#### BJR

Received: 17 April 202 21 Accepted: 24 May 2021

Cite this article as:

Revised:

Vassileva J, Holmberg O. Radiation protection perspective to recurrent medical imaging: what is known and what more is needed?. Br J Radiol 2021; 94: 20210477.

### CONTEMPORARY ISSUES IN RADIATION PROTECTION IN MEDICAL IMAGING SPECIAL FEATURE: REVIEW ARTICLE

# Radiation protection perspective to recurrent medical imaging: what is known and what more is needed?

#### JENIA VASSILEVA, PhD and OLA HOLMBERG, PhD

Radiation Protection of Patients Unit, International Atomic Energy Agency, Vienna, Austria

Address correspondence to: Dr Jenia Vassileva E-mail: J.Vassileva@iaea.org

#### ABSTRACT

This review summarises the current knowledge about recurrent radiological imaging and associated cumulative doses to patients. The recent conservative estimates are for around 0.9 million patients globally who cumulate radiation doses above 100 mSv, where evidence exists for cancer risk elevation. Around one in five is estimated to be under the age of 50. Recurrent imaging is used for managing various health conditions and chronic diseases such as malignancies, trauma, end-stage kidney disease, cardiovascular diseases, Crohn's disease, urolithiasis, cystic pulmonary disease. More studies are needed from different parts of the world to understand the magnitude and appropriateness. The analysis identified areas of future work to improve radiation protection of individuals who are submitted to frequent imaging. These include access to dose saving imaging technologies; improved imaging strategies and appropriateness process; specific optimisation tailored to the clinical condition and patient habitus; wider utilisation of the automatic exposure monitoring systems with an integrated option for individual exposure tracking in standardised patient-specific risk metrics; improved training and communication. The integration of the clinical and exposure history data will support improved knowledge about radiation risks from low doses and individual radiosensitivity. The radiation protection framework will need to respond to the challenge of recurrent imaging and high individual doses. The radiation protection perspective complements the clinical perspective, and the risk to benefit analysis must account holistically for all incidental and long-term benefits and risks for patients, their clinical history and specific needs. This is a step toward the patient-centric health care.

#### INTRODUCTION

Medical imaging is essential in modern health care and the benefits for the individuals and for the society are undebatable. There has been a tremendous evolution of medical imaging technologies which currently include various modalities using ionising radiation, further referred to as "radiological imaging", as well as others such as ultrasonography and MRI. Imaging is used today for providing timely and accurate definition of patient condition or illness, planning, guiding and monitoring result of treatment and for long-term follow-up of patient's chronic conditions. The rapid increase of medical imaging equipment and procedures globally<sup>1</sup> and the recognised need for their further growth, especially in the low- and middle-income (LMI) countries,<sup>2</sup> pose additional responsibility for the appropriate use of radiological imaging and minimisation of associate radiation risks for patients, both tissue reactions and long-term stochastic effects such as cancer.<sup>3–5</sup> The evidence for unjustified and non-optimised radiological procedures

have triggered worldwide actions for strengthening radiation protection of patients, including stringent requirements in the International Basic Safety Standards (BSS)<sup>6</sup> and related national legislations, following the recommendations of the International Commission on Radiological Protection (ICRP),<sup>7,8</sup> as well as safety initiatives by different stakeholders.<sup>4,9,10</sup> Not to limit the individual benefits, dose limits do not apply to patients, and the emphasis is placed on improving application of the radiation protection principles of justification and optimisation.<sup>6–8,11</sup> Many international and national studies in the last two decades demonstrated dose reduction due to the technological developments and improved appropriateness and optimisation, with a trend of slowing down the increase of collective dose from medical imaging.<sup>12,13</sup> While all these actions will continue to be valid, the specific question to be discussed further in this review is the radiation protection of those individuals who undergo more imaging procedures than others. Recurrent radiological imaging, also called multiple

or frequent imaging, can be defined as a sequence of radiological imaging procedures performed to the same individual over time for managing a specific clinical condition, or for not-related reasons. This topic attracted attention due to the recent studies highlighting that the magnitude of recurrent radiological imaging and associated higher cumulated exposure might be bigger than previously known.<sup>14–16</sup> This review aims to summarise, from the perspective of radiation protection, what is known about recurrent radiological imaging and what the areas are where future work, research and consensus are needed. The review is based on published studies and commentaries, as well as the authors' involvement in consultancies on this subject organised through the International Atomic Energy Agency (IAEA).<sup>15,17</sup>

