facilities.

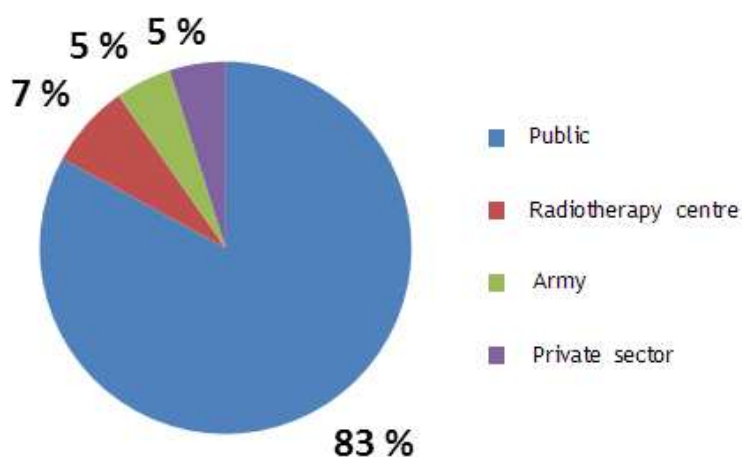


Figure 6: Distribution of the public/private location of the 41 CT scanners over 10 years old

However, this illustrates the fact that, while the drop in flat fees after seven years is a strong incentive for the replacement of CT scanners, this applies mainly to private facilities.

Indeed, it should be recalled that there are two ways of pricing procedures performed in public facilities:

- for outpatients, the method of reimbursement is identical to that of private facilities and is based on the flat fee and CCAM coding;
- for hospitalised patients, the reimbursement system is different. It is based on the number of relative cost index points. The number of relative cost index points is assigned and valued for each technique. There is no equivalent to the flat fee in this valuation system.

According to the professional societies, in public hospitals with several CT scanners, the dual invoicing system encourages the regular replacement of any CT scanners used for outside activity every seven years, while CT scanners used for the hospital's own needs are replaced after a longer period. This means that hospitalised patients, who are generally those with the most serious pathologies, are often treated on the oldest CT scanners.

This observation reflects the budget difficulties of public facilities mentioned by professionals during the hearings and also raised by Veran [7]: "There is a real and worrying risk in the short and medium term of deterioration in hospital equipment and consequently of a decline in safety and quality of care."

2.2 Analysis of impact of year of manufacture on doses delivered

2.2.1 History of technological developments and prospects

Figure 7 provides a brief overview of the main technological developments in CT scans since the 1990s. Important developments in dose reduction and management are shown in red.

In particular, in the early 2000s, automatic current modulation became available and, more recently, automatic voltage modulation. These technological developments constitute a major contribution to optimising doses to the patient since they make it possible to adapt the dose to the body size and morphology of each patient and to reduce doses accordingly [8-10].

Since the early 2010s, dose reduction has become a major concern for manufacturers. This concern has undoubtedly been spurred in the United States by an awareness of the increase in the number of CT scan examinations and the significant doses associated with these exams. During this period, the "image gently" campaign in paediatrics was launched to improve the safety and effectiveness of patient care involving paediatric imaging [11].

