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Radiation Dose to Patients from Radiopharmaceuticals

A fourth addendum to ICRP Publication 53

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1. Introduction

In 1987, the International Commission on Radiological Protection (ICRP) published a report entitled 'Radiation dose to patients from radiopharmaceuticals' as ICRP *Publication 53* (ICRP, 1988). This report contained calculations of absorbed doses per unit activity administered for some 120 radiopharmaceuticals in regular use at the time. The calculations were based on biokinetic models and best estimates of biokinetic data for individual radiopharmaceuticals.

A first addendum to *Publication 53* was included in *Publication 62* (ICRP, 1992). This contained biokinetic and dosimetric data for six new radiopharmaceuticals, and a table of effective doses per unit administered activity for those radiopharmaceuticals that had been discussed in Publication 53.

In the second addendum to *Publication 53*, included in *Publication 80* (ICRP, 1998), the Joint Task Group on Radiopharmaceuticals of ICRP Committees 2 and 3 presented biokinetic and dosimetric data on 10 new radiopharmaceuticals, and recalculations of dose data for 19 of the most frequently used radiopharmaceuticals in *Publication 53*. A number of minor corrections and recalculations of older data were also provided.

The third amendment to *Publication 53*, *Publication 106* (ICRP, 2008a), provides biokinetic and dosimetric models for 33 radiopharmaceuticals, as well as recommendations related to breast feeding for mothers who have undergone a nuclear medicine investigation.

This document is the fourth amendment, providing biokinetic models, absorbed doses, and effective doses per unit activity for the following radiopharmaceuticals: ^{18}F-FET; ^{18}F-FLT; ^{18}F-choline; ^{11}C-raclopride: and ^{18}F-fluoride. Two corrections to ICRP *Publication 106* are also provided. This document is being released through the ICRP website to make the results available to users as soon as possible.

However, to provide users with a single referenceable volume, a compendium of all relevant results, including those in this report, will soon be published under a single cover.

In recent years, new tissue and radiation weighting factors, nuclear decay data, and reference computational phantoms, have been published (ICRP, 2007, 2008a,b, 2009). In due course, new biokinetic models and absorbed doses per unit activity will be provided based on this new information, superseding the currently available results.

2. Limitation of the use of the values

As noted in Chapter 6 of ICRP *Publication 106* (ICRP, 2008a), 'The effective dose was developed primarily for radiation protection of occupationally exposed persons (ICRP, 1977, 1991). It attributes weighting factors w_T to organs or tissues, representing the fraction of the total stochastic risk (i.e. fatal cancer and serious inherited disorders) resulting from the irradiation of that organ or tissue T when the whole body is irradiated uniformly. (Para. 53)'

Nonetheless 'The concept of effective dose to patients can also be useful in nuclear medicine and other medical investigations using ionising radiation. (Para. 57)', because 'Effective dose can be of practical value for comparing the relative doses related to stochastic effects from: different diagnostic examinations and interventional procedures; the use of similar technologies and procedures in different hospitals and countries; and the use of different technologies for the same medical examination provided that the representative patients or patient populations for which the effective doses are derived are similar with regard to age and gender. (Para. 58)'

'However, comparisons of effective doses are inappropriate when there are significant dissimilarities between the age and gender distributions of the representative patients or patient populations being compared (e.g. children, all females, elderly populations) and the Commission's reference distribution of both genders and all ages. (Para 58)', and also 'The effective dose should not be used to assess risks of stochastic effects in retrospective situations for exposures in identified individuals, nor should it be used in epidemiological evaluations of human exposure. (Para. 59)'

3. Corrections to ICRP *Publication 106*

For ^{99m}Tc-tetrofosmin at rest: Due to a late editorial mistake by the publisher, the same dose table was used for ^{99m}Tc-tetrofosmin at rest as at stress. A table with the correct dose data for ^{99m}Tc-tetrofosmin at rest is included (Annex 6).