#### INDIVIDUAL DOSES FROM RECURRENT RADIOLOGICAL IMAGING: REVIEW OF PUBLISHED STUDIES

Recurrent radiological imaging is not a new phenomenon, it has been documented in many articles published over the last two decades. Our analysis includes studies with information about the cohort, type of imaging, period of assessment and statistical analyses in terms of number of procedures or cumulative dose. Despite the limitations and large uncertainties in estimation of effective dose (E) for patients, and the controversy around the use of cumulative effective dose (CED),<sup>18-22</sup> these were the metrics used by researchers to quantify recurrent imaging pattern. Methods used to assess E and organ doses, when available, were reviewed. The further focus on CED above 100 mSv is explained by the existing evidence from epidemiology<sup>7,23,24</sup> for an increased cancer risk above such doses, classified by ICRP as "moderate", compared to "negligible", "minimal" and "low" from a single imaging procedure.<sup>18</sup> At such CED values, there are organs/tissues receiving equivalent dose  $\geq 100 \text{ mSv}^{25}$ . A look at the lower dose range of 50-100 mSv is motivated by the recent epidemiological studies supporting the linear no-threshold (LNT) dose-respond model.<sup>26,27</sup> Quantification of the cancer risk for individual patients is not recommended<sup>18</sup> and was out of scope for our review.

The earlier studies (2004-2010) on recurrent radiological imaging, mainly from academic centers, included small cohorts of patients with specific clinical conditions, due to the resourceconsuming process of manual mining of data and lack of standard dosimetry.<sup>28-40</sup> Such studies, however, as well as many others demonstrating high variations of patient doses due to non-optimised practice, along with the process of expansion and digitalisation of medical imaging, facilitated the standardisation of dose data recording and presentation. Digital Imaging and Communications in Medicine (DICOM) introduced in 2005 the Radiation Dose Structured Report (RDSR), and in 2017 the Patient RDSR. The information exchange and interoperability between modalities was further coordinated by the Integrating the Healthcare Enterprise through their Radiation Exposure Monitoring (REM) Profile.<sup>41</sup> These developments allowed for the emergence of software tools for automatic collection and analyses of exposure data (referred further to as REM systems) and their utilisation in many hospitals for dose management and quality improvement.<sup>42-44</sup> Some of the available REM systems allow for

tracking of exposure data for individuals over time. Tracking has been promoted through the SmartCard project initiated by the IAEA in 2006 with the goal to develop methodologies for tracking individual patient's radiation exposure history and its proper utilisation.<sup>45,46</sup> The easier access today to big amount of digital data allowed for a new insight into the recurrent radiological imaging.

## Studies focused on patients with specific clinical conditions

Reviews are available by Brambilla et al<sup>47</sup> for chronic adult patients, Brambilla et al<sup>15</sup> and Rehani and Nacouzi<sup>48</sup> for patients with CED  $\geq 100$  mSv, and by Brambilla et al<sup>49,50</sup> and Marcu et al.<sup>51</sup> for the paediatric group. Table 1 and the text below summarise selected studies, classified in six major groups, including the size of the cohorts and the period of follow-up, and a detailed information is provided in the Annex.

#### Emergency department patients

The use of imaging and especially CT in the emergency department has grown dramatically.<sup>4,5,32</sup> Among the emergency department patients, those at risk for high doses include patients with trauma, renal colic, abdominal pain or other life-threatening condition or a chronic disease.<sup>32,52</sup> Griffey et al<sup>32</sup> found over a half of the cohort to receive  $\geq 10$  CT examinations and CED  $\geq 91$  mSv accumulated in 7.7 years mainly from body CT. Bullard et al<sup>52</sup> found 12% of emergency patients (42% at age under 50), to accrue  $\geq 100$  mSv in 5 years, suggesting that those with conditions such as renal colic and chronic/recurrent pain could be imaged with an alternative modality.

A significant fraction of patients with trauma and especially polytrauma, many at young age, receive multiple CT and other imaging which is lifesaving and critical.<sup>33</sup> You et al<sup>53</sup> estimated that among trauma patients who received CED  $\geq$  100 mSv within a short period, the common causes were pedestrian or vehicle injury or falling. Ahmadinia et al<sup>54</sup> found doubling the number of CTs per trauma patients over 6 years, despite no change in mortality or injury severity. The authors stressed the importance of establishing institutional imaging algorithms for addressing emergency clinical scenarios and tracking imaging history of patients, especially those with recurrent emergency department visits.<sup>28,32,33,52–54</sup>

### Patients with renal colic and end-stage kidney disease

Urinary stones have 35–40% recurrence rate over 10 years and imaging plays an important role in managing renal colic.<sup>29</sup> Katz et al<sup>29</sup> found that 4% of patients with urolithiasis accumulated in 6 years CED between 20 and 154 mSv. Ferrandino et al<sup>34</sup> estimated an annual CED  $\geq$ 50 mSv in 20% of adults presented with a primary acute stone episode. Similar frequency of 17.3% in the first year was found by Fahmy et al<sup>55</sup> who noted decrease of CED because of higher use of ultrasound during the second year of follow-up. Stein et al<sup>36</sup> found increase of patients with CED  $\geq$ 50 mSv, from 6.8 to 11.1% when prolonging the follow-up from 3 to 5 years. When CT is needed, dedicated low-dose protocol is recommended for managing renal colic.<sup>56</sup>