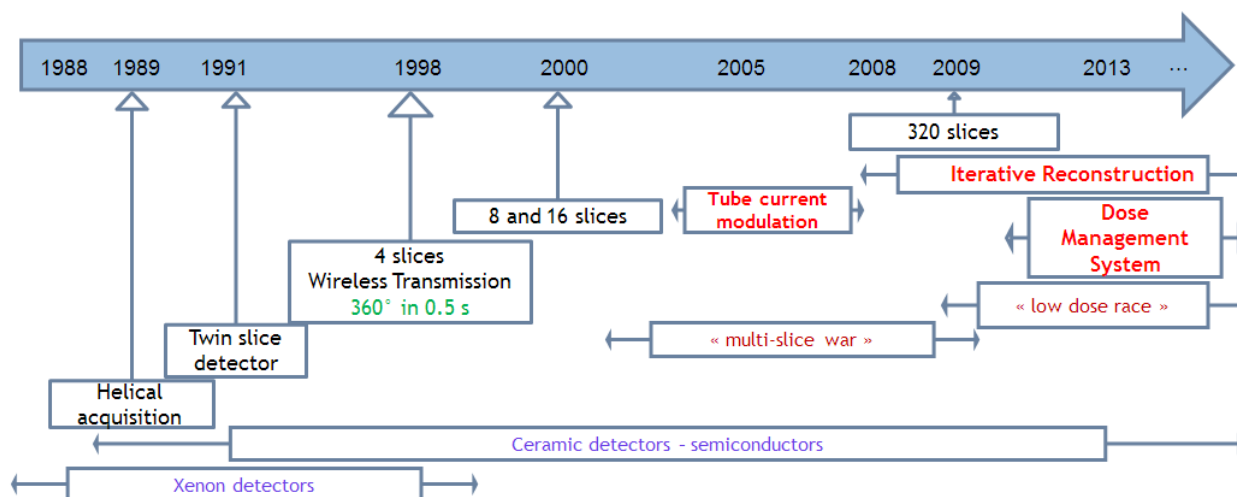


Figure 7: History of technological developments in CT scanning from the 1990s

The use of iterative reconstruction algorithms since 2008 is a step forward in dose reduction [12, 13]. These algorithms, which work by successive approximations, make it possible to reduce the noise in the images and thus reduce exam doses. Initially offered as an option by some manufacturers, these algorithms are now part of the basic characteristics of CT scanners regardless of the manufacturer, and are used as part of the clinical routine. Manufacturers are continuing to develop and improve in this area and are now offering the fourth generation of these algorithms [10, 12-14].

Dose archiving and communication systems (DACS) have been developed in recent years to improve the monitoring of doses delivered to patients and thus indirectly contribute to their optimisation. Improvements continue to be made to these systems.

On the basis of the information available to IRSN, there is no major technological innovation expected in the next two or three years that could have a significant impact on dose delivery. Further software development is expected, including progress in iterative reconstruction.

Development in CT scanning is thus primarily linked to continuous improvement of techniques. The average replacement time for CT scanners of between five and seven years seems to be in line with the cycle of technical developments.

2.2.2 Influence of the age of the CT scanner on the dose

In its 2013-2015 review of diagnostic reference levels [15], IRSN noted, “The value of the dose indicator is inversely proportional to the age of the CT scanner. While the mere use of a recent scanner does not imply that practices are optimised from a dosimetric point of view, it nevertheless appears that the most recent devices make it possible to achieve the best performance in terms of optimisation.”

Indeed, the analysis of the annual dose assessments submitted by health care facilities showed a decrease of around 20-30% in the computed tomography dose indices (CTDI) between CT scanners installed before 2009 and those installed in 2015.

Figure 8 illustrates this observation.

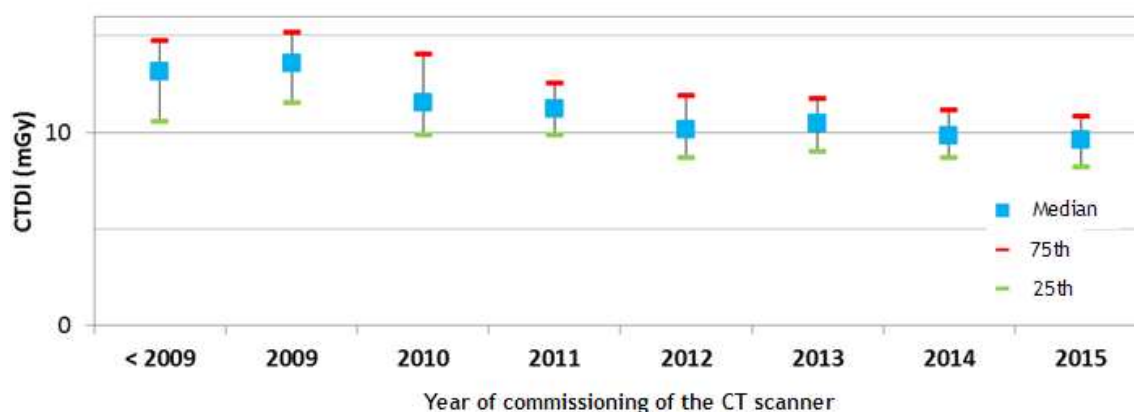


Figure 8: Influence of the year of commissioning of the CT scanner on the median, 75th and 25th percentile of the CTDI. Example of an abdominal-pelvic CT scan examination

This can be explained by two reasons for which it is not possible to separate the influences:

- technological developments, in particular iterative reconstruction which produces substantial gains in dose [10, 12-14];
- optimisation of protocols and awareness of good practices among users. Indeed, the replacement of a CT scanner is also an opportunity for professionals to optimise protocols and reconsider their practices.

Figure 8 also illustrates that dose reduction is relatively gradual and that there is no “leap” related to the introduction of iterative reconstruction, for example. There are several reasons for this:

- innovations are introduced gradually. They are initially offered by a single manufacturer, as an option on some of its systems only. The other manufacturers then gradually take it over and innovation is finally proposed on all systems of all brands;
- along with its distribution, manufacturers are encouraged to develop improvements on the innovation itself and propose new, more efficient versions;
- users may take time to adopt these new techniques. This is the case with iterative reconstruction, for example, which produces images whose appearance may have at first disturbed professionals who had to take time to get used to and train themselves to reading this new type of image.

2.3 Recommendations for the CT scanner installed base

IRSN considers that the average age of CT scanners at the time of replacement, between five and seven years, is consistent with the cycle of technical development and has not identified any reasons to change the seven-year period after which flat fees are reduced. However, **particular attention should be paid to technological developments that have a positive impact on the doses delivered to patients so that they can benefit the entire installed base, ensuring that CT scanners are uniformly replaced between the public and private sectors.**

As a priority, IRSN therefore recommends the replacement of any scanners that are more than ten years old, or more than seven years old in paediatrics or, failing that, the introduction of an incentive for upgrading scanners when the proposed changes have a beneficial effect on their performance (dose and image quality).

The CT scanner installed base should be reviewed periodically to ensure that the measures taken are effective and the condition of the installed base provides the best performance in terms of optimising doses delivered to patients.

3 FINDINGS AND RECOMMENDATIONS FOR GOOD RADIATION PROTECTION PRACTICES IN MEDICAL IMAGING

3.1 Findings on radiation protection practices in medical imaging

3.1.1 Continuing increase in the number of procedures

All professionals interviewed for this study report an increase in the number of procedures. The professionals gave several reasons to explain this shared observation.

New clinical indications appear regularly, thus contributing to an increase in the number of imaging procedures. The ageing of the population is also responsible for the increase. However, other reasons mentioned raise concerns for IRSN because they may contradict one of the fundamental principles of radiation protection, which is the requirement to justify the use of ionising radiation.

First of all, it should be recalled that the very principle of fee-for-service can be a major incentive to increase the number of procedures. The Cour des Comptes has already raised this issue in its 2016 report [2]: “While the doctor’s fee-for-service payment in the private sector constitutes an incentive to productivity, it also conceals a risk of inflating the number of examinations beyond what is necessary and sufficient, to the detriment of the quality and efficiency of the care provided.”

It is therefore not surprising that one of the reasons highlighted by some health professionals is that the principle of fee-for-service, combined with successive reductions in prices, encourages more procedures to be performed.

In addition, the development of outpatient care and the reduction in the number of beds are also driving an increase in imaging procedures. Indeed, outpatient care is facilitated by the performance of interventional radiology procedures. In addition, imaging procedures such as CT scans can remove doubts about the diagnosis and avoid keeping patients under observation.

The increase in CT scans carried out at the request of emergency departments was also mentioned. The CT scanner is increasingly used as a screening tool to manage emergencies, whereas it is not necessarily the most suitable imaging procedure depending on the case (management of abdominal pain, for example). This is due in particular to a problem with the general organisation of patient care and the reduced availability of health professionals, particularly at night (see Section 3.6.1).

These elements thus raise the issue of the suitability of the procedures in general, which the Ministry of Health has already identified. Indeed, in the dossier relating to the National Health Strategy 2018-2022 [16], the proportion of unnecessary procedures is estimated at between 20% and 30%. It notes, “This situation concerns, for example, the use of ionising radiation for medical purposes, for which the implementation of the principle of justification shall make it possible to avoid overexposure that could generate undesirable effects.”