For ^{18}F FDG: Page 81, last sentence, says 60% is excreted via the urine and 40% via the GI-tract. In the table on page 83, the proportions are given as 90 % and 10 % respectively; figures which are also used for the dose calculations. Therefore, the text should be corrected accordingly, which means: A total of 90% of the administered activity is assumed to be excreted in the urine and 10% via the gastrointestinal tract.

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ICRP, 2009. Adult Reference Computational Phantoms. ICRP Publication 110. Ann. ICRP 39 (2).

Annex 1

O-(2-[^{18}F]-Fluorethyl)-L-Tyrosine (2-[^{18}F]FET)

^{18}F

Biokinetic model

^{18}F-fluroethyltyrosine (^{18}F-FET) is actively taken up in tumor cells via amino acid transport system L, but is neither incorporated into proteins nor readily degraded, resulting in high intracellular concentrations of this imaging agent. Reflecting the increased amino acid transport capacity of tumor cells, ^{18}F]FET is useful in PET brain tumor imaging because ^{18}F-FDG, commonly used in PET tumor imaging, is relatively insensitive for detecting tumors in the brain due the high levels of glycolytic metabolism in the normal cortex and to a lesser extent in white matter.

The currently available information about the biokinetics, organ and tissue distribution of 2-[^{18}F]FET in humans or animals is limited to the first 3 to 5 hours after intravenous injection. Studies in mice and humans after administration of 2-[^{18}F]FET (Heiss et al., 1999; Wester et al., 1999; Pauleit et al., 2003; Tang et al, 2003; Abe et al., 2006; Langen et al., 2006) showed that the activity was very rapidly removed from the blood plasma. Clinical PET studies with 2-[^{18}F]FET, carried out in 7 patients (Pauleit et al., 2003) and 4 normal men (Abe et al., 2006) showed that the uptake of the radiopharmaceutical in the tissues studied was maximal within 0.25 h, and then decreased mono-exponentially with a biological half-time of between 8 and 12 h. The removal of the radioactivity from the blood plasma appeared to be bi-exponential with biological half-times of <0.05 h (40%) and ≈14 h (60%) (Pauleit et al., 2003). About 25% of the administered substance was excreted in the urine in 5 h, this suggests an elimination-half-time of ~14 h (Pauleit et al., 2003; Langen et al., 2006).

Estimates of radiation dose to human tissues after injection of 2-[^{18}F]FET based on biokinetic data for mice were published by Taylor (2000) and Tang et al. (2003) and an estimate based on clinical PET studies was reported by Pauleit et al. (2003). In general, these agree relatively well with each other. In order to take account of the human data published by Abe et al. (2006) all the available biokinetic data have been re-analysed and a cautious biokinetic model for 2-[^{18}F]FET was developed (See below1).

It was assumed that the (2-[^{18}F]FET) entering the systemic circulation was very rapidly distributed into the organs and tissues and then eliminated with a biological half-time of 14 h. The fractional uptake in the various organs is shown in columns 1 and 2 of Table 1. It was also assumed that 99% of the ^{18}F from (2-[^{18}F]FET) was excreted through the urinary bladder with a biological half-time of 14 h; the remaining 1 % of the administered activity was assumed to be eliminated via the small intestine and faeces. The selection of 14 h as the elimination half-time means that ~99% of the administered activity decays in the body.

The effective dose is nearly the same as that calculated by Pauleit et al. (2003) for 2-[^{18}F]FET, 1.65E–02 mSv/MBq; the dose to the urinary bladder is higher than that calculated by Pauleit et al. (2003), 6.0E-02 mGy/MBq, because a longer bladder voiding interval (3.5 h) is assumed here compared to that assumed by Pauleit et al. (2003) (2 h).