cal condition/ disease ency department patients ency patients with trauma ency patients with trauma ted renal colic age kidney disease: on age kidney disease: on dialysis or kidney transplant ted or known heart disease ransplants and surgery ransplants repair (EVAR) nary diseases matory bowel disease matory bowel disease	Number of selected         studies and country of         their origin         3 studies from USA (3), Ireland         (1)         3 studies from USA (6), Canada (1), Germany (1), Korea (1), Italy (1), Thailand         5 studies from USA (4), Canada (1)         5 studies from USA (4), Canada (1)         7 studies from USA (4), Canada (1)         7 studies from USA (4), Canada (1)         8 studies from USA (2), (1)         3 studies from USA (2), (1)         3 studies from USA (2), UK (1)         2 studies from USA (2), Ireland         3 studies from USA (2), Ireland         17 studies from USA (2), Ireland         10         11         2 studies from USA (2), Ireland         11         11         11         12< studies from USA (2), Ireland         11         11         11         11         12< studies from USA (2), Ireland         11	Cohorts130, 421, 1243 patients130, 421, 1243 patientsFrom 36 to 11,676 patientsFrom 104 to 4562 patientsFrom 70 to 1225From 50 to 952,420 patients31,202,337 patients71 and 59 patients71 and 59 patients5 and 10786-1429 patients	Modalities included in the analysis         Only CT in 1 study, All imaging in 3         Only CT in 1 study, All imaging in 3         Only CT in 5 studies, Radiography and CT in 8         All imaging in 3         All imaging in 3         All imaging only FGI in one         All imaging         All          All          All	Period of exposure history         1-7.7 years         1-7.7 years         During the trauma episode         10 months - 8 years         0.8-4.1 years         0.8-4.1 years         1 year - 20 years         1-4.8 years         3-8 years         3-8 years         3-8 years         3-5 years
d non-Hodgkin	8 studies from Canada (2), USA (2), Belarus (1), Germany (1), Taiwan (1), Turkey (1)	29–4874 patients	All in 4 studies, CT and PET/CT in 3, CT in one	2–6 years
efer to the Annex.				

Table 1. Summary of studies focused on patients with specific clinical conditions<sup>a</sup>

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Patients with end-stage kidney disease are among the heavily submitted to recurrent radiological imaging, especially those on haemodialysis (HD).<sup>15,47</sup> CED  $\geq$ 100 mSv was estimated for 16% of HD patients in 3 years follow-up by De Mauri et al,<sup>57</sup>  $\geq$ 75 mSv in 13% in 3.4 years by Kinsella et al,<sup>37</sup> and  $\geq$ 50 mSv in 5% in 1 year by Postorino et al.<sup>58</sup> Compared to HD, CED in kidney transplant patients is lower: CED  $\geq$ 100 mSv was found in 12% of post-transplants during the 3 years follow-up by DeMauri et al.<sup>59</sup> and  $\geq$ 50 mSv in 2% during a single year by Postorino et al.<sup>58</sup> Young patients on HD who are on the waiting list for kidney transplant tation are at higher risk for high doses.<sup>15</sup>

#### Patients with cardiovascular diseases

Among patients with heart diseases, those with acute cardiac infarction (ACI) and cardiac transplants, especially young patients, cumulate high doses from recurrent radiological imaging.<sup>15</sup> McDonnel et al<sup>60</sup> estimated that 91% of CED is from catheterisations, 31% during the transplant admission, and 62% during follow-up. For ACI, Eisenberg et al<sup>61</sup> estimated that 18% of patients accrue >30 mSv in the first year after ACI, and Lawler et al<sup>40</sup> found mean CED of 11.8 mSv during the acute phase and 19 mSv up to 3 years. Bedetti et al<sup>31</sup> assessed 25% of cardiac patients to accumulate lifetime CED >100 mSv, with the main contribution from fluoroscopy-guided interventions (FGI), myocardial perfusion imaging (MPI) and CT. Einstein et al<sup>62</sup> found that 31.4% of patients who underwent MPI accrued >100 mSv and 10.9% >200 mSv in 20 years. For a 30 years follow-up, Chen et al<sup>63</sup> found 2.5% with annual CED 20 mSv and 0.08% with >50 mSy, out of which 74% from MPI and 21% from FGI. Jones et al<sup>64</sup> studied 117 children (mean age 3.5 years) with congenital heart disease and found 9.4% accruing CED ≥50 mSv and 1.7% ≥100 mSv.

High CED was also documented in the group of patients undergoing endovascular aortic aneurysm repair (EVAR).<sup>15,65,66</sup> All patients followed-up for 1.8 years by Brambila et al<sup>65</sup> received CED >50 mSv and 93% CED >100 mSv. Kalender et al<sup>66</sup> found mean CED of 109 mSv during the first year and 16 mSv annually subsequently, 27.7% of which from EVAR.

#### Patients with pulmonary diseases

For patients with pulmonary thromboembolic disease, Stein et al<sup>36</sup> found the mean CED in 3 years to be 21.7 mSv and 12.4% to reach CED >50 mSv in 8 years. Takahashi et al<sup>67</sup> found 15.7% of patients with suspected pulmonary embolism with CED >50 mSv and 0.05% with >100 mSv in 4 years. For patients with cystic fibrosis until lung transplantation, O'Connel<sup>68</sup> identified 2.6% with CED >50 mSv, 74.8% of which from CT and 11.8% from FGI procedures. For lung transplants with mean period of 6.5 years follow-up, Rosengarten et al<sup>69</sup> estimated mean CED 138 mSv, similar to Fitton et al<sup>70</sup> who found 110 mSv, 73% of which from chest CT. A recent IAEA study indicated that COVID-19 pandemic posed an additional challenge for recurrent radiological imaging, identifying the need for guidelines.<sup>71</sup>

#### Patients with inflammatory bowel disease (IBD)

Radiological procedures are common among both adult and paediatric patients with IBD, including Crohn's disease (CD) or ulcerative colitis (UC). The average age of these patients is low, especially for CD. Researchers found higher CED for the group of CD compared to UC, *e.g.* mean CED of 21.1 *vs* 15.1 mSv for CD and UC respectively,<sup>35</sup> 14.3 *vs* 5.9 mSv<sup>72</sup> and 53.6 *vs* 16.4 mSv.<sup>73</sup> A substantial fraction of patients accumulates high doses, 75–78% of which from CT.<sup>72,73</sup> The group of CD patients with CED  $\geq$ 50 mSv varied from 7% in the studies of Levi et al<sup>35</sup> up to 34% in Kroeker et al.<sup>72</sup> Researchers noted that although in the past evaluation of IBD was limited to barium studies and CT,<sup>35</sup> other modalities including ultrasound and MRI offer potential for dose reduction and should be prioritised, especially in children.

#### Patients with lymphoma

The accurate and timely imaging is very important for contributing survival of oncology patients, but on the other side, improved survival rates, especially for childhood cancers, together with improved life expectancy raised concerns related to long-term radiation risks of second cancer due to the extensive use of radiological imaging.<sup>51,74,75</sup> Among cancers with significantly improved survival are Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL) what motivates the studies on imaging doses for adults and children.<sup>38,39</sup> CED >100 mSv from CT and PET/CT was found in 83% of 29 children by Chong et al<sup>38</sup> and in 27% of 78 children by Chawla et al<sup>39</sup>. Higher CED was found for the groups with HL compared to NHL.<sup>76</sup> Fabritius et al<sup>74</sup> concluded that more imaging was used than recommended by the available imaging guidelines for managing lymphoma. Optimised radiological imaging protocols and alternative methods such as MRI are recommended for dose management.

#### Population-based studies

Population-based surveys involving large cohorts became possible with the improved access to digital data through the hospital digital information system, electronic health records and REM systems. The review found 20 such studies from 2009 to date focused on identifying patients with high CED, a summary of which is presented in Table 2.<sup>14,15,25,77–93</sup> 10 of the studies come from the USA,  $^{77-81,83,85,89,90,93}$  8 from Europe,  $^{25,85-88,91,92}$ 1 from Republic of Korea<sup>82</sup> and 2 are international,<sup>14,15</sup> with a total number of over 11 million patients: 61.3% from the USA, 38.5% from Europe, less than 0.2% from Asia and Africa, and no data from Latin America. This disproportion is explained by the lack of digital archives and REM systems in LMI countries, as well as the shortage of human resources and especially imaging medical physicists to support data analyses.<sup>15</sup> A half of these studies are very recent, some motivated by the IAEA meetings in 2019 and 2020.<sup>17</sup> The period of retrospective evaluation of exposure history varied between 1 and 22 years, most frequently 3-5 years (Table 2).

The first population-based study published by Sodickson et al<sup>77</sup> in 2009 found that 33% of the cohort had  $\geq$ 5 and 5% between 22 and 132 lifetime CTs, which resulted in CED  $\geq$ 100 mSv in 15% of patients and in 4% between 250 and 1375 mSv. Fazel et al<sup>78</sup> identified a fraction of 0.2% of nonelderly adults (18–64 years) with CED  $\geq$ 50 mSv and concluded that CT and nuclear medicine (NM) contributed to 75.4% of dose, and 81.8% of the CT dose come from outpatients setting. Lutterman et al<sup>80</sup> found 16% of inpatients with  $\geq$ 3 CTs and 1% with CED  $\geq$ 100 mSv during

Table 2. Population-based studies aimed to identify patients with recurrent procedures and high cumulative effective dose (CED)

uthor, year	Country/ region	Cohort (specific criteria, # patients, age group)	Type of procedures	Period of exposure history	Main findings in number of procedures or % of patient with CED above a certain value in mSv
dickson et al <sup>77</sup>	USA	31,462 patients, mean age 56.9 y in an academic medical center	CT	22 years	33% had ≥5 CTs, 5% had 22–132 CTs 15% had CED ≥100 mSv, 4% had 250–1375 mSv
zel et al <sup>78</sup>	USA	952,420 nonelderly adults, mean age 35.6 y in five health care markets	All	3 years	1.9% had annual CED > 3–20 mSv; 0.2% had >50 mSv 75.4% of CED from CT and NM
orfinan et al <sup>79</sup>	USA	355,088 children, mean age 9.0 (0–18) y, in five health care markets	All	3 years	25.2% had ≥2 and 16% had ≥3 imaging procedures 22.3% had ≥2 X-rays, 3.5% had ≥2CT scans
itterman et al <sup>80</sup>	USA	200 consecutive inpatients ≥ 18 y, mean 60.4 y, two academic hospitals	All	During a single hospital stay	16% had ≥3 CTs, 5.5% had CED ≥50 mSv, 1% had ≥100 mSv
ostani et al <sup>81</sup>	USA	34,672 patients, academic hospital	CT	1 year	2.7% with CED ≥100 mSv 1/3 trauma patients
ee et al <sup>82</sup>	Korea	13,803 children age <15 y In an academic hospital	CT	5 years	0.07% had ≥3 CTs, in this group, median 9 (3-28) CTs 0.1% had CED ≥20 mSv, 0.001% had ≥30 mSv
topsack et al <sup>83</sup>	USA	26,377 adults, median age 44 y	CT	10 years	17.5% had 5−10 CTs, 8.8% had ≥10 CTs. 1.9% had CED ≥100 mSv
umbreras et al <sup>84</sup>	Spain	154,520 (68.8% of all patients) with ≥1 exam, 14% children < 15 y	All	12 years	52.9% had ≥5 exams; 25.4% had ≥5 CTs 3.1% had CED 50–100 mSv, 1.5% ≥ 100 mSv.
ehani et al <sup>14</sup>	USA, Europe	2,504,585 patients in 4 institutions (A, B, C, D) with 324 hospitals	CT	1–5 years	1.33% had CED ≥100 mSv: 3.4% in institution A (5 γ), 1.4% in B (2γ7m), 1.5% in C (5 γ), 0.64% in D (1γ1m).
rambilla et al <sup>15</sup>	USA, Europe, Asia, Africa	702,205 patients in 20 hospitals in 20 countries	CT	0.4–6.1 years	CED $\ge$ 100 mSv from 0 to 5% across institutions Average 0.65% patients with CED $\ge$ 100 mSv
ehani et al <sup>85</sup>	USA	8,952 with CED ≥100 mSv in an academic hospital	CT	5 years	123 patients: 9.6% with non-malignant conditions and 1.4% with age ${\leq}40~y~({\rm mean}~{\rm age}~{3}1.9~y)$
itousi et al <sup>86</sup>	Belgium	900,000 patients in 23 hospitals	CT, FGI	1 year	0.14% had CED ≥100 mSv Median CED 125 (IQR 110–151) mSv Mean 6.2 (IQR: 5–6.8) exams
RSN <sup>87</sup>	France	National sample of 319,187 patients with ≥1 exam	CT	1–6 years	0.49% had CED ≥100 mSv in 1 year, 1.44% in 3 year and 2.25% in 6 year; 25% aged <55 y
wee et al <sup>88</sup>	Netherlands	100,966 patients with ≥1 CT in a tertiary care center	CT	10 years	0.06% had ≥40 CTs (40-92) Mean CED 187.4 mSv (120.7–278.4)
trellano et al <sup>89</sup>	USA	8,952 who had CED ≥100 mSv in an academic hospital	CT	5 years	33 had $E \ge 100$ mSv in a single CT guided intervention, 12% age <50 y
i et al <sup>90</sup>	USA	25,253 patients, mean age 58.2 (≥18) y, academic hospital	FGI	109 months	4.0% had CED ≥100 mSv 41.7% had only 1 FGI, 79.1% had 100 mSv in 1 year
eukens et al <sup>91</sup>	Netherlands	49,978 patients, median age 62 (0–103) y, academic hospital	CT	Maximum 5 years	4.7% had 6−10 CTs, 0.8% had ≥11 CTs 482 (1%) had CED ≥100 mSv

	Country/	Cohort (specific criteria,	Type of	Period of exposure	Main findings in number of procedures or % of
Author, year	region	# patients, age group)	procedures	nistory	patient with CED above a certain value in mov
Frija et al <sup>92</sup>	Europe	1,218,429 patients from 18 hospitals in Europe	CT	4 years	Between 0 and 2.7% (mean 0.5%) had CED $\geq \! 100 \ {\rm mSv}$
Rehani et al <sup>93</sup>	USA	3,880,524 patient-days, mean age 57.8 y in 279 USA hospitals	CT	5 years	0.8% had ≥50 mSv, 0.03% had CED ≥100 mSv in a single day
Brambilla et al <sup>25</sup>	Italy	28,870 patients, tertiary care center	CT	2.4 years	6.1% had CED ≥100 mSv; 4% of them had 100 mSv in a single procedure and 24% in a month

CED, cumulative effective dose.

a single hospitalisation episode. Bostani et al<sup>81</sup> found 2.7% with CED ≥100 mSv from CT in a year. The "top-10" highest CED was associated with FGI, CT-guided ablations and head trauma. Stopsack et al<sup>83</sup> found 26.3% with >5 CTs and 1.9% with CED ≥100 mSv in 10 years. Lumbreras et al<sup>84</sup> estimated 25.4% with ≥5 CTs, 1.8% with ≥5 FGI procedures, and 1.5% with CED  $\geq 100 \text{ mSv.}$ 

Two studies of paediatric population<sup>79,82</sup> identified a small fraction of children who underwent frequent procedures: 3.5% with  $\geq$ 2 CTs<sup>79</sup> and 6.7% with >3 CTs<sup>82</sup> respectively. Dorfman et al<sup>79</sup> used age-specific conversion factors from dose-length product (DLP) to calculate E and found a low fraction (0.1%) with CED ≥20 mSv, most common in children with malignant tumours (58%), followed by the groups with ventriculoperitoneal shunt, liver transplant and trauma.

Two large multinational studies were published in 2020 by Rehani et al<sup>14</sup> and Brambilla et al<sup>15</sup> with a total of about 3.2 million patients, the second of which from the IAEA coordinated study in 20 countries. Rehani et al<sup>14</sup> identified the fraction of patients with CED ≥100 mSv from CT to vary between 0.64 and 3.4% across institutions (average 1.33%), and Brambilla et al<sup>15</sup> found larger variations, from 0% in Africa and Asia up to 5% in a hospital in Europe (average 0.65%). The contributing factors were not studied, but in addition to the associated uncertainties of CED and different periods of data collection, could be explained by factors such as differences in the case mix, pattern of appropriateness, level of optimisation of radiological imaging protocols, type of reimbursement, access to alternative non-radiological imaging modalities, local preferences and others.<sup>14,15,77</sup> A conservative estimation was made using the lowest average frequency of 0.64% that there may be annually 0.9 million patients globally with CED  $\geq$  100 mSv from recurrent radiological imaging.<sup>14,15</sup> Using the CT procedures statistics for 35 countries from the Organization for Economic Co-operation and Development (OECD), Rehani and Hauptmann<sup>16</sup> estimated the total number of patients with CED  $\geq 100 \text{ mSv}$  in a 5 years period to be 2.5 million (0.21% of the population), with nearly sixfold variation between countries, between 0.51 and 2.94 per 1000. These numbers may be underestimated, since, e.g. their prediction for France was for 145,998 cases in 5 years, which is lower compared to the findings of a recent national study in France. Researchers from the French Radiation Protection Institute (IRSN) showed increase over the period of follow-up of the cohort of patients exposed to  $CED \ge 100 \text{ mSv}$ , from 33,000 (0.49%) of all patients undergoing CT) in 1 year, to 212,000 (1.44%) in 3 years and 506,000 (2.25%) in 6 years of follow-up.87

A study of Fitousi et al<sup>86</sup> involving 23 hospitals found 0.14% with CED ≥100 mSv in a year (0.7% in a large university hospital), with a median number of 6.2 CT or FGI procedures (9.1 for the university hospital) for this group. Reasons for high CED were multiphase abdominal CT, polytrauma and combined CT exams. A study of Jeukens et al<sup>91</sup> found 1% with CED  $\geq 100 \text{ mSv}$ and presented graphically the increase in probability of receiving high CED over time, with 1.9% for females and 1.5% for males in 4.5 years.<sup>91</sup> The probability of high E was assessed to 0.01%

<sup>able 2.</sup> (Continued)

from 1 to 2 CT, 16% from 6 to 10 CT examinations and 32% from  $\geq$ 11 CT examinations.<sup>91</sup> The studies of Rehani et al<sup>93</sup>, Arellano et al<sup>89</sup> and Brambilla et al<sup>25</sup> showed that CT-guided interventions such as ablations, myelograms, drainages and biopsies, as well as chest, abdomen and pelvis CT, often used in recurrent radiological imaging, may results in  $\geq$ 100 mSv in a single episode of care, single day or even a single procedure. The study of Li et al<sup>90</sup> found that 4.0% had CED  $\geq$ 100 mSv from FGI procedures within 109 months, of which 41.7% had a single FGI and 79.1% received 100 mSv in a year. The clinical indications for these procedures were cancer (41%), chronic disease of torso (20%), internal bleeding (18%), trauma (4%), organ transplant (6%), and cerebrovascular disease (1%).

A study of Frija et al,<sup>92</sup> involving 18 hospitals from the Euro-Safe Imaging network, found variations of the fraction of patients with CED  $\geq$ 100 mSv between 0 and 2.7% (mean 0.5%), similar to the other European studies, except those of Brambilla et al,<sup>25</sup> reporting higher rate of 6.1% in 2.4 years. Kwee et al<sup>88</sup> focused on the patients with  $\geq$ 40 CTs over 10 years-period (CED 120.7–278.4 mSv) and found this to be a small fraction (0.06%) of patients, all related to malignant disease. This lower number could be partly explained with the higher inclusion criteria (>40 CTs).

An important conclusion from the large population-based studies is that although the majority of patients submitted to high dose from recurrent radiological imaging are older people with malignancies and other serious medical problems, there is a significant fraction of younger patients with no history of malignancy or with curable cancer, who might be at increased risk. The fraction of patients with CED  $\geq 100 \text{ mSv}$  under the age of 50 was between 13 and 28% across institutions in the study of Rehani et al<sup>14</sup>, 18.3% in Jeukens et al<sup>91</sup>, 22% in Lumbreras et al<sup>84</sup>, 27.4% in Fazel et al<sup>78</sup> and 40% in Stopsack et al<sup>83</sup> The French study found 25% aged under 55.<sup>87</sup>

Sodickson et al<sup>77</sup> demonstrated that among those with CED  $\geq 100 \text{ mSv}$ , 40% had no malignancy or had a cancer history with no active disease. This fraction was 9.6% in the cohort followed by Rehani et al,<sup>14</sup> 20% by Jeukens et al<sup>91</sup> and 27% by Lumbreras et al<sup>84</sup>. Frija et al<sup>92</sup> found 58% with oncological disease, 13.7% chronic disease, 21.1% trauma, 1.3% transplant, 5.9% others. Brambilla et all<sup>25</sup> identified a higher fraction, 69%, related to non-oncological conditions, among them, the polytrauma subgroup (mean age of 53 years), was on average 13 years younger of the subgroup of cancer patients. These numbers, although varying due to local specifics or disease prevalence, indicate the general pattern.

Few studies aimed to evaluate what fraction of recurrent radiological imaging was unjustified. Bostani et al<sup>81</sup> reviewed patient records of top 20 patients with high doses and concluded that most exams contributing to high CED were warranted and necessary, especially for trauma and cancer. Rehani et al<sup>85</sup> analysed imaging appropriateness of 123 patients under 40 years with non-malignant conditions and found that in 87.5–100% of cases imaging followed appropriateness criteria and was properly justified through the clinical decision support (CDS) system. They identified nearly half of CT exams unrelated to follow-up of a primary chronic disease. The results of the study showed the need for solutions beyond strengthening justification such as lower dose technology.<sup>85,94,95</sup> Their findings, however, coming from an academic centre with a documented minimal fraction of inappropriate imaging as a result of the use of CDS, cannot be automatically translated to other hospitals. Further analyses of clinical appropriateness are needed, as well as of the sufficiency of guidance for the use of imaging in the management of patients with specific clinical conditions that might require serial imaging and long period of follow-up.<sup>14,15,17,85,92,94</sup>

#### Methods for dose estimation

The methods used to estimate *E* and their associated uncertainty varied across studies and included: (1) typical E values from the literature (largest uncertainties)<sup>31,32,35,52,59,63,68,70,72,73,78,83,84</sup>; (2) calculation from a modality-specific quantity (e.g. DLP for CT) with tabulated conversion factors which ignore patient's habitus and irradiation field<sup>14,25,67,73,76,77,80,85,88,90,93</sup>; (3) from organ doses calculated with Monte Carlo-based software and generic phantoms weighted with the tissue weighting factors (a closer representation of the patient exposure)<sup>65,68,70,74,85,89</sup>; (4) applying patient-specific organ dosimetry by matching a patient to an atlas of realistic human models that is the most patient-relevant technique, already integrated in few of the REM systems.<sup>25,85,86,91</sup> Since these methods do not result in identical estimates, the values should be compared with caution. Despite the limitations, the value of these studies is that they identified the problem with high cumulative doses for specific groups. They also showed a need for improved and standardised patient-specific dosimetry and guidelines for its proper use.

#### Conclusions from the studies

The findings of the recent published studies can be summarised as follows:

- (1) The magnitude of recurrent radiological imaging is higher than previously known, with a trend to increase. Data are available from only a part of the world with a lack of information from the LMI countries.
- (2) The current estimates are for around 0.9 million patients globally who cumulate effective dose above 100 mSv, where evidence exists for the cancer risk elevation.
- (3) Recurrent radiological imaging is used for managing various health conditions and chronic diseases such as malignancies, trauma, end-stage kidney disease, cardiovascular diseases, Crohn's disease, urolithiasis, cystic pulmonary disease. Some patients might suffer a combination of diseases or conditions at the same time or in consequence.
- (4) Although the majority are seriously ill old people, around one in five is aged under 50.
- (5) The existing studies do not indicate that a significant fraction of paediatric patients is submitted to recurrent radiological imaging. More studies are needed to clarify the situation.
- (6) Most population-based studies are limited to CT or FGI, while the contribution of NM is not well studied. There is a lack of data of the total doses from different modalities.

- (7) The few available studies showed that most recurrent radiological imaging was needed and appropriately selected. This aspect requires further investigation in different settings.
- (8) The interpretation of data is complicated by the lack of standardisation of the methods for estimation of *E* and lack of patient-specific organ dose estimation.
- (9) Automatic REM systems are powerful tools to support optimisation and quality improvements through monitoring modality-specific exposure metrics. Some systems provide for exposure history tracking in *E* and just few in patient-specific organ doses. REM are not widely available and their calculations and analyses not sufficiently standardised.

#### **AREAS OF FUTURE WORK**

The studies triggered discussion at international level, from which the following areas have been identified to need further research and actions by different stakeholders.<sup>14,15,20,49,50,75,92,94–98</sup>, This is also reflected in the recently published Joint Position Statement and Call for Action by nine international organisations.<sup>99</sup>

#### Imaging technology

Further hardware and software development of imaging modalities is expected, with a focus on dose saving and quality improvement techniques in CT, FGI and PET/CT. Machine learning and artificial intelligence are promising in this regard. Warranting access to newer technologies worldwide will be a challenging task.

#### Specific justification and appropriateness

Actions from the professional clinical bodies are expected to review/ update/create clinical imaging guidelines and strategies, in terms of type of imaging and its frequency, for the clinical situations that can be predicted to involve recurrent radiological imaging. Wider utilisation of CDS will help guide the clinical decisions and improve documentation of the appropriateness. This is linked to the need of continuous awareness actions and audits.

#### Specific optimisation

Multidisciplinary teams need to ensure availability of standardised and size-specific optimised imaging protocols for diagnostic and follow-up of clinical conditions requiring serial imaging. Education of staff and audit are critical for ensuring adherence to protocols. DRLs for clinical indications specific to recurrent radiological imaging, and perhaps for the entire series of imaging, will help benchmark local practices. Modalityspecific metrics in the individual exposure history may help in optimisation, as a patient undergoing recurrent radiological procedures may act as a self-reference.

#### Automatic radiation exposure monitoring systems

There is a strong need to wider utilise REM systems and standardies their functionalities and calculation methods. In addition to the essential collection and analyses of the relevant modalityspecific metrics for optimisation and quality improvement, they need to provide for tracking of exposure history of individuals. Ideally, this should be in patient-specific metrics such as organ doses, accompanied with uncertainty estimation.<sup>100-102</sup> Until this is possible, *E* calculated with standardised conversion coefficients, is the pragmatic solution. Like any other data in REM systems, the proper quality control by clinical medical physicists of dose calculations is essential. User groups of REM systems and their access level need to be carefully considered to ensure proper use. For most effective use, REM systems should be integrated with the other health-care electronic systems.

#### Radiation protection framework

The current radiation protection system does not specifically address recurrent radiological imaging, and this might need strengthening. For the individual justification of a procedure by referring physicians and radiologists, the International BSS<sup>6</sup> requires relevant information from the previous procedures to be provided. The Safety Guide SSG-46<sup>11</sup> further explains that "The results (images and reports) of previous examinations should be made available, not only at a given radiology facility but also for consultation at different facilities. Digital imaging modalities and electronic networks should facilitate this process. Individual patient exposure records should be used to facilitate the decision-making process if available." Consensus is still lacking on the proper utilisation of the dose information from the previous procedures, and the concern for misuse and misinterpretation, especially by referring physicians and patients,<sup>22</sup> needs to be addressed. Like any other aspect of medical uses of ionising radiation, the competence and awareness of users of dose information is paramount, and this is linked to the knowledge, education, training and communication.

#### **Research studies**

The improved access to patient-specific organ doses, linked to patients health records, will allow for strengthening the studies of low-dose effects from medical exposure, particularly in childhood, while accounting for reverse causation and confounding factors.<sup>18</sup> Another important area of research is the biodosimetric methods and quantification of patients' radiosensitivity and radiosusceptibility, to assist the transition to the precision medicine.

#### CONCLUSION

This review provides the radiation protection perspective to the recurrent radiological imaging to complement the clinical perspective. The need for lower dose imaging modalities and techniques is highlighted, as well as improved imaging strategies and appropriateness process and specific optimisation tailored to the clinical condition and patient habitus. The technological developments and data science provide improved methodologies for patient exposure tracking in support of the appropriate and optimal use of radiological imaging, and for improved quantification of individual radiation risks. This knowledge, if properly utilised, would add the holistic clinical decision process that accounts for all incidental and long-term benefits and risks for patients, their clinical history and specific needs. This is a step toward the patient-centric health care.

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