As the Cour des Comptes points out, “There are profitability gaps in the volume of examinations and in the suitability of procedures within the framework of a medical approach to expenditure (procedures not necessary for the establishment of the diagnosis, redundant procedures, etc.)” [2].

3.1.2 Practices that may result from the reimbursement system that have an impact on patient radiation protection

During the hearings, certain practices that may result from the fee-for-service system and that have an impact on patient radiation protection were also discussed.

These practices are more or less recognised by health professionals. This is a difficult subject to address and practices in this area appear quite varied. They may depend on the type of facility and may be more or less common depending on the regions concerned.

However, IRSN considered that these practices were worth mentioning because they contradict the principle of justification.

Some codes in the Common Classification of Medical Procedures (CCAM) still take into account the number of incidences. This is the case, for example, with code NAQK007: “Radiography of the pelvic girdle according to two incidences” whose cost is €33.25 and NAQK015 code: “Radiography of the pelvic girdle according to 1 incidence” whose cost is €19.95 [17]. This difference in the fee schedule according to the number of incidences may lead to an increase in the number of unjustified incidences to the detriment of patient radiation protection. However, in the age of digital imaging, it no longer seems appropriate to differentiate costs according to the number of incidences. Indeed, thanks to digital imaging, any additional incidences do not require additional consumables or development time.

Another practice mentioned is splitting procedures. When a request for an examination concerns several anatomical areas, it may happen that the examination is carried out in several stages a few days apart to circumvent the rules of the common classification of medical procedures (Rule 1: “A user shall code the procedure in accordance with the principle of overall procedure, choosing the simplest, most complete and most succinct method of description”) and “cost” several procedures rather than a single overall procedure. For example, a thorax CT scan of the abdomen and pelvis can be broken down into CT scans of the chest and of the abdomen and pelvis. This practice, in addition to the disadvantage of bringing the patient back, does not favour radiological protection because of the overlaps of anatomical zones.

3.1.3 Other points to consider

Other points related to patient radiation protection must also be considered.

The problem of implementing so-called “maximal” protocols was also mentioned by the professionals interviewed, for example. When radiologists are not immediately available, for example when radiologists are requested at several workstations at the same time, it may be decided to set up this type of protocol which allows an exploration beyond what is required, either using higher acquisition parameters or covering a larger anatomical area, in order to be sure that an exhaustive exploration is carried out without exposing the patient to diagnostic errors. This practice raises justification issues and therefore patient radiation protection.

In addition, it’s important to recall that patients, increasingly involved in their health, as well as doctors are also demanding imaging procedures that are sometimes unjustified and exert strong pressure to perform procedures. Indeed, as the European Commission pointed out in 2010, “The practical application of the system of justification for X-ray

radiological imaging leaves much to be desired, since medically unjustified procedures represent at least one fifth of all examinations, and even three quarters in certain specific cases” [18]. The inclusion in the new guidelines defining postgraduate medical education [19] of universal cross-disciplinary lessons (ETU) on radiation protection and good practices for requesting examinations should contribute, through the widespread use of the *Guide du Bon Usage des Examens d’Imagerie Médicale* [20], to a better approach by doctors in this field for all specialised fields.

It should be noted, however, that radiologists often find it very difficult to refuse or substitute unjustified examinations. Indeed, validating a justification is time-consuming. Time should be taken to explain to the patient and sometimes to the requesting physician the reasons for this refusal or substitution in order to convince them of the validity of the decision. However, the time required to validate the justification, to substitute or refuse the procedure is not taken into account by the reimbursement system. In addition, the longer time frames required for MRI examinations do not make it easier to use them instead of CT scanner examinations. For example, it is difficult to convince a patient that the MRI he can have in three weeks is a more appropriate examination for his case than the CT scan he could have done the same day. In addition, from the point of view of responsibility, it is difficult for health professionals to refuse a prescribed examination given the stakes for the patient.

Finally, as specified in the ICRP and HERCA [21, 22], there are several levels of justification. In particular, justifying radiological procedures, which are the responsibility of national and international professional societies in conjunction with the competent radiation protection authorities, must be distinguished from justifying application of a procedure to an individual patient. This justification is the responsibility of the practitioner. [22]

3.1.4 Recommendations: making the justification of procedures a priority issue

Optimising patient exposure to ionizing radiation, a fundamental principle of patient radiation protection, has been the priority in recent years, with, among other things, the implementation of diagnostic reference levels and quality control of medical devices, as well as the development of guides for conducting examinations. However, the observations mentioned above show that many issues related to the justification or suitability of examinations remain. While technical efforts already implemented will soon have reached their limits in terms of dose optimisation, there is however still much to be gained in terms of collective dose reduction by focusing on justification.

IRSN believes that the justification of imaging procedures involving radiological exposure - which is linked with the more general notion of suitable care mentioned in the National Health Strategy 2018-2022 [7] - must become a priority issue for public authorities.

To this end, IRSN recommends that alternatives to radiological imaging be available. In particular, examinations that do not require radiation such as ultrasound and MRI should be made more accessible, while the potential adverse effects of these techniques must be kept in mind.

IRSN also recommends that the various stakeholders become more aware of the principle of justifying radiological examinations. To this end, IRSN recommends:

- recalling, in daily practice, the roles of health professionals involved in the care pathway in order to strengthen the radiologist's position in choosing the best imaging strategy appropriate for each patient;
- continuing efforts to train referring physicians, including emergency physicians, in patient radiation protection; further training of practising physicians is still to be planned;

- making patients aware of the importance of justifying examinations and involving them in the discussions that will be carried out at national level on this subject.

Finally, IRSN considers that the application of the principle of justification should be encouraged by changing the reimbursement system relying solely on a procedure- or activity-based fee schedule by taking into account the time required for substituting or refusing procedures and by eliminating the differentiation of fees according to the number of incidences for all conventional radiology procedures.

These recommendations are in line with the guidelines of the National Health Strategy 2018-2022 [16], the Cour des Comptes [2] and Veran's report [7]: "Experiment with new methods of funding care, on the basis of pathway or episode, depending on the situation, across the country, based on the initiative of health professionals, by betting on increased quality and suitable care for patients, and on an efficiency dividend reinvested to fund innovation."

3.2 Quality assurance and clinical audit

3.2.1 Regulatory developments

There are many regulatory provisions contributing to the radiation protection of patients in radiology, in particular relating to the justification and optimisation of delivered doses: training of personnel, quality control of medical devices, dose analysis with regard to diagnostic reference levels, etc. Feedback from experience shows that these regulatory provisions, some of which have existed for more than 10 years, are not implemented by all facilities.

The quality assurance requirement introduced by Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for health protection against the dangers arising from exposure to ionising radiation [23] has already been transposed into French law in Article L. 1333-19 of the Public Health Code. This requires that "Acts using ionising radiation for medical diagnosis purposes (...) be subject to an obligation of quality assurance from the justification of the choice of the act, the optimisation of the doses delivered to patients and until the result of the act is delivered." A draft ASN decision intended to oversee implementation of the quality assurance requirement introduced by this article for the field of medical radiology is currently being prepared. In particular this decision shall concern the processes for implementing the principles of justifying examinations using ionising radiation and optimising doses delivered to patients, primarily by incorporating all the regulatory provisions contributing to the radiological protection of radiology patients.

Without waiting for regulatory implementation, radiologists have launched a process to label imaging practices and services on a voluntary basis. According to the professionals interviewed, the centres involved in this approach are better in implementing good practices and complying with radiation protection regulations. They also take better account of the need for access to equipment to carry out "non-clinical" actions (maintenance, quality control, medical physics measurements, etc.).

The performance of clinical audits "in accordance with national procedures" is also a requirement of European Directive 2013/59/Euratom [23] which will be included in the public health code. The implementation of this type of peer review was thus initiated by the Ministry of Health with the professionals concerned.

In this regard, the Cour des Comptes recommends that the "quality approach being defined be based on the patient pathway, taking into account radiation protection issues, good practices and the suitability of examinations given the patient's indications" [2].

Quality assurance therefore has a full role to play in radiation protection and this approach appears inseparable from that of clinical peer review.

3.2.2 Recommendations

IRSN recommends using the regulations on quality assurance in medical imaging, which are currently being prepared, as a means of ensuring that procedures are suitable.

