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PAPER

How much should we be concerned about cumulative effective doses in medical imaging?

Colin J Martin[1,*] **and Michael Barnard**[2]

[1] Department of Clinical Physics and Bioengineering, University of Glasgow, Gartnaval Royal Hospital, Glasgow, United Kingdom
[2] Department of Radiation Physics and Protection, Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom
[*] Author to whom any correspondence should be addressed.

E-mail: colin.j.martin@ntlworld.com

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Abstract

The International Atomic Energy Agency issued a statement calling for action to strengthen the radiation protection of patients undergoing recurrent imaging. This followed reports of patients receiving cumulative effective doses over 100 mSv from multiple computed tomography examinations. In order to evaluate excess risks of cancer incidence among UK patients, data from an exposure management system covering three hospitals within one trust have been studied over 5½ years. Cumulative effective doses for 105 757 patients, from whom 719 (0.68%) received effective dose over 100 mSv, have been analysed using age and sex specific risk factors for stochastic effects. Two cancers might be expected to be initiated in the patients receiving over 100 mSv, while five might be expected to develop cancer among patients receiving 50–100 mSv. However, the calculations ignore health conditions for which the patients are being treated that may shorten their lives, and rely on the linear-no-threshold dose-effect model which is a subject of debate, so they are likely to overestimate cancer incidence. If health of the patients receiving >100 mSv is taken into account, the risk of mortality from cancer initiated by medical exposure might be the order of 1 in 2000. Recommendations on further strengthening of optimisation should be applied to imaging procedures for all patients with special focus on those performed on children and adolescents.

1. Introduction

There has in the last two years been a considerable amount of discussion about doses that individual patients can accrue from multiple imaging procedures. This has been more apparent since patient radiation exposure management systems have been installed in many US hospitals. These calculate organ, tissue, and effective doses for each computed tomography (CT) patient that can be accessed for subsequent analysis. Effective doses accumulated from multiple scans performed on individual patients have been summed in a number of centres in the USA and Europe, revealing that significant numbers of patients receive cumulative effective doses that often exceed 100 mSv from these scans [1–3]. The doses from CT scans make up the largest component of the collective doses to patients [4, 5], although patients will receive additional doses from other radiology and nuclear medicine procedures [6]. There is concern that in many countries, particularly those with private healthcare systems, examinations are carried out unnecessarily without proper planning and justification. However, when patients are severely ill repeated imaging is frequently necessary for successful management of the patient's illness, to check the tissues affected, show the progression of disease, and monitor the progress of treatment. The concern is that these examinations carry an increased risk of stochastic effects, primarily cancer. However, many of the patients who receive multiple examinations are in the last third of their life when these risks are lower, and the conditions for which they are being treated may shorten their lives further.

The International Atomic Energy Agency (IAEA) has recently issued a position statement, endorsed by a number of other international organisations, calling for action to strengthen radiation protection of patients undergoing recurrent radiological imaging procedures [7]. Many of the actions covered in the statement,

such as strengthening radiation protection education and training, customising imaging protocols for individual patients, improving technology to reduce doses, ensuring proper justification, and developing strategies for clinical conditions where recurrent imaging is required will be beneficial to all. The statement also calls for the dissemination of automatic radiation exposure monitoring systems to provide effective tracking of the radiation exposure history of individual patients. Dose tracking has become more widely used in recent years [8, 9] and can be considered as part of the justification process in some countries. But this has not been widely applied in the UK, and is not supported by the American Association of Physicists in Medicine, the American College of Radiology, and the Health Physics Society which have issued a joint statement that 'the decision to perform a medical imaging exam should be based on clinical grounds, including the information available from prior imaging results, and not on the dose from prior imaging-related radiation exposures' [10]. The introduction of dose tracking could require significant extra focus on the group of patients that receive recurrent exposures and detract from service provision in other areas, so it is important to consider whether such a feature is necessary and likely to be beneficial. There are a number of questions that need to be answered. How large are the risks to those receiving effective doses over 100 mSv? Is a special focus on this group justified? Is tracking of the dose histories for these patients necessary in the UK? How significant are the risks for patients that undergo imaging, but for whom the cumulative effective doses do not reach 100 mSv? In order to attempt to shed some light on these questions, data from a UK patient radiation exposure management system have been analysed using age and sex specific risk factors [11] to compute the numbers of patients that might present with cancers that were initiated by radiation from medical exposures.

2. Methods

The study used data from Radimetrics™ dose management software (version 3.0A; Bayer AG Berlin, GDR) [12] that is installed on a virtual machine hosted by the Oxford University Hospitals NHS Foundation Trust. The methodology has been described in a previous paper considering the radiation risks relating to cardiovascular and cerebrovascular disease [13] and will only be described briefly here. Dose sheets and images from 12 CT scanners at three hospitals within the Trust are sent to the picture archiving communication system and forwarded on to the Radimetrics platform for processing. The CT scanners were four GE Lightspeed VCTs, three GE Revolution HDs, three Siemens Somatom Drives, one Canon Aquilion 64, and one GE Revolution CT (256 slice). The Radimetrics Platform uses a Monte Carlo simulator to model x-ray interactions with patients represented by a set of stylised phantoms [14, 15]. The phantom selected for each patient is based on age, gender and mid-scan diameter or weight. The software contains simulations run for different scan protocols for each phantom and data on the energy deposited in every organ and tissue within each slice are obtained from a look-up table, based on the scan parameters and patient information. The organ doses for individual scans are scaled based on the volume averaged CT dose index ($CTDI_{vol}$) and calibrations of the displayed values of $CTDI_{vol}$ for each scanner are confirmed at two year intervals. Values for the effective dose are calculated using ICRP 103 tissue weighting factors [16].

Patient and examination data were exported from the Radimetrics platform through summary pages in the user interface and transferred to an Excel™ spreadsheet. Records can be listed in three levels, patient, examination, and acquisition, and filters were applied to the data based on examinations, which included summed data from all acquisitions during the event. The examination events were filtered by date, modality, device, and master protocol. All head and body master protocols were included in the filter, but extremity and interventional procedures were excluded. Fields from the records selected for export included protocol name, series description, date performed, device, patient medical record number (MRN), gender, age at exam, and effective dose.

Data for 215 194 CT examinations performed on 105 757 patients receiving CT scans over a period of $5^1/_2$ years from 26 October 2015 to 6 May 2021 were downloaded into an Excel workbook. About 65 394 patients had body CT scans, 58 430 had head scans, and 18 067 had both. Patient MRNs were removed and replaced with a unique nonidentifiable key. Effective doses from all CT scans performed on each patient were summed. Protocol names in the data exported from Radimetrics were edited manually and labelled as either body or head examinations to facilitate application of risk factors. If a patient had received both head and body examinations, the numbers of each were recorded.

Although in principle doses to individual organs and tissues for each patient could all have been downloaded and analysed separately using age and sex specific risk coefficients, this would have considerably increased the amount of data, and required many more calculations, so lengthening the time required both for the download and analysis. In order to facilitate the use of effective dose for assessments of this type, ICRP have tabulated values of risk coefficients in ICRP Publication 147. These give the total lifetime risk of

Table 1. Total lifetime risk of cancer incidence (cases per 100 000 persons) mSv^{-1} effective dose by age at exposure and sex calculated using risk data for an ICRP composite Euro-American population for two CT examinations [11, 17].

CT scan	Chest + abdomen + pelvis		Head	
Sex	Female	Male	Female	Male
Age at exposure (y)				
0–9	18	11	17	22
10–19	13	9	12	15
20–29	10	7	8	11
30–39	8	5	6	7
40–49	6	4	4	5
50–59	5	3	3	3
60–69	4	2	2	2
70–79	2	1	0.9	0.8
80–89	1	0.5	0.4	0.3
90–99	0.1	0.1	0	0.1

cancer incidence by age at exposure and sex per unit effective dose for a range of x-ray examinations [11, 17]. Data are provided for five different CT examinations for ICRP Euro-American and Asian populations, the former being used here. Although there may be differences in the scan limits between those used in the patient scans and those used to derive the coefficients, they were considered to be sufficiently accurate for a study of this type.

The cumulative effective doses from all scans performed for each patient were separated into two groups; body scans and head scans within the Excel Workbook. Those who had undergone both body and head scans were included in the body scan group, since in almost all cases the larger component of the effective dose was from the body scans. Each group was then ordered according to dose level, and numbers of patients receiving effective doses within ranges >100 mSv, 50–100 mSv, 20–50 mSv and < 20 mSv copied to separate sheets within the workbook. These groupings were chosen to cover the full range of effective doses. The data within each group were then first split into male and female sections, and then ordered by age to allow age and sex specific risk factors to be applied.

Variations in risk coefficients for CT scans covering different parts of the trunk are ±20%. The coefficients for chest, abdomen and pelvis scans were chosen for application to the body scan data, as any of the regions in the trunk or all three together might be included in a body CT scan, so this was considered to provide a better average value, and risk coefficients for CT head scans were applied to the head data. The risk coefficients are given in terms of cases per 100 persons Sv^{-1} effective dose, but are expressed as cases per 100 000 mSv^{-1} effective dose here, since this study includes 105 757 patients and CT scan effective doses are expressed in mSv (table 1). The age and sex specific risk coefficient for the relevant examination was then applied to the cumulative effective dose for each patient in the study group and numbers summed to derive the number of cancer cases that might be anticipated based on the linear no threshold (LNT) cancer risk-dose model. This is the model currently used for predicting cancer risks, although there is considerable uncertainty and debate about the relationship at lower doses [11].

3. Results

The numbers of patients receiving cumulative effective doses in different ranges are shown in figure 1. There is almost an order of magnitude between the numbers of patients within each group as one moves down the selected dose ranges. About 718 patients received cumulative doses over 100 mSv from body scans and one from head scans, amounting to 0.68% of all patients examined during the $5^1/_2$ years of data collection. Three patients received over 400 mSv, with the highest being 468 mSv, and eight had between 300 and 400 mSv. The cumulative effective doses for 83% of all patients were below 20 mSv.

The numbers of excess cancers that might be expected during the lifetimes among the groups of patients receiving cumulative effective doses in different dose ranges, based on the LNT model, are shown as a bar chart in figure 2. Since the total number of patients in the study was just above 100 000, the data in the figure have been normalised to 100 000 patients to allow easy reference. This relates to the lifetime risk of cancer incidence based on the LNT model. The largest number occurs in the lowest dose group, because the number of patients involved is much larger. To put this into context, these numbers are dwarfed by the natural incidence of cancer, which is about one in two, so the number of patients in figure 2 should be compared

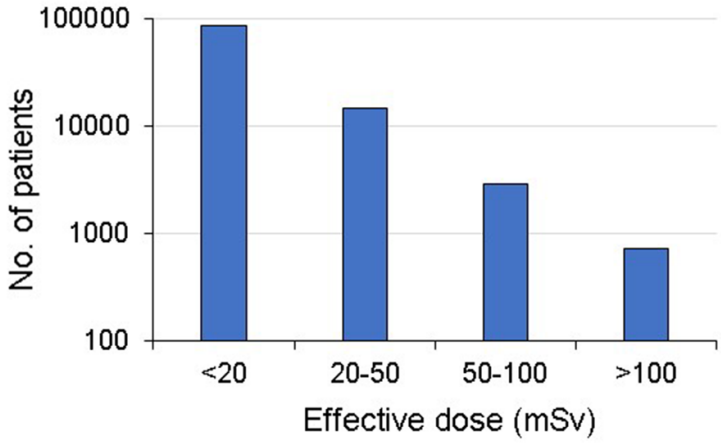

Figure 1. Numbers of patients in the study receiving effective doses in different ranges.

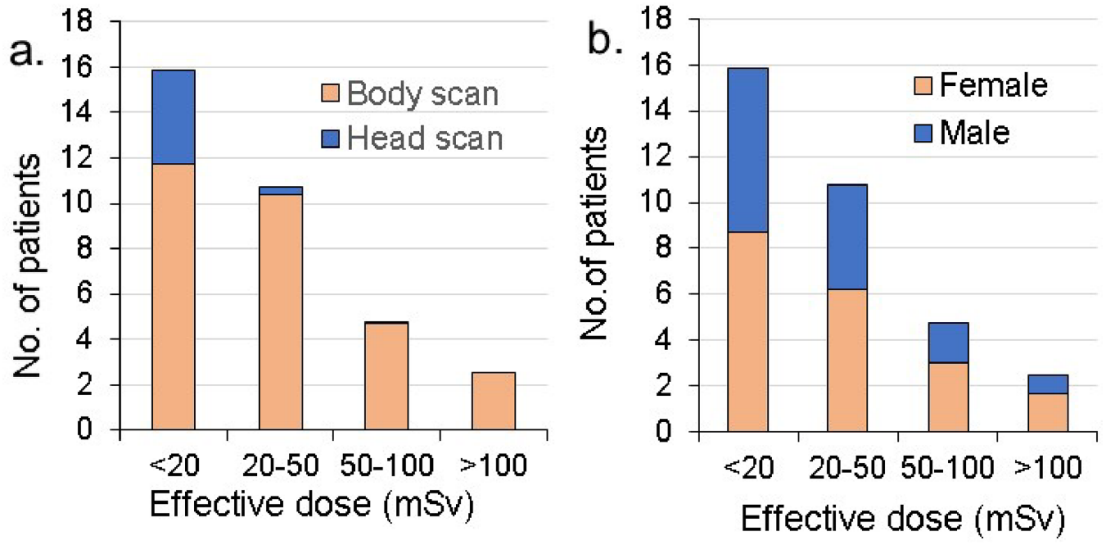

Figure 2. Total lifetime risk of cancer incidence scaled for 100 000 patients from CT examinations received over a period of 5½ years, calculated from data for 105 757 patients in the study, using risk data in table 1 based on the LNT dose-risk model; showing (a) proportions for CT examinations of the body and head, and (b) the risks for females and males.

with 50 000 who might be expected to develop cancer during their lifetimes, with more than one in four of all deaths being due to cancer in the UK [18].

The contribution from head scans only becomes significant in the lowest dose group, as only 13 patients received effective doses over 50 mSv from head scans (figure 2(a)). The results suggest that if the LNT model were correct, two cancers could occur in the group receiving over 100 mSv (making up 0.36% of the high dose group) and 30 could be initiated in patients who received less than 100 mSv (0.03% of the remaining patients). However, the majority of these patients lie in the lowest dose group. The proportions of males and females having CT scans were similar, with 49.3% of all patients being female and 47.6% in the group receiving over 100 mSv, but because of the higher risks of radiation cancer induction from exposure of the trunk for females (table 1), they bore 58% of the overall risk, with a similar pattern across all dose groups (figure 2(b)).

The distributions of ages among the different dose groupings are shown in figure 3, scaled to allow easier comparison. Twenty-two of the patients receiving over 100 mSv were under 40 years and 38 were in their 40s. The proportions of patients in the groups receiving over 50 mSv were generally lower for patients under 50 years, while those receiving over 100 mSv were proportionally higher for those in their 50s, 60s, and 70s.

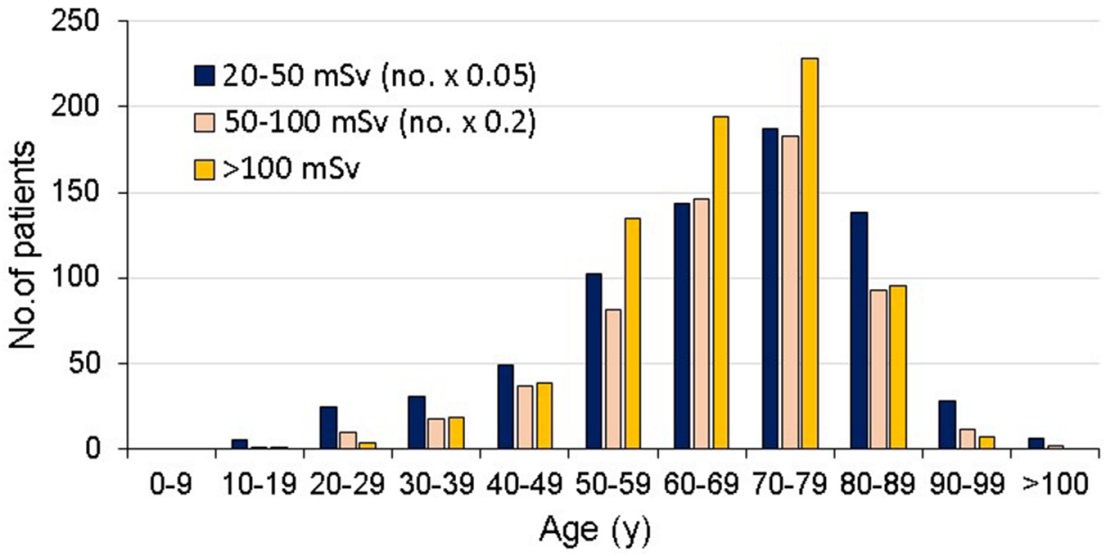

Figure 3. Numbers of patients receiving cumulative effective doses within different ranges as a function of age. The purpose of the figure is to allow comparison of age distributions for patients in different dose groupings and the data have been scaled to allow comparisons to be made more readily.

4. Discussion

4.1. Risks to patient from cumulative doses for CT examinations

The numbers of patients receiving effective doses from CT examinations over 100 mSv during the course of this study amounted to 0.68% of all patients examined. Based on the ICRP risk coefficients, this would suggest that two additional cancers might be initiated among this group. However, the risk coefficients have been derived from application to a general population comprised predominantly of healthy persons, and the fact that these patients have received so many examinations indicates that their health status is severely compromised and this is likely to reduce their long term survival, so the actual number is likely to be lower.

Recent studies in many centres have shown that substantial numbers of patients receive effective doses over 100 mSv from multiple CT scans in the USA [1, 2] and Europe [3]. This study confirms that cumulative effective doses often exceed 100 mSv in the UK in a similar manner. However, what these studies have not done is consider the much larger numbers of patients who receive fewer scans. Bar charts of cancer incidence calculations in figure 2, based on sex and age adjusted risk coefficients, suggest that if the LNT model were correct, then the numbers of cancers induced among patients receiving effective doses less than 100 mSv could be substantially greater than for those receiving over 100 mSv, simply because of the large number of patients involved. The LNT approach suggests that numbers of cancers initiated in patients in the different dose groups are approximately 2.5 for those receiving >100 mSv, five for 50–100 mSv group, and 11 for the 20–50 mSv group. However, caution is required in interpreting these results. The figures rely heavily on the assumed accuracy of the LNT model. A recent evaluation of data from 29 epidemiological studies by the National Council on Radiation Protection and Measurements suggested that an LNT approach is valid [19] and the ICRP support use of the LNT model for radiation protection purposes. But ICRP qualify this by stating that 'the computation of numbers of cases of cancer based on collective effective doses involving extremely low exposures to very large populations should be avoided' [11]. It is generally accepted that epidemiological data shows that risks extend down to 100 mSv, 50 mSv, and possibly lower, but the form of the risk relationship and whether this might apply to all individuals in an exposed population are unknown. Nevertheless, it is unlikely that there is a sharp threshold at 100 mSv, so in all probability there are risks to patients receiving doses less than 100 mSv and collectively these are likely to be greater than those to the small group of patients receiving higher doses.

4.2. Recommendation for radiation protection of patients undergoing recurrent imaging

Any patient with a serious health condition requiring extensive examinations for diagnosis and follow-up has the potential to accumulate doses greater than 100 mSv over time. However, there are groups of patients with certain conditions who are more likely to receive multiple examinations. Patients with malignancies form a significant group [20], as do patients being treated for cardiac conditions who are frequently in the 35–54 years age group [3]. A study by Stein *et al* [21] reported that 20% of patients diagnosed with cardiac

disease received an effective dose greater than 50 mSv over an eight years period and Einstein *et al* found that 34% from 1097 patients who underwent myocardial perfusion imaging received effective does over 100 mSv during a 20-year follow-up [22].

Studies on patients with kidney disease have reported that 15%–30% of patients on haemodialysis accumulate effective doses of 50–100 mSv in 3–4 years [23–25], with similar percentages for kidney transplant patients who tend to be younger [25, 26]. Patients with pulmonary embolism also require frequent imaging with 16% of patients reported to receive cumulative effective doses greater than 50 mSv over a four-year period [27].

Patients with Crohn's disease form another group that may undergo regular imaging. Desmond *et al* reported cumulative effective doses above 75 mSv from imaging in 16% of patients followed up for 15 years [28] and Magro *et al* reported that 16% of Crohn's patients received over 50 mSv in an 11-year period with 4% over 100 mSv [29]. Paediatric patients with Crohn's disease receive more exposure during the early years following diagnosis, but also have repeated examinations over subsequent years and Sauer *et al* estimated that 60% would exceed 50 mSv by the age of 35 years [30].

Endovascular repair (EVAR) is recognised as being an interventional procedure having high associated exposures giving effective doses over 100 mSv as well as 8–16 mSv for follow-up in subsequent years [31, 32]. Higher rates of abdominal cancer have been reported in patients who have undergone EVAR procedures [33], but the risk of not performing EVAR are significant and patients tend to be in the 70–80 years age range when risks from initiating cancer are lower.

The IAEA have issued a statement calling for action in terms of strengthening radiation protection of patients undergoing recurrent imaging procedures and developing strategies for clinical conditions where multiple imaging is required such as those described [7]. The actions recommended are:

(a) Assess the level of recurrent radiological imaging and associated radiation doses.
(b) Identify clinical conditions where recurrent radiological imaging is likely to lead to relatively high cumulative doses in patients.
(c) Develop strategies for radiological imaging in clinical conditions that require recurrent imaging.
(d) Ensure justification and appropriateness of the entire series of radiological procedures for a patient.
(e) Monitor radiation exposure history of patients.
(f) Further reduce doses through technological developments.
(g) Customise imaging protocols to address each patient's clinical problem.
(h) Strengthen radiation protection education and training of health professionals.
(i) Strengthen communication.

The majority of these points are valuable, and serve as a reminder of the importance of having proper procedures in place, especially for patients likely to receive multiple exposures, but the value of additional monitoring of radiation exposure history of these patients can be debated. In countries with private healthcare provision, where there may be less control over imaging services, patients may see it as their right to be imaged, there may be a greater risk of litigation if conditions are not diagnosed, and there may also be financial incentives to imaging. In these circumstances there may be a need to impose further controls, but that is not necessarily the case in publicly funded institutions such as the UK National Health Service, where the stringent requirements of the Ionising radiation (medical exposure) regulations [34], together with financial constraints on hospital services, restrict the majority of unnecessary procedures.

4.3. Questions raised

Returning to the questions raised in the introduction to this paper.

Q: How large are the risks to those receiving effective doses over 100 mSv?

A: Risk calculations based on ages and sexes of the patients in the group studied suggest that cancers might be initiated in 2 of the 719 patients receiving effective doses above 100 mSv. However, the health conditions requiring more frequent imaging are likely to shorten the lives of many of these individuals. Malignancies and cardiac disease, for which many of the patients would be being investigated [20], are two of the main causes of death, making up 44% of the total deaths in the UK in 2018 [35]. At least half of those being treated for malignancy are likely to die from their cancer [18], as are a significant proportion of those with cardiac disease. Other conditions requiring multiple exposures are also likely to shorten patients' lives. For example, the age-adjusted mortality risk from Crohn's disease is over 50% greater than for the general population [36], while kidney patients on dialysis or following transplant also have a higher mortality [37]. Therefore, a more realistic assessment of the risk of a cancer being initiated by the medical radiation exposure in one of the patients who received an effective dose of over 100 mSv might be 1 in 1000, with mortality from the cancer being about half that at 1 in 2000.

Q: Is a special focus on this group justified?

A: It is useful that awareness of these groups that are likely to require recurrent imaging has been raised, so that strategies for imaging can be developed with appropriate customised protocols and a proper system of justification. But any specific focus on following the exposure history of these patients that might be to the detriment of more general dose monitoring would not be appropriate.

Q: Is tracking of the dose histories for these patients necessary in the UK?

Justification for medical imaging procedures in the UK is based on the clinical condition from the patient's history, taking account of the potential dose from the imaging procedure. While the tracking of doses to individual patients has highlighted issues of overuse of imaging in some countries, the potential benefit in the UK is unlikely to be as significant at the present time. The introduction of more exposure management systems is to be encouraged to raise awareness of healthcare staff about the doses from imaging procedures, provide staff with an understanding of dose factors, and promote more optimisation, but the introduction will be dependent on competition for scarce resources in the NHS.

Q: How significant are the risks for patients that undergo imaging, but for whom the cumulative effective doses do not reach 100 mSv?

A: The risks to individual patients receiving effective doses between 10 mSv and 100 mSv are described as low, although those to children and adolescents are higher, and the risks for those undergoing examinations with lower doses will be very low or minimal [11]. However, because of the large numbers of patients involved, it is likely that more cancers will be initiated in this group than in the smaller number of patients exposed to over 100 mSv, so it is important to have proper justification and optimisation of procedures for all exposures. It should be remembered that the numbers of cancers that might be induced by radiation is small compared to the natural incidence of about one in two, causing more than one in four deaths in the UK [18]. The IAEA recommendations on further reducing doses through technological developments, customising imaging protocols to address each patient's clinical problem, and strengthening radiation protection education and training of health professionals should apply to all imaging procedures, and especially to those performed on children and adolescents for whom risks are known to be higher.

5. Limitations of this study

The calculations of risk, although they take account of differences in radiation risk with age and sex, rely on the LNT dose-risk model. If there is any gradation in effects at lower doses, then the level of cancer incidence from exposures under 100 mSv will be
exaggerated.

Risk coefficients for chest, abdomen and pelvis scans were applied to all the body scan data, rather than identifying individual scanned regions. However, the variation between coefficients for CT scans of different regions of the trunk was only about ±20%. The uncertainty in the risk coefficients is large, but they represent the best that can be achieved with the available epidemiological data. The calculations of risks to patients take no account of the health of individual patients and so are likely to overestimate risks.

The results are based on patients scanned in hospitals within one UK Trust over a 5½ year period, it is uncertain how representative these are of practice throughout the UK. Effective doses are based on Monte Carlo simulations using stylised phantoms that approximate the shapes of real patients.

Doses for spine CT examinations on one CT scanner were based on a 16 cm phantom instead of the 32 cm, which affected 205 patients within the dataset. This would double the calculated effective doses for those scans, but they make up less than 0.2% of the total.

6. Conclusion

The IAEA recently issued a statement calling for the strengthening of radiation protection for patients undergoing recurrent imaging procedures. A study has been carried out to evaluate risks from cumulative effective doses received by patients from CT examinations performed in a UK NHS Health Trust. Cumulative effective doses were summed for 105 757 patients scanned on 12 CT scanners over a period of 5½ years. Risks of cancer incidence have been calculated for patients within different ranges of cumulative effective dose with age and sex adjusted risk coefficients based on the ICRP LNT dose-risk model. Results suggest that the number of cancers induced among patients receiving effective doses less than 100 mSv will be higher than that for those receiving doses over 100 mSv, because of the larger numbers involved. This is without taking account of the serious health conditions of patients receiving recurrent exposures, which are likely to shorten the lives of these patients. Recommendations on further reducing doses through technological developments, customising imaging protocols to address each patient's clinical problem, and strengthening radiation protection education and training of health professionals are welcomed. However, the efforts should apply to

imaging procedures on all patients, and if a special focus is given, this should be to procedures performed on children and adolescents.

ORCID iDs

Colin J Martin https://orcid.org/0000-0002-0784-9002
Michael Barnard https://orcid.org/0000-0003-3323-1158

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