References for 2-[^{18}F]FET

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Biokinetic data for 2-[^{18}F]FET

Organ (S)	F_S	T(h)	a	$\tilde{A}/A_0$ (h)
Liver	0.04	14	1.0	0.093
Lungs	0.02	14	1.0	0.047
Red bone marrow	0.02	14	1.0	0.047
Kidneys	0.01	14	1.0	0.023
(from excretion proc.)				0.0093
Other organs and tissues	0.90	14	1.0	2.10
Gastrointestinal tract contents				
Small intestine	0.01			0.0018
Upper large intestine	0.01			0.00010
Lower large intestine	0.01			0.00018
Urinary bladder contents	0.99			
≥ 10 y				0.15
5 y				0.14
1 y				0.10

F_s = Fraction of the injected activity in the organ. T_b = Biological half-time. a = Fraction of F_s eliminated with half-time T. $\tilde{A}_s/A_0$ = Time–integrated activity (cumulated activity) in organ *S*.

Absorbed doses after intravenous administration of 2-[^{18}F]FET

F-18

1.83 hours

Organ	Absorbed dose per unit activity administered [mGy/MBq]				
	Adults	15 y	10y	5 y	1 y
Adrenals	1.4E-02	1.7E-02	2.6E-02	4.2E-02	7.7E-02
Bladder	8.5E-02	1.1E-01	1.6E-01	2.2E-01	3.0E-01
Bone surfaces	1.3E-02	1.6E-02	2.4E-02	3.9E-02	7.4E-02
Brain	1.0E-02	1.3E-02	2.1E-02	3.4E-02	6.4E-02
Breasts	9.5E-03	1.2E-02	1.8E-02	3.0E-02	5.7E-02
Gall bladder	1.4E-02	1.7E-02	2.6E-02	3.8E-02	6.8E-02
Gastrointestinal tract:					
Stomach wall	1.3E-02	1.6E-02	2.4E-02	3.8E-02	6.9E-02
Small intestine	7.6E-03	9.4E-03	1.4E-02	2.0E-02	3.2E-02
Colon	1.1E-02	1.3E-02	2.1E-02	3.2E-02	5.4E-02
(Upper large intestine	1.0E-02	1.3E-02	2.0E-02	3.1E-02	5.4E-02)
(Lower large intestine	1.2E-02	1.4E-02	2.2E-02	3.3E-02	5.4E-02)
Heart	1.3E-02	1.6E-02	2.6E-02	3.9E-02	7.2E-02
Kidneys	2.7E-02	3.3E-02	4.6E-02	6.9E-02	1.2E-01
Liver	1.7E-02	2.2E-02	3.2E-02	4.8E-02	8.8E-02
Lungs	1.4E-02	2.0E-02	2.8E-02	4.2E-02	8.1E-02
Muscle	1.2E-02	1.4E-02	2.3E-02	3.6E-02	6.7E-02
Oesophagus	1.2E-02	1.5E-02	2.3E-02	3.6E-02	6.9E-02
Ovaries	1.5E-02	1.8E-02	2.8E-02	4.3E-02	7.7E-02
Pancreas	1.4E-02	1.8E-02	2.7E-02	4.3E-02	7.8E-02
Red bone marrow	1.3E-02	1.6E-02	2.4E-02	3.8E-02	7.2E-02
Skin	9.0E-03	1.1E-02	1.8E-02	2.9E-02	5.5E-02
Spleen	1.3E-02	1.6E-02	2.4E-02	4.0E-02	7.3E-02
Testes	1.2E-02	1.6E-02	2.5E-02	3.8E-02	7.0E-02
Thymus	1.2E-02	1.5E-02	2.3E-02	3.6E-02	6.9E-02
Thyroid	1.2E-02	1.5E-02	2.4E-02	3.9E-02	7.3E-02
Uterus	1.7E-02	2.1E-02	3.4E-02	5.1E-02	8.6E-02
Remaining organs	1.2E-02	1.4E-02	2.2E-02	3.5E-02	6.6E-02
Effective dose (mSv/MBq)	1.6E-02	2.1E-02	3.1E-02	4.7E-02	8.2E-02

Annex 2

3'-Deoxy-[^{18}F]-3'-flourothymidine ([^{18}F]FLT)

^{18}F

Biokinetic model

The antiviral nucleoside 3'-deoxy-[^{18}F]-3'-flourothymidine ([^{18}F]FLT) is an analogue of the natural nucleoside thymidine, an essential component of the DNA molecule. The ^{18}F-labelled compound can be applied for the scintigraphic visualisation of cell proliferation in tumours and other tissues using positron emission tomography, and thus for the monitoring of cancer therapy using cytotoxic drugs or radiation (Grierson et al., 1995; Shield et al., 1996; Cobden et al., 2003; Vesselle et al., 2003; Buchmann et al., 2004; Choi et al., 2003).

Non-radioactive 3'-deoxy-3'-flourothymidine was developed for the treatment of human immunodificiency virus (HIV) infections (Shinazi et al., 1990). Clinical studies (Flexner et al., 1994) showed that the administration of ~0.5 mmol FLT/d led to unacceptable toxicity in 6 out of 10 patients. At the biochemical level FLT inhibits DNA synthesis and leads to apoptosis (cell death). In vitro tests suggest that FLT exhibits a relatively strong mutagenicity. It is however assumed that the single administration of 400 MBq and ~0.01 μmol [^{18}F]FLT would not cause any demonstrable chemical toxicity or mutagenic effect.

Studies in humans (Cobden et al., 2003; Vesselle et al., 2003; Buchmann et al., 2004), dogs and monkeys (Shinazi et al., 1990) suggested that the substance was not extensively metabolised in vivo, but was excreted largely unchanged mainly in the urine (Muzi et al., 2005). Shortly after injection [^{18}F]FLT is taken up by rapidly proliferating cells, especially in bone marrow and in tumours (Vesselle et al., 2003; Buchmann et al., 2004). Studies in dogs suggest that during the first hour after injection the Standardised Uptake Value (SUV) in the bone marrow reached 4.2, and that significant uptake into the kidneys and urinary bladder were seen (Shields et al., 2002).

Clinical PET studies with [^{18}F]FLT indicate that the activity is relatively rapidly distributed throughout the body and then taken up by the body tissues. The maximum uptake in kidneys, liver and bone marrow was found within 5 minutes of injection. The following SUV were calculated: bone marrow 10, liver 4-8, kidneys 2-6, spleen 2-4, lungs 0.5-1.2 (Vesselle et al., 2003; Buchmann et al., 2004). There is little information on the elimination rates from the tissues. Vesselle et al. (2003) reported that the maximum uptake in the kidneys occurred within 1.5 minutes and that thereafter 80% of the radioactivity was eliminated with a biological half-time of 0.05 h, the remainder was lost with a longer half-time. A clinical PET study suggested that 20% of the injected [^{18}F]FLT accumulated in the urinary bladder within 1.5h (Vesselle et al., 2003).

Vesselle et al. (2003) calculated radiation doses for men and women following intravenous injection of [^{18}F]FLT. On the basis of the limited human data mentioned above, the following cautious biokinetic model was developed. It was assumed that immediately following intravenous injection of [^{18}F]FLT, the uptake in the liver, bone marrow, kidneys and spleen would be, respectively, 14, 10, 8 and 0.6% of the injected activity. Of the activity deposited in the kidneys it is assumed that 75% would be eliminated with a biological half-time of 0.05 h. Because no good human data were available for the retention times in the various organs and tissues, a biological half-time of 24 h was assumed for all tissues. It was further assumed that 15% of the total radioactivity is eliminated in the urine.

References for [^{18}F]FLT

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Biokinetic data for [^{18}F]FLT

Organ (S)	F_S	T(h)	a	$\tilde{A}/A_0$ (h)
Red bone marrow	0.10	24	1.0	0.245
Liver	0.14	24	1.0	0.343
Kidneys	0.08	0.05	0.75	0.0533
		24	0.25	
(from excretion proc.)				0.0015
Spleen	0.006	24	1.0	0.0147
Other tissues	0.674	24	1.0	1.65
Urinary bladder contents	0.15			
≥ 10 y				0.030
5 y				0.027
1 y				0.020

F_S = Fraction of the injected activity in the organ. T = Biological half-time. a = Fraction of F_S eliminated with half-time T. $\tilde{A}_s/A_0$ = Time –integrated activity (cumulated activity) in organ *S*.

Absorbed doses after intravenous administration of [^{18}F]FLT

F-18

1.83 hours

Organ	Absorbed dose per unit activity administered (mGy/MBq)				
	Adults	15 y	10y	5 y	1 y
Adrenals	1.6E-02	1.9E-02	2.9E-02	4.4E-02	7.7E-02
Bladder	2.3E-02	2.8E-02	4.2E-02	6.2E-02	9.2E-02
Bone surfaces	1.9E-02	2.4E-02	3.7E-02	6.1E-02	1.3E-01
Brain	8.2E-03	1.0E-02	1.7E-02	2.8E-02	5.2E-02
Breasts	8.2E-03	1.0E-02	1.6E-02	2.5E-02	4.9E-02
Gall bladder	1.8E-02	2.1E-02	3.0E-02	4.6E-02	8.5E-02
Gastrointestinal tract:					
Stomach wall	1.2E-02	1.4E-02	2.2E-02	3.5E-02	6.6E-02
Small intestine	1.3E-02	1.6E-02	2.5E-02	3.8E-02	6.9E-02
Colon	1.2E-02	1.5E-02	2.3E-02	3.6E-02	6.5E-02
(Upper large intestine	1.3E-02	1.5E-02	2.4E-02	3.8E-02	6.9E-02)
(Lower large intestine	1.2E-02	1.4E-02	2.2E-02	3.4E-02	5.9E-02)
Heart	1.2E-02	1.5E-02	2.4E-02	3.6E-02	6.5E-02
Kidneys	4.3E-02	5.1E-02	7.2E-02	1.1E-01	1.9E-01
Liver	4.8E-02	6.3E-02	9.4E-02	1.4E-01	2.6E-01
Lungs	1.1E-02	1.4E-02	2.1E-02	3.2E-02	6.0E-02
Muscle	9.8E-03	1.2E-02	1.9E-02	3.0E-02	5.6E-02
Oesophagus	9.8E-03	1.3E-02	1.9E-02	3.0E-02	5.6E-02
Ovaries	1.2E-02	1.5E-02	2.4E-02	3.6E-02	6.6E-02
Pancreas	1.5E-02	1.9E-02	2.9E-02	4.4E-02	7.9E-02
Red bone marrow	2.6E-02	3.0E-02	4.8E-02	8.6E-02	1.9E-01
Skin	7.5E-03	9.2E-03	1.5E-02	2.4E-02	4.6E-02
Spleen	2.2E-02	3.1E-02	4.7E-02	7.3E-02	1.3E-01
Testes	8.8E-03	1.1E-02	1.7E-02	2.7E-02	5.2E-02
Thymus	9.8E-03	1.3E-02	1.9E-02	3.0E-02	5.6E-02
Thyroid	9.4E-03	1.2E-02	1.9E-02	3.1E-02	5.8E-02
Uterus	1.2E-02	1.5E-02	2.4E-02	3.7E-02	6.6E-02
Remaining organs	1.0E-02	1.3E-02	2.0E-02	3.3E-02	6.0E-02
Effective dose (mSv/MBq)	1.5E-02	1.9E-02	2.9E-02	4.6E-02	8.8E-02

Annex 3

^{18}F-choline

^{18}F

Biokinetic model

Choline uptake is increased in cancerous tissues because the high metabolic rates of tumor cells require choline for the synthesis of phospholipids. For example, choline kinase is overexpressed in prostate cancer cells (Ackerstaff et al., 2003; Ramirez de Molina et al., 2002), thus making choline a suitