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The radiation dose associated with common radiological investigations and their impact on children with cystic fibrosis

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4 **The radiation dose associated with common radiological investigations and their impact**
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6 **on children with cystic fibrosis**
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38 with the clinical data. All authors reviewed and revised the manuscript and approved the final
39 manuscript as submitted.
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Abstract

Objectives

Cumulative radiation exposure is associated with increased risk of malignancy. This is important in cystic fibrosis (CF) as frequent imaging is required to monitor disease progression and diagnose complications. Previous estimates of cumulative radiation are outdated as the imaging was performed on older equipment likely to deliver higher radiation. Our objectives were to determine the radiation dose delivered to children during common radiological investigations using modern equipment and to identify the number of such investigations performed in a cohort of children with CF to calculate their cumulative radiation exposure.

Design, Setting and participants

Data including age at investigation and radiation exposure measured as estimated effective dose (EED) were collected on 2,827 radiological studies performed on children at one UK paediatric centre. These were combined with the details of all radiological investigations performed on 65 children with CF attending the same centre to enable calculation of each child's cumulative radiation exposure.

Results:

We report the mean EED associated with chest and abdominal X-rays; chest, abdominal and sinus CT scans and fluoroscopy guided procedures for children when performed using modern radiological equipment. The mean EED is also compared between axial and helical chest CT scans. These data are presented in five age bands: 0 to <1 year, 1 to <5 years, 5 to <10 years, 10 to <15 years and 15 to <18 years. The mean annual cumulative EED for our cohort of children with CF was 0.15mSv/year with an estimated cumulative paediatric lifetime EED (0-18 years) of 3.5mSv.

Conclusions:

This study provides up-to-date estimations of the radiation exposure when using common radiological investigations. These doses and the estimates of cumulative radiation exposure in children with CF are lower than previously reported. This reflects the reduced EED associated with modern equipment and the use of age-specific scanning protocols.

Strengths and Limitations of the study

- This study provides up-to-date information on the radiation dose associated with common radiological investigations.
- It also gives an accurate estimation of cumulative radiation exposure for children with cystic fibrosis if modern radiological equipment and protocols are used.
- This study is limited by the lack of a historical cohort to compare the results to.

Introduction

Since their discovery in 1895, X-rays have been utilised with ever increasing levels of sophistication to perform radiographs and computerised tomography (CT) scans. These investigations have revolutionised medical care but their benefits must be balanced against possible adverse effects, one being the increased risk of malignancy associated with cumulative radiation dose.[1–3] This is especially important in children as they are more sensitive to radiation than adults.[4,5] When discussing radiological investigations with a child and family it is vital that paediatricians know the radiation dose to which that child will be exposed. Unfortunately, calculating the radiation dose associated with radiographs and particularly CT scans is more complicated than most clinicians recognise. This is because it varies depending on the type of investigation, on the make and model of scanner, on the scan protocol and the scan sequence as well as on the age and size of the child.

Monitoring cumulative radiation exposure in children with cystic fibrosis (CF) is particularly important as they undergo many radiological investigations. At UK Paediatric CF Centres, chest radiographs (CXR) are performed annually to monitor disease progression as recommended in clinical guidelines.[6] There is no UK national guidance about the use of CT scans in children with CF. They are usually performed as required to assess the severity of lung disease and for the diagnosis of complications such as non-tuberculous mycobacterium lung disease. In some parts of Europe, Chest CT scans are performed routinely, as often as every two years. Abdominal and sinus CT scans may be required for the diagnosis of complications and if a Totally Implanted Venous Access Device (TIVAD) is required, it is inserted under fluoroscopy (real-time x-ray) guidance. The implementation of CF newborn screening programmes has reduced the age at which radiological investigations commence. At the same time, improvements in life expectancy have increased the time in which the stochastic (carcinogenic) risk associated with radiation exposure can be expressed.[7]

It is known that individuals with CF have an increased incidence of certain digestive tract malignancies later in life.[8] Although a causal link has not been established between the increased

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3 cancer risk and total radiation exposure, it would be remiss not to record the cumulative radiation
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5 dose to which patients with CF are exposed. Previous studies have estimated this both in children
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7 and adults.[9,10] The calculations were based on historical data using a catalogue of mean radiation
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9 doses for radiological and nuclear medicine examinations.[11] These estimates are now out-of-date
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11 and do not reflect the lower radiation doses associated with modern imaging equipment.[12]
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13 Knowledge of present day radiation exposure using the newest equipment is important to ensure
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15 that discussions between clinicians and families are based on accurate information.
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18 19 **Aims**

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21 The aims of this study were twofold:
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25 1. To determine the radiation doses of common radiological investigations performed for
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27 any indication on children using modern equipment and protocols in our hospital.
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29 2. To identify the number of radiological investigations performed in a cohort of children
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31 with CF to calculate each child's cumulative radiation exposure.
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34 35 **Methods**

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37 We retrospectively reviewed the radiation dose delivered to children in our institution undergoing
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39 common radiological investigations. The measure of radiation exposure we used was the estimated
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41 effective dose (EED). This is the tissue-weighted sum of the equivalent doses in all specified tissues
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43 and body organs and represents the overall stochastic health risk. We combined these data with a
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45 review of the total number of radiological investigations in a cohort of children with CF of varying
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47 ages to determine the burden of our imaging practises in children with CF.
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Radiation dose associated with common radiological investigations

Data were obtained on all chest X-rays (CXRs), abdominal X-rays (AXRs), chest CT scans, abdominal and pelvic CT scans, sinus CT scans and fluoroscopy-guided TIVAD insertion performed on children in our unit. This included; make, model and name of scanner or imaging instrument, name of protocol, name of the scan sequence (for CT scans), patient age at investigation and the EED (mSv). Four years of CT scan data were collected from April 2012 when the imaging department moved to a new hospital and acquired four new CT scanners (1 x Siemens Somatom Definition Flash [256-slice] and x3 Siemens Somatom Definition AS+ [128-slice]). Fluoroscopy data were collected over the same period. Data on CXR and AXR were only collected for one year as the numbers were much higher than for the other investigations. The mean EED associated with each investigation was calculated according to the age of the child (ranges: 0 to <1 year, 1 to <5 years, 5 to <10 years, 10 to <15 years and 15 to 18 years). The exact details of how the radiation dose was calculated are given in Appendix 1.

Number of radiological investigations performed on children with CF at our centre

We reviewed the patients' medical records and their picture archiving and communication system (PACS) for all children (0-18 years) with CF who only attended the Royal Stoke University Hospital for their CF care. Those who had recently transferred their care to our centre were excluded. Sixty five children were included with a mean (SD) age of 8.8 (5.5) years. The number of radiological investigations performed throughout the child's lifetime was recorded, as was the child's age at each investigation. These data were combined with the mean EED associated with each radiological investigation to determine the individual child's predicted cumulative radiation exposure if our current technology and protocols had been used. Linear regression was used to determine the likely cumulative EED delivered by the age of 18 years. The relative contribution of each investigation to the child's total radiation exposure was also calculated.

Results

Complete data were available on 2,140 CXRs, 92 chest CT scans, 482 AXRs, 73 abdomen and pelvis CT scans, 24 sinus CT scans and 16 fluoroscopy guided TIVAD insertions. The mean EED of radiation received by children undergoing each of these radiological investigations is given for the five age bands in Table 1. The EED for the chest CT scans is split into helical (volumetric) and axial (non-contiguous) scans in Table 2.

Table 1: Estimated effective dose of radiation received by children undergoing various radiological procedures for any indication at our centre.

		0 to <1 year	1 to <5 years	5 to <10 years	10 to <15 years	15 to <18 years
CXR	No. performed	179	789	542	213	417
	EED (mSv)	0.02	0.02	0.01	0.01	0.01
AXR	No. performed	69	115	99	100	99
	EED (mSv)	0.03	0.03	0.03	0.09	0.11
HRCT Chest	No. performed	9	28	29	16	10
	EED (mSv)	0.57	0.90	0.91	1.27	1.69
Abdomen & Pelvis CT	No. performed	0	0	15	15	43
	EED (mSv)	-	-	2.9	3.4	3.9
Sinus CT	No. performed	0	0	0	10	14
	EED (mSv)	-	-	-	0.21	0.20
Fluoroscopy	No. performed	0	4	6	4	2
	EED (mSv)	-	0.52	0.20	0.15	0.19

CXR: chest radiograph, AXR: abdominal radiograph. EED data are presented as mean.

Table includes four years of data for CT scans and fluoroscopy and one year of radiograph data.

Table 2: Estimated effective dose of radiation received by children undergoing chest CT for any indication at our centre separated into helical and axial scans.

		0 to <1 year	1 to <5 years	5 to <10 years	10 to <15 years	15 to <18 years
Helical CT Chest	No. performed	9	28	24	10	5
	EED (mSv)	0.57	0.90	1.06	1.69	2.79
	Equivalent number of CXRs	29	45	106	169	279
Axial CT Chest	No. performed	0	0	5	6	5
	EED (mSv)	-	-	0.22	0.58	0.59
	Equivalent number of CXRs	-	-	22	58	59
All Chest CT's	No. performed	9	28	29	16	10
	EED (mSv)	0.57	0.90	0.91	1.27	1.69
	Equivalent number of CXRs	29	45	91	127	169

The EED data represents the mean dose per scan.

A summary of the total number of each type of radiological investigations performed in children with CF at our unit is given in Table 3, grouped into the same five age bands. These data were combined with those in Table 1 to calculate the relative contribution of each investigation to the child's total radiation exposure (Table 3) as well as the cumulative lifetime radiation exposure for each child with CF (Figure 1). The mean annual cumulative EED was 0.15 mSv/year, this increased from 0.05 mSv/year in those aged 0 to < 1 year to 0.20 mSv/year in those aged 15 to 18 years. The predicted lifetime radiation dose for a child aged 18 with CF at our unit is approximately 3.5mSv (Figure 1).

Table 3: The relative contribution of different radiological investigations to total radiation exposure in children with CF at our centre.

Age of Child		0 to <1 year	1 to <5 years	5 to <10 years	10 to <15 years	15 to <18 years
CXR	Number*	1 (1-2)	5 (3-8)	9 (4-20)	12 (10-15)	17 (5-22)
	% total radiation**	100%	77%	23%	10%	7%
HRCT Chest	Number*	0 (0-0)	0 (0-1)	1 (0-5)	2 (1-2)	2(1-3)
	% total radiation**	0%	19%	65%	84%	79%
AXR	Number*	0 (0-0)	0 (0-1)	0 (0-3)	0 (0-1)	0 (0-2)
	% total radiation**	0%	4%	3%	0%	1%
Abdomen & Pelvis CT	Number*	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-2)
	% total radiation**	0%	0%	0%	0%	5%
Sinus CT	Number*	0 (0-0)	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-1)
	% total radiation**	0%	0%	0%	1%	2%
Fluoroscopy	Number*	0 (0-0)	0 (0-0)	0 (0-4)	0 (0-1)	1 (0-3)
	% total radiation**	0%	0%	9%	5%	5%

*Total number of investigations performed on children that age presented as median (range).

**% total radiation presented as mean

Figure 1: Cumulative radiation exposure associated with radiological investigations for 65 children with CF

Discussion

This study provides important information on the radiation dose received by children undergoing common radiological investigations. It can be used to help discussions between paediatricians and their patients about the risks and benefits of such investigations.

We have shown lower radiation doses than those listed in the most frequently cited catalogue of radiation doses and lower estimates of cumulative radiation exposure for children with CF.[11] This can be explained by the use of up-to-date radiological equipment used at our centre which is associated with lower radiation exposure.[12] The 'catalogue of radiation doses' uses radiation data

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3 from 1992 and is likely to have included data from CT scans performed on single and dual slice
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5 scanners which would expose patients to much higher doses of radiation. We have shown that the
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7 radiation dose associated with CT scans increases with the child's age. This differs from older
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9 reports which showed the opposite trend (2.85mSV for CT Chest in a 1 year old decreasing to
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11 1.65mSV for CT Chest in a 15 year old).[9,11] This difference means that the EED of a chest CT in an
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13 infant at our centre is one fifth of the previously published value (0.57mSv compared to 2.85mSv).
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15 This is again explained by the previous use of historical data. Using a modern multi-slice CT scanner,
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17 EED would be expected to be lower in younger children as the dose-saving features optimise
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19 radiation dose based on patient size and the region scanned. These features include modulation of
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21 the tube current and voltage along with adaptive collimation, iterative reconstruction and most
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23 importantly the use of age specific paediatric scan protocols.[13–15] This trend of an increasing
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25 effective dose being associated with scans performed in older children along with a general overall
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27 reduction in the relative dose across age ranges has previously been reported. [12]
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32 Of interest is the variation in the EED associated with different types of chest CT scan. The EED from
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34 helical CT scans was three to five times higher than the dose from an axial CT scan. Helical scans can
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36 be performed more quickly and therefore require less patient co-operation than axial CT scans.
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38 They are therefore particularly useful in younger children. They may also be more sensitive in
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40 detecting bronchiectasis.[16] The radiation dose associated with helical scans is however higher
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42 than axial scans. To minimise the radiation exposure in children with CF, every effort should be
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44 made to ensure that the CT protocol and technique is tailored to the child and the clinical question
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46 that needs to be answered. If an axial scan is likely to provide enough accuracy, clinicians should
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48 consider waiting to request a CT scan until the child is old enough to co-operate with an axial scan.
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50 Radiologists should ensure they have maximal skill and patience with children to enable such a
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52 procedure to be successful.
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3 This study shows if all radiological investigations are performed on up-to-date equipment, a typical
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5 18 year old patient with CF will be exposed to a cumulative EED of approximately 3.5mSv. Based on
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7 an estimated average cancer risk of 11% per Sv for patients aged 0-18 years, this relates to an
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9 additional lifetime cancer risk of approximately 1 in 2500.[17] Another way of conveying this
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11 message relates to background radiation. In the UK the average annual background radiation is
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13 2.6mSv.[18] Therefore we estimate that the cumulative radiological investigations performed on an
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15 18 year old with CF add the equivalent to an additional 18 months background radiation. In children
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17 with CF, CXRs are the most frequently performed radiological investigation but beyond five years of
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19 age they are responsible for a minority of the child's total radiation exposure. In contrast, after five
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21 years of age, CT scans of the chest become responsible for the majority of the child's total exposure.
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23 In our cohort, abdominal CT scans were infrequently performed but when undertaken markedly
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25 increased the child's cumulative EED. This is well shown in Figure 1 where the 18 year old with a
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27 cumulative EED of 11.2mSV had two abdominal CT scans performed which contributed 65% of the
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29 radiation exposure.
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34 The aim of this review was to assess the cumulative radiation dose associated with CF radiological
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36 investigations using modern scanners. We therefore did not collect historical data obtained from
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38 older scanners. Children with CF may require radiological investigations for non-CF issues such as
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40 injuries and trauma. These investigations will be performed ad-hoc and will vary greatly between
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42 patients so we did not collect this information.
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45 **Conclusions**

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48 Paediatricians need to be well informed on radiation doses produced by imaging technologies.
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50 Modern equipment has the potential to reduce the EED associated with such investigations. This
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52 effect is greatest for CT scans in younger children. Even if all investigations were performed on
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54 modern radiological equipment, the cumulative radiation dose for children with CF remains
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56 substantial and every effort should be made to keep it to a minimum. All scans should be optimised
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with regards to image quality and patient dose by using age specific protocols. Paediatricians and radiologist should be aware of the risks and benefits of axial and helical CT scans. Lowering the cumulative lifetime radiation dose in children with CF will reduce their associated stochastic risks.

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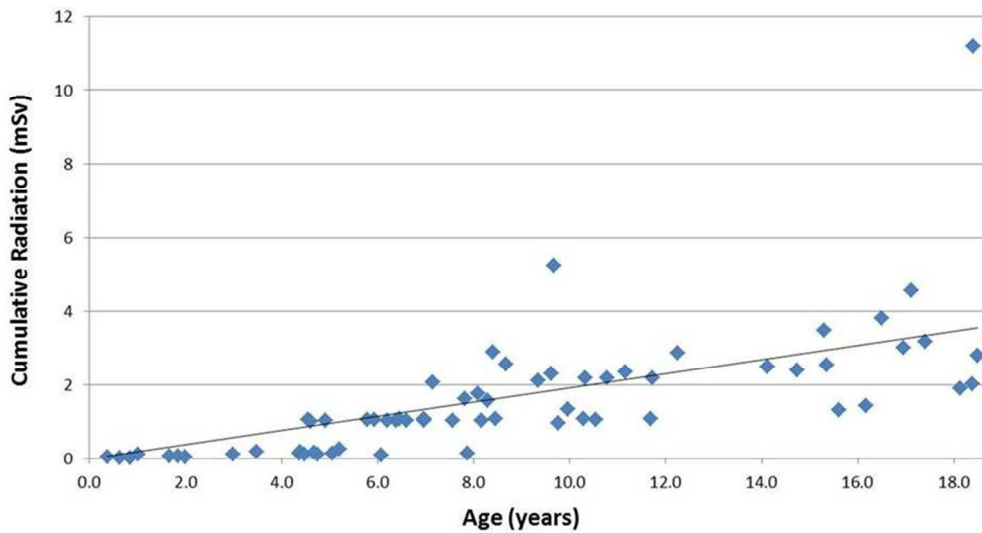


Figure 1: Cumulative radiation exposure associated with radiological investigations for 65 children with CF

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Appendix 1: Calculation of Radiation Dose

Abdomen and Chest X-Ray doses

A download was made of all children (0 to <18 years) who underwent a single plain film (abdomen or chest X-ray) examination between April 2015 and May 2016 at our centre. The dose indices recorded by radiographers on Computerised Radiology Information System (CRIS) is dose area product (DAP). This result was collected. Outliers were removed by calculating the interquartile range (IQR) and excluding any data that fell less than 1.5x the IQR below the first quartile, or greater than 1.5x the IQR above the third quartile. Consequently the mean DAP value for an abdomen and chest X-ray was calculated as per the specified age range.

Reference was made to NRPB-R279.¹ This report provides conversion coefficients for the deviation of effective dose from DAP values taken during commonly performed paediatric radiographs. The coefficients have been calculated using *Monte Carlo* mathematical simulations on a series of mathematical phantoms that represent 0, 1, 5, 10 and 15 year old children. As a result the coefficients take account of the patient size and the increased proximity of organs just outside the primary X-ray relative to that of an adult.

For example for an abdominal x-ray in a 15-18 year old patient the mean DAP for a plain film was 50cGy.cm². Based on the performance of the X-ray sets currently in use in the Trust and the AP technique routinely used, the conversion coefficient is 0.225mSv.Gy⁻¹.cm⁻². Therefore the estimated effective dose is (50/100)x0.225=0.11mSv.

Computerised Tomography (CT) Scan Dose

A download was made from CRIS for all children (0 to <18 years) who underwent either (or combinations of) CT Chest, CT abdomen, CT Pelvis and CT sinus examinations between April 2012 and May 2016. The dose indices recorded by the radiographers on CRIS is the Dose Length Product (DLP) measured in mGy.cm. This takes into account the dose per slice and the length of the scan and is a measure of stochastic risk for an exam type that covers the same anatomical region. This was recorded.

During the period of data collection our unit has had four scanners; three Siemens Somatom Definition AS+ and one Siemens Somatom Definition Flash. These scanners are near identical (the flash having two X-ray tubes and 2 detector arrays) and as a result have been set up so that the same scan protocols for any anatomical programme. The scanners have the facility for iterative reconstruction, adaptive collimation, modulated tube current and kV.

The Dose Length Product (DLP) data was then subdivided into appropriate age ranges at the time of the examination and the mean value was calculated. To convert the mean DLP into an effective dose, it is standard to use a conversion factor. The conversion factor needs to take account of the dose, anatomical region scanned and the radiosensitivity of the organs exposed. In order to calculate this, the ImPACT Dosimetry software² was utilised and values established specific to the

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2
3 anatomy exposed for each specified exam protocol (i.e. Chest, Abdomen & Pelvis). The units of the
4 correction factor are ($\text{mSv.mGy}^{-1}.\text{cm}^{-1}$). ImPACT utilises the National Radiological Protection Board
5 (NRPB) Monte Carlo simulation data sets. It also takes account of the most recent tissue weighting
6 factors published in by the International Commission of Radiological Protection Report 103.³
7

8
9 Multiplying the DLP by the calculated conversion factor would give an estimated effective dose for
10 an adult. However additional correction needs to be introduced for paediatrics to account for
11 different habitus size for different age ranges. The ImPACT software² provides corrections to
12 account for this for Head & Neck, Chest and Abdomen & Pelvis scans.
13

14
15 *Example: For a 5-10 year old undergoing an Abdomen & Pelvis CT scan the mean DLP was estimated*
16 *to equal 120mGy.cm. The conversion factor for this region of the body was 0.015mSv.mGy⁻¹cm⁻¹*
17 *¹. The correction for patient size for an Abdomen and Pelvis scan was 1.6 (worst case scenario based*
18 *on a possible range from 1.2-1.6). Therefore the estimated effective dose = 120x0.015x1.6≈2.9mSv*
19

20 21 22 **Fluoroscopy (port-a-cath insertion)**

23
24 Radiology Physics were provided with the details of 21 paediatric patients with cystic fibrosis and
25 who underwent port-a-cath insertions using fluoroscopy at our centre. Using the patients ID
26 numbers it was possible using both RIS and PACS to determine the patients age at the time of the
27 examination, the total DAP (Dose Area Product) for the procedure and the X-ray equipment used.
28

29
30 Using NRPB-R279¹ conversion factors can be derived that are based on anatomy (chest) and patient
31 age. This value can be then multiplied by the DAP value to produce an effective dose. This is very
32 similar to the method used in assessing abdomen and chest x-ray doses.
33
34

35 36 **References**

37
38 ¹ NRPB-R279: Coefficients for Estimating Effective Doses from paediatric X-ray examinations

39
40 ² CTDosimetry_1.0.4.xls, Impact CT Patient Dosimetry Calculator Version 1.0.4, IMPACT 2011

41
42 ³ ICRP 103 –The 2007 Recommendations of the International Commission on Radiological Protection
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STROBE Statement—checklist of items that should be included in reports of observational studies

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

Continued on next page

Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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

Radiation dose from common radiological investigations and cumulative exposure in children with cystic fibrosis: an observational study from a single UK centre

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4 **Radiation dose from common radiological investigations and cumulative exposure in**
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6 **children with cystic fibrosis: an observational study from a single UK centre**
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26

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36 conceptualized and designed the study, he also redrafted the article. PC, MJ and DT assisted with
37 the collected the radiological data and calculation of the radiation dose. WC, AH and WL assisted
38 with the clinical data. All authors reviewed and revised the manuscript and approved the final
39 manuscript as submitted.
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46 **Data Sharing Statement:** All data from this article is available upon request to the corresponding
47 author.
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Abstract

Objectives

Cumulative radiation exposure is associated with increased risk of malignancy. This is important in cystic fibrosis (CF) as frequent imaging is required to monitor disease progression and diagnose complications. Previous estimates of cumulative radiation are outdated as the imaging was performed on older equipment likely to deliver higher radiation. Our objectives were to determine the radiation dose delivered to children during common radiological investigations using modern equipment and to identify the number of such investigations performed in a cohort of children with CF to calculate their cumulative radiation exposure.

Design, Setting and participants

Data including age at investigation and radiation exposure measured as estimated effective dose (EED) were collected on 2,827 radiological studies performed on children at one UK paediatric centre. These were combined with the details of all radiological investigations performed on 65 children with CF attending the same centre to enable calculation of each child's cumulative radiation exposure.

Results:

The mean EDD for the common radiological investigations varied according to age. The range was 0.01-0.02 mSv for chest x-rays, 0.03-0.11 mSv for abdominal x-rays, 0.57-1.69 mSv for CT chest, 2.9-3.9 mSv for abdominal and pelvic CT, 0.20-0.21 mSv for sinus CT and 0.15-0.52 mSv for fluoroscopy guided procedures. The mean EDD was x3-5 higher for helical compared to axial chest CT scans. The mean annual cumulative EED for our cohort of children with CF was 0.15mSv/year with an estimated cumulative paediatric lifetime EED (0-18 years) of 3.5mSv.

Conclusions:

This study provides up-to-date estimations of the radiation exposure when using common radiological investigations. These doses and the estimates of cumulative radiation exposure in children with CF are lower than previously reported. This reflects the reduced EED associated with modern equipment and the use of age-specific scanning protocols.

Strengths and Limitations of the study

- This study provides up-to-date information on the radiation dose associated with common radiological investigations.
- It also gives an accurate estimation of cumulative radiation exposure for children with cystic fibrosis if modern radiological equipment and protocols are used.
- This study is limited by the lack of a historical cohort to compare the results to.
- The estimated cumulative radiation exposure is only applicable to other centres / countries that have similar policies regarding radiological investigations in children with CF.

Introduction

Since their discovery in 1895, X-rays have been utilised with ever increasing levels of sophistication to perform radiographs and computerised tomography (CT) scans. These investigations have revolutionised medical care but their benefits must be balanced against possible adverse effects, one being the increased risk of malignancy associated with cumulative radiation dose.[1–3] This is especially important in children as they are more sensitive to radiation than adults.[4,5] When discussing radiological investigations with a child and family it is vital that paediatricians know the radiation dose to which that child will be exposed. Unfortunately, calculating the radiation dose associated with radiographs and particularly CT scans is more complicated than most clinicians recognise. This is because it varies depending on the type of investigation, on the make and model of scanner, on the scan protocol and the scan sequence as well as on the age and size of the child.

Monitoring cumulative radiation exposure in children with cystic fibrosis (CF) is particularly important as they undergo many radiological investigations. At UK Paediatric CF Centres, chest radiographs (CXR) are performed annually to monitor disease progression as recommended in clinical guidelines.[6] There is no UK national guidance about the use of CT scans in children with CF. They are usually performed as required to assess the severity of lung disease and for the diagnosis of complications such as non-tuberculous mycobacterium lung disease. In some parts of Europe, Chest CT scans are performed routinely, as often as every two years. Abdominal and sinus CT scans may be required for the diagnosis of complications and if a Totally Implanted Venous Access Device (TIVAD) is required, it is inserted under fluoroscopy (real-time x-ray) guidance. The implementation of CF newborn screening programmes has reduced the age at which radiological investigations commence. At the same time, improvements in life expectancy have increased the time in which the stochastic (carcinogenic) risk associated with radiation exposure can be expressed.[7]

It is known that individuals with CF have an increased incidence of certain digestive tract malignancies later in life.[8] Although a causal link has not been established between the increased

1
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3 cancer risk and total radiation exposure, it would be remiss not to record the cumulative radiation
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5 dose to which patients with CF are exposed. Previous studies have estimated this both in children
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7 and adults.[9,10] The calculations were based on historical data using a catalogue of mean radiation
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9 doses for radiological and nuclear medicine examinations.[11] These estimates are now out-of-date
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11 and do not reflect the lower radiation doses associated with modern imaging equipment.[12]
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13 Knowledge of present day radiation exposure using the newest equipment is important to ensure
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15 that discussions between clinicians and families are based on accurate information.
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18 19 **Aims**

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22 The aims of this study were twofold:

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25 1. To determine the radiation doses of common radiological investigations performed for
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27 any indication on children using modern equipment and protocols in our hospital.
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30 2. To identify the number of radiological investigations performed in a cohort of children
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32 with CF to calculate each child's cumulative radiation exposure.
33

34 35 **Methods**

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38 We retrospectively reviewed the radiation dose delivered to children in our institution undergoing
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40 common radiological investigations. The measure of radiation exposure we used was the estimated
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42 effective dose (EED). This is the tissue-weighted sum of the equivalent doses in all specified tissues
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44 and body organs and represents the overall stochastic health risk. We combined these data with a
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46 review of the total number of radiological investigations in a cohort of children with CF of varying
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48 ages to determine the burden of our imaging practises in children with CF.
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Radiation dose associated with common radiological investigations

Data were obtained on all chest X-rays (CXRs), abdominal X-rays (AXRs), chest CT scans, abdominal and pelvic CT scans, sinus CT scans and fluoroscopy-guided TIVAD insertion performed on children in our unit. This included; make, model and name of scanner or imaging instrument, name of protocol, name of the scan sequence (for CT scans), patient age at investigation and the EED (mSv). Four years of CT scan data were collected from April 2012 when the imaging department moved to a new hospital and acquired four new CT scanners (one Siemens Somatom Definition Flash [256-slice] and three Siemens Somatom Definition AS+ [128-slice]). Fluoroscopy data were collected over the same period. Data on CXR and AXR were only collected for one year as the numbers were much higher than for the other investigations. The mean EED associated with each investigation was calculated according to the age of the child (ranges: 0 to <1 year, 1 to <5 years, 5 to <10 years, 10 to <15 years and 15 to 18 years). The exact details of how the radiation dose was calculated are given in Appendix 1.

Number of radiological investigations performed on children with CF at our centre

We reviewed the patients' medical records and their picture archiving and communication system (PACS) for all children (0-18 years) with CF who only attended the Royal Stoke University Hospital for their CF care. Those who had recently transferred their care to our centre were excluded. Sixty five children were included with a mean (SD) age of 8.8 (5.5) years. The number of radiological investigations performed throughout the child's lifetime was recorded, as was the child's age at each investigation. These data were combined with the mean EED associated with each radiological investigation to determine the individual child's predicted cumulative radiation exposure if our current technology and protocols had been used. Linear regression was used to determine the likely cumulative EED delivered by the age of 18 years. The relative contribution of each investigation to the child's total radiation exposure was also calculated.

The aim of this review was to assess the cumulative radiation dose associated with CF radiological investigations using modern scanners. We therefore did not collect historical data obtained from older scanners. Children with CF may require radiological investigations for non-CF issues such as injuries and trauma. These investigations will be performed ad-hoc and will vary greatly between patients so we did not collect this information.

Results

Complete data were available on 2,140 CXRs, 92 chest CT scans, 482 AXRs, 73 abdomen and pelvis CT scans, 24 sinus CT scans and 16 fluoroscopy guided TIVAD insertions. The mean EED of radiation received by children undergoing each of these radiological investigations is given for the five age bands in Table 1. The EED for the chest CT scans is split into helical (volumetric) and axial (non-contiguous) scans in Table 2.

Table 1: Estimated effective dose of radiation received by children undergoing various radiological procedures for any indication at our centre.

		0 to <1 year	1 to <5 years	5 to <10 years	10 to <15 years	15 to <18 years
CXR	No. performed	179	789	542	213	417
	EED (mSv)	0.02	0.02	0.01	0.01	0.01
AXR	No. performed	69	115	99	100	99
	EED (mSv)	0.03	0.03	0.03	0.09	0.11
Chest CT	No. performed	9	28	29	16	10
	EED (mSv)	0.57	0.90	0.91	1.27	1.69
Abdomen & Pelvis CT	No. performed	0	0	15	15	43
	EED (mSv)	-	-	2.9	3.4	3.9
Sinus CT	No. performed	0	0	0	10	14
	EED (mSv)	-	-	-	0.21	0.20
Fluoroscopy	No. performed	0	4	6	4	2
	EED (mSv)	-	0.52	0.20	0.15	0.19

CXR: chest radiograph, AXR: abdominal radiograph. EED data are presented as mean.

Table includes four years of data for CT scans and fluoroscopy and one year of radiograph data.

Table 2: Estimated effective dose of radiation received by children undergoing chest CT for any indication at our centre separated into helical and axial scans.

		0 to <1 year	1 to <5 years	5 to <10 years	10 to <15 years	15 to <18 years
Helical CT Chest	No. performed	9	28	24	10	5
	EED (mSv)	0.57	0.90	1.06	1.69	2.79
	Equivalent number of CXRs	29	45	106	169	279
Axial CT Chest	No. performed	0	0	5	6	5
	EED (mSv)	-	-	0.22	0.58	0.59
	Equivalent number of CXRs	-	-	22	58	59
All Chest CT's	No. performed	9	28	29	16	10
	EED (mSv)	0.57	0.90	0.91	1.27	1.69
	Equivalent number of CXRs	29	45	91	127	169

The EED data represents the mean dose per scan.

A summary of the total number of each type of radiological investigations performed in children with CF at our unit is given in Table 3, grouped into the same five age bands. These data were combined with those in Table 1 to calculate the relative contribution of each investigation to the child's total radiation exposure (Table 3) as well as the cumulative lifetime radiation exposure for each child with CF (Figure 1). The mean annual cumulative EED was 0.15 mSv/year, this increased from 0.05 mSv/year in those aged 0 to < 1 year to 0.20 mSv/year in those aged 15 to 18 years. The predicted lifetime radiation dose for a child aged 18 with CF at our unit is approximately 3.5mSv (Figure 1).

Table 3: The relative contribution of different radiological investigations to total radiation exposure in children with CF at our centre.

Age of Child		0 to <1 year	1 to <5 years	5 to <10 years	10 to <15 years	15 to <18 years
CXR	Number*	1 (1-2)	5 (3-8)	9 (4-20)	12 (10-15)	17 (5-22)
	% total radiation**	100%	77%	23%	10%	7%
HRCT Chest	Number*	0 (0-0)	0 (0-1)	1 (0-5)	2 (1-2)	2(1-3)
	% total radiation**	0%	19%	65%	84%	79%
AXR	Number*	0 (0-0)	0 (0-1)	0 (0-3)	0 (0-1)	0 (0-2)
	% total radiation**	0%	4%	3%	0%	1%
Abdomen & Pelvis CT	Number*	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-2)
	% total radiation**	0%	0%	0%	0%	5%
Sinus CT	Number*	0 (0-0)	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-1)
	% total radiation**	0%	0%	0%	1%	2%
Fluoroscopy	Number*	0 (0-0)	0 (0-0)	0 (0-4)	0 (0-1)	1 (0-3)
	% total radiation**	0%	0%	9%	5%	5%

*Total number of investigations performed on children that age presented as median (range).

**% total radiation presented as mean

Figure 1: Cumulative radiation exposure associated with radiological investigations for 65 children with CF

Discussion

This study provides important information on the radiation dose received by children undergoing common radiological investigations. It can be used to help discussions between paediatricians and their patients about the risks and benefits of such investigations.

We have shown lower radiation doses than those listed in the most frequently cited catalogue of radiation doses and lower estimates of cumulative radiation exposure for children with CF.[11] This can be explained by the use of up-to-date radiological equipment used at our centre which is associated with lower radiation exposure.[12] The 'catalogue of radiation doses' uses radiation data from 1992 and is likely to have included data from CT scans performed on single and dual slice

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3 scanners which would expose patients to much higher doses of radiation. We have shown that the
4 radiation dose associated with CT scans increases with the child's age. This differs from older
5 reports which showed the opposite trend (2.85mSV for CT Chest in a 1 year old decreasing to
6 1.65mSV for CT Chest in a 15 year old).[9,11] This difference means that the EED of a chest CT in an
7 infant at our centre is one fifth of the previously published value (0.57mSv compared to 2.85mSv).
8
9 This is again explained by the previous use of historical data. Using a modern multi-slice CT scanner,
10 EED would be expected to be lower in younger children as the dose-saving features optimise
11 radiation dose based on patient size and the region scanned. These features include modulation of
12 the tube current and voltage along with adaptive collimation, iterative reconstruction and most
13 importantly the use of age specific paediatric scan protocols.[13–15] This trend of an increasing
14 effective dose being associated with scans performed in older children along with a general overall
15 reduction in the relative dose across age ranges has previously been reported. [12]
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30 Of interest is the variation in the EED associated with different types of chest CT scan. The EED from
31 helical CT scans was three to five times higher than the dose from an axial CT scan. Helical scans can
32 be performed more quickly and therefore require less patient co-operation than axial CT scans.
33 They are therefore particularly useful in younger children. They may also be more sensitive in
34 detecting bronchiectasis.[16] The radiation dose associated with helical scans is however higher
35 than axial scans. To minimise the radiation exposure in children with CF, every effort should be
36 made to ensure that the CT protocol and technique is tailored to the child and the clinical question
37 that needs to be answered. If an axial scan is likely to provide enough accuracy, clinicians should
38 consider waiting to request a CT scan until the child is old enough to co-operate with an axial scan.
39 Radiologists should ensure they have maximal skill and patience with children to enable such a
40 procedure to be successful. Attempts to limit the radiation dose delivered from CT scans is
41 especially important in some European countries in which biennial CT scans are performed routinely.
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3 This study shows if all radiological investigations are performed on up-to-date equipment, a typical
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5 18 year old patient with CF will be exposed to a cumulative EED of approximately 3.5mSv. Based on
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7 an estimated average cancer risk of 11% per Sv for patients aged 0-18 years, this relates to an
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9 additional lifetime cancer risk of approximately 1 in 2500.[17] Another way of conveying this
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11 message relates to background radiation. In the UK the average annual background radiation is
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13 2.6mSv.[18] Therefore we estimate that the cumulative radiological investigations performed on an
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15 18 year old with CF add the equivalent to an additional 18 months background radiation. In children
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17 with CF, CXRs are the most frequently performed radiological investigation but beyond five years of
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19 age they are responsible for a minority of the child's total radiation exposure. In contrast, after five
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21 years of age, CT scans of the chest become responsible for the majority of the child's total exposure.
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23 In our cohort, abdominal CT scans were infrequently performed but when undertaken markedly
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25 increased the child's cumulative EED. This is well shown in Figure 1 where the 18 year old with a
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27 cumulative EED of 11.2mSV had two abdominal CT scans performed which contributed 65% of the
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29 radiation exposure.
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34 **Conclusions**

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36 Paediatricians need to be well informed on radiation doses produced by imaging technologies.
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38 Modern equipment has the potential to reduce the EED associated with such investigations. This
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40 effect is greatest for CT scans in younger children. Even if all investigations were performed on
41
42 modern radiological equipment, the cumulative radiation dose for children with CF remains
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44 substantial and every effort should be made to keep it to a minimum. All scans should be optimised
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46 with regards to image quality and patient dose by using age specific protocols. Paediatricians and
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48 radiologist should be aware of the risks and benefits of axial and helical CT scans. Lowering the
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50 cumulative lifetime radiation dose in children with CF will reduce their associated stochastic risks.
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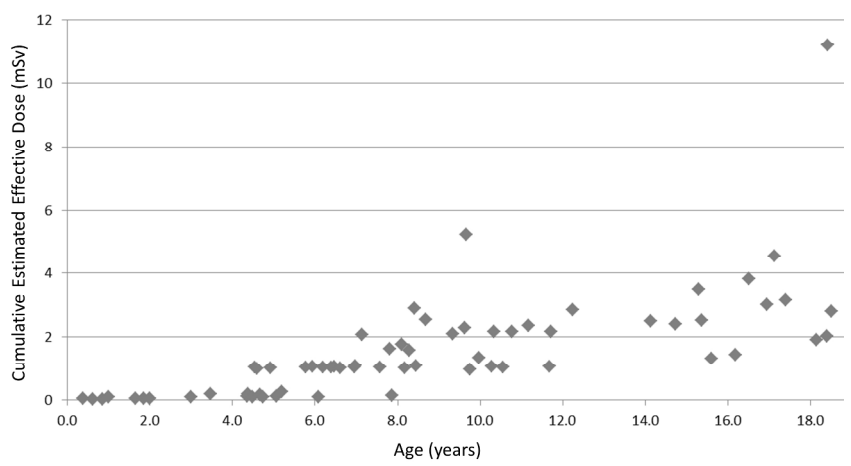


Figure 1: Cumulative radiation exposure associated with radiological investigations for 65 children with CF

254x190mm (300 x 300 DPI)

Appendix 1: Calculation of Radiation Dose

Abdomen and Chest X-Ray doses

A download was made of all children (0 to <18 years) who underwent a single plain film (abdomen or chest X-ray) examination between April 2015 and May 2016 at our centre. The dose indices recorded by radiographers on Computerised Radiology Information System (CRIS) is dose area product (DAP). This result was collected. Outliers were removed by calculating the interquartile range (IQR) and excluding any data that fell less than 1.5x the IQR below the first quartile, or greater than 1.5x the IQR above the third quartile. Consequently the mean DAP value for an abdomen and chest X-ray was calculated as per the specified age range.

Reference was made to NRPB-R279.¹ This report provides conversion coefficients for the deviation of effective dose from DAP values taken during commonly performed paediatric radiographs. The coefficients have been calculated using *Monte Carlo* mathematical simulations on a series of mathematical phantoms that represent 0, 1, 5, 10 and 15 year old children. As a result the coefficients take account of the patient size and the increased proximity of organs just outside the primary X-ray relative to that of an adult.

For example for an abdominal x-ray in a 15-18 year old patient the mean DAP for a plain film was 50cGy.cm². Based on the performance of the X-ray sets currently in use in the Trust and the AP technique routinely used, the conversion coefficient is 0.225mSv.Gy⁻¹.cm⁻². Therefore the estimated effective dose is (50/100)x0.225=0.11mSv.

Computerised Tomography (CT) Scan Dose

A download was made from CRIS for all children (0 to <18 years) who underwent either (or combinations of) CT Chest, CT abdomen, CT Pelvis and CT sinus examinations between April 2012 and May 2016. The dose indices recorded by the radiographers on CRIS is the Dose Length Product (DLP) measured in mGy.cm. This takes into account the dose per slice and the length of the scan and stochastic risk for an exam type that covers the same anatomical region. This was recorded.

During the period of data collection our unit has had four scanners; three Siemens Somatom Definition AS+ and one Siemens Somatom Definition Flash. These scanners are near identical (the flash having two X-ray tubes and 2 detector arrays) and as a result have been set up so that the same scan protocols for any anatomical programme. The scanners have the facility for iterative reconstruction, adaptive collimation, modulated tube current and kV.

The Dose Length Product (DLP) data was then subdivided into appropriate age ranges at the time of the examination and the mean value was calculated. To convert the mean DLP into an effective dose, it is standard to use a conversion factor. The conversion factor needs to take account of the dose, anatomical region scanned and the radiosensitivity of the organs exposed. In order to calculate this, the ImPACT Dosimetry software² was utilised and values established specific to the anatomy exposed for each specified exam protocol (i.e. Chest, Abdomen & Pelvis). The units of the

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2
3 correction factor are ($\text{mSv}\cdot\text{mGy}^{-1}\cdot\text{cm}^{-1}$). ImPACT utilises the National Radiological Protection Board
4 (NRPB) Monte Carlo simulation data sets. It also takes account of the most recent tissue weighting
5 factors published in by the International Commission of Radiological Protection Report 103.³
6

7
8 Multiplying the DLP by the calculated conversion factor would give an estimated effective dose for
9 an adult. However additional correction needs to be introduced for paediatrics to account for
10 different habitus size for different age ranges. The ImPACT software² provides corrections to
11 account for this for Head & Neck, Chest and Abdomen & Pelvis scans.
12

13 *Example: For a 5-10 year old undergoing an Abdomen & Pelvis CT scan the mean DLP was estimated*
14 *to equal 120mGy.cm. The conversion factor for this region of the body was 0.015mSv.mGy⁻¹cm⁻¹*
15 *¹. The correction for patient size for an Abdomen and Pelvis scan was 1.6 (worst case scenario based*
16 *on a possible range from 1.2-1.6). Therefore the estimated effective dose = 120x0.015x1.6≈2.9mSv*
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19

20 21 **Fluoroscopy (port-a-cath insertion)**

22
23 Radiology Physics were provided with the details of 21 paediatric patients with cystic fibrosis and
24 who underwent port-a-cath insertions using fluoroscopy at our centre. Using the patients ID
25 numbers it was possible using both RIS and PACS to determine the patients age at the time of the
26 examination, the total DAP (Dose Area Product) for the procedure and the X-ray equipment used.
27
28

29 Using NRPB-R279¹ conversion factors can be derived that are based on anatomy (chest) and patient
30 age. This value can be then multiplied by the DAP value to produce an effective dose. This is very
31 similar to the method used in assessing abdomen and chest x-ray doses.
32
33

34 35 **References**

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37 ¹ D. Hart, D. G. Jones, B. F. Wall. Coefficients for Estimating Effective Doses from paediatric X-ray
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STROBE Statement—checklist of items that should be included in reports of observational studies

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

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	5
		(c) Explain how missing data were addressed	5
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed	N/A
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	6-8
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	N/A
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	6-8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	6-8
		(b) Report category boundaries when continuous variables were categorized	6-8
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	6-8
Discussion			
Key results	18	Summarise key results with reference to study objectives	8
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10
Generalisability	21	Discuss the generalisability (external validity) of the study results	10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

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

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