To this end, IRSN recommends that the technical provisions meeting the obligation for quality assurance be combined with a system of quantifiable action indicators related to the suitability of the procedures and radiation protection, such as, for example, annual transmission of the results of dose assessments concerning diagnostic reference levels [5].

However, IRSN points out that it would not be desirable to include one of these indicators in the dose delivered to the patient. Such an indicator could indeed encourage facilities in race for the lowest dose, and have a negative impact on diagnostic information.

In addition, IRSN considers it necessary to promote this approach by making the results of these indicators available to patients.

Finally, IRSN recommends establishing a connection between the quality assurance process and that of clinical audit.

3.3 Dose archiving system and medical physics support

3.3.1 Promote good radiation protection practices

Dose archiving and communication systems (DACs), introduced several years ago, now constitute an *essential tool* for medical physicists to monitor patient dose. Indeed, they monitor individual doses and can provide an alert if certain levels are exceeded, and produce statistics to establish local reference levels. This equipment therefore makes an important contribution to optimising patient doses. However, the centres are poorly equipped because these costly systems, considered "non-productive", are not considered a priority. This is also the case for the equipment necessary for medical physics measurements (dosimeters, test objects, etc.) or for the medical physics services themselves.

Ordinance 2017-48 of 19 January 2017 [24] recognises the profession of medical physicist as a health profession and defines the role of the medical physicist: "He brings his expertise to any question relating to the physics of radiation or any other physical agent in medical applications within his field of specialisation. He is responsible for image quality, dosimetry and exposure to other physical agents. In particular, he ensures that the equipment, data and calculation procedures used to determine and deliver doses and the radioactivity of substances administered to the patient is appropriate and contributes to optimising exposure to ionising radiation." The role of the medical physicist is therefore essential in the process of optimising the doses delivered to the patient. However, ASN and SFPM noted in 2013 [25] that "ASN inspections in the field of imaging as well as feedback from events reported to ASN highlighted failures in the area of optimising practices due in particular to the failure to include the person specialised in medical radiological physics." Since 2013, few medical imaging physicist positions have been created. Professionals evoke a lack of funding as the difficulty in recruiting a physicist or using an external service.

Thus, in general, medical physics and radiation protection are considered as cost centres in health care facilities. This does not facilitate hiring and investment in time, equipment and/or services in these areas. Thus, it does not encourage the application of good practices in this area.

Faced with these difficulties, health professionals stress the importance of ASN inspections, which are well perceived in the field. These inspections highlight the issues related to the application of regulatory requirements for radiation protection and are a tool for making funds available, thereby improving how facilities take into consideration aspects of radiation protection.

Some positive initiatives are also worth noting. In some centres, multidisciplinary teams made up of radiologists, radiologic technologists, medical physicists, radiation protection officers, etc. have been created. This experience has produced numerous positive effects in terms of radiation protection, such as implementing procedures, optimising patient doses and facilitating feedback, for example.

3.3.2 Recommendations

These factors have led IRSN to make the following recommendations:

- take into account medical physics work in the reimbursement system as part of the recognition of the profession of medical physicist as a health profession granted by Ordinance 2017-48 [24];
- encourage facilities to invest in Dose Archiving and Communication System (DACs), given the essential role of these tools in monitoring doses to the patient and ultimately in their optimisation;
- encourage the establishment of multidisciplinary teams in imaging departments dedicated to patient radiation protection and its assessment through the quality indicators mentioned in point 3.2.2, for example.

Finally, IRSN underlines the benefits of inspections of radiology departments.

3.4 Shared medical records and networks

Electronic storage of patient files should allow access to all the information available in the patient file and thus avoid requests for redundant radiological examinations. Procedures for creating the Shared Medical Record (DMP) are currently being tested in certain French departments (Bas-Rhin, Bayonne, Côtes d'Armor, Doubs, Haute-Garonne, Indre-et-Loire, Puy de Dôme, Somme and Val de Marne) and should soon be extended throughout the country [26]. This would make it possible to respond to “The need to provide everyone with a shared, secure information system containing all the information needed for good patient care” raised by Veran [7].

Along the same lines, picture archiving and communication systems (PACS) connected to regional networks should provide healthcare professionals with access to all images of examinations performed for a given patient. In this way, redundant tests can be avoided. PACS thus constitute an effective means of reducing unjustified radiological examinations. This observation was also made by the Cour des Comptes, and stressed the opportunity to potentially reduce expenditure related to the operation of these systems [2]: “In addition to their contribution to streamlining supply, PACS are potentially powerful tools for improving the efficiency of medical imaging and offer significant savings opportunities.” Experiments, such as the ORTIF projects in Ile-de-France and PRATIC in Normandy, are being launched in some regions under the impetus of regional health agencies. But health professionals note a lack of consistency between the different projects, which are not all progressing at the same pace and pose implementation difficulties.

The widespread use in France of the DMP and information sharing systems such as regional PACS will reduce redundant examinations. **IRSN recommends ensuring they are consistent at the national level.**

3.5 Teleradiology and website for scheduling appointments

Teleradiology, which includes the analysis and interpretation of images remotely from the site of the radiological examination, has many advantages. As Veran [7] points out, it “constitutes an important tool for improving care, particularly in areas with limited access.” Professionals report positive feedback when teleradiology is performed under very precise conditions under an agreement, which takes justification into account, between the centre performing the procedure and the facility interpreting the images.

There is a teleradiology charter developed by the French Professional Radiology Council and the French Medical Council [27]. Updated in 2014, it specifies the basic principles for ethics in teleradiology. However, this document remains succinct.

Teleradiology also raises some issues from the point of view of patient radiation protection due to the absence of a radiologist in the place where the procedure is performed. In addition to the matter of validating the justification for the examination, which requires a specific organisation, ultrasound scanning is impossible without a radiologist. This may encourage facilities to carry out radiological examinations that are unjustified or could have been replaced by another type of exam. In addition, it was pointed out that the absence of a radiologist could lead centres to apply “maximum protocols” that are not optimised from the point of view of patient radiation protection (see Section 3.1.3). Finally, some professionals raised the issue of the pace of teleradiology examinations, which is sometimes incompatible with the quality of patient care and image analysis in particular.

Another point related to implementing the validation of justification should be addressed here. These are appointment scheduling websites such as “www.doctolib.fr” for example. With this type of appointment scheduling website, the patient can schedule his or her own appointment for a radiological examination, without prior verification of the justification for the examination, or even the existence of a request, by a medical secretary able to redirect or refuse the appointment. Once the patient is on site, with the slot on the equipment blocked, it is more difficult for health professionals to refuse or find a substitute for the scheduled examination.

IRSN recommends that teleradiology and appointment scheduling websites be supervised to ensure that the justification validation process is integrated into these practices.

3.6 Paediatrics

3.6.1 An underfunded field

All the professionals interviewed agree that the current system makes paediatrics chronically underfunded. The field involves few procedures but requires specific equipment and a particular organisation as well as a lot of time. Since children are more sensitive to the effects of ionising radiation, professionals are particularly attentive to aspects related to radiation protection and each step requires more time than for an adult. This is because:

- validation of the justification for the examination is essential for a child. Substitution, or the refusal of an exam, can be quite time-consuming because it is necessary to convince both parents and the attending physician;
- preparation for the exam must be rigorous to ensure the exam is performed correctly and does not need to be repeated;

- in order to ensure that the child does not move during the examination, sedation may be necessary. This requires a significant amount of time and special skills.

Thus, it is a very specific activity requiring a particular organisation for which there is no specific formal quality assurance.

In addition, in the field of paediatrics, the reimbursement system is inconsistent and may favour radiological examinations. The common classification of medical procedures provides for the application of “modifiers” which make it possible to charge more for certain specific circumstances in which procedures are carried out. For paediatrics, there are modifiers for conventional radiology and CT scanning that apply to children under five years of age and in nuclear medicine for children under three years of age. There is no such system for non-irradiating examinations such as ultrasound and MRI for children, while the problem of the time required, particularly for sedation, also exists for these procedures. It is very complicated to perform an MRI examination on a child, as the noise of the equipment can provoke anxiety. For financial reasons, this difference in treatment by the reimbursement system could encourage performing unjustified radiological exams instead of non-irradiating exams.

The time required to carry out imaging examinations in paediatrics, in particular sedation, and the specific organisation it requires, do not appear to be adequately taken into account by the reimbursement system. The Cour des Comptes had already identified paediatrics as a field that could justify the application of a variable flat fee [2]: “...the amount of the flat fee is the same regardless of the type of examination performed. However, the duration of examinations varies according to the population and the indications. This is particularly the case in paediatrics.”

Therefore, it must be considered that paediatric imaging procedures are carried out under good conditions in large facilities that can handle a loss-making operation while investing in the appropriate equipment and organisation. Performance of these procedures in non-specialised centres that do not have the appropriate organisation may be perfected from the point of view of patient radiation protection as the conditions for optimising doses are not met.

Paediatric radiology professionals also highlight a problem of general organisation of the care of patients in night emergencies already mentioned in 3.1.1. Although many CT scan examinations are not justified, they are performed because they take less time than ultrasound, and do not require the presence of a radiologist on site. This problem is particularly evident when treating abdominal pain in paediatric medicine, where professionals observe excesses in the number of abdominal-pelvic CT scans performed. Professionals consider that ultrasound in this particular case should be performed as a first-line procedure and CT scans should not be allowed until an ultrasound has been performed. However, the reimbursement system does not encourage the use of a radiologist to perform an ultrasound.

In addition, there are innovative techniques that use little or no radiation, such as voiding colour Doppler ultrasound with echo enhancement [28], which can be substituted for conventional retrograde cystography with X-rays in children, or diagnostic radiology devices using wire-chamber detectors, which substantially reduce the doses delivered to the patient [29]. But these techniques are still not widely available and used, due to their innovative nature; they remain expensive.

Finally, it should be stressed that, as professionals specialised in paediatric radiology are particularly aware of radiation protection, it is a driving force in terms of good practices in this field.

3.6.2 Recommendations

Given the specific nature of paediatric imaging, IRSN recommends that good radiation protection practices generally used in paediatrics be promoted in the reimbursement system by taking into account the time and organisation required for proper paediatric examinations and the regular use of sedation in children.

IRSN also recommends that paediatric-specific criteria be included in the quality assurance system. This would highlight good radiation protection practices in paediatrics and encourage their use in adult radiology.

IRSN recommends facilitating access to alternative options to radiological imaging in paediatrics by promoting these methods through funding and organisation, while keeping in mind the possible undesirable effects of these techniques. In particular, IRSN recommends:

- making the reimbursement system consistent so as to avoid favouring imaging procedures using ionising radiation instead of ultrasound and MRI in young children and to facilitate investment in innovative low- or non-irradiating imaging techniques specifically intended for paediatric imaging;
- taking better account of radiation protection in the organisation of paediatric emergency departments, for example by providing continuous access to ultrasound.

4 CONCLUSIONS

This report has highlighted that the reimbursement system encourages the replacement of CT scanners in France every 7 years, primarily in the private sector. In addition, the reimbursement system does not provide an incentive to upgrade equipment over time. The data from the annual dose assessments sent to IRSN by health care facilities as part of the regulations on diagnostic reference levels demonstrate the gradual decrease in dose indices according to the year the CT scanners were installed. The replacement and upgrades of CT scanners are therefore a major component of patient radiation protection. CT scanners in the public and private sectors must therefore be replaced at the same rate.

The hearings of the professionals also revealed a desire shared by all the professions for the reimbursement system to be modified to foster appropriateness. Thus, professionals appear to agree with the objective stated in the National Health Strategy 2018-2022 of “Changing funding models so that they encourage the quality and suitability of care (pricing by care pathway or episode), and not only by volume of activity” [16]. IRSN fully supports this approach, which would be an effective way of improving patient radiation protection by justifying radiology examinations.

To this end, the implementation of a quality assurance program and quality indicators linked to the clinical peer review process would make it possible to ensure suitable procedures are performed. IRSN notes that DACS and support from medical physics promote good radiation protection practices and their implementation must be encouraged. Electronic storage of patient records and PACS regional networks are methods for improving the suitability of care and radiation protection. In this respect, it is recommended that their widespread adoption and application in France be consistent at the national level. Teleradiology has many advantages but nevertheless requires careful oversight to avoid possible deviations in terms of the need for the prescribed examinations. Finally, paediatrics faces very specific organisational issues that need to be taken into account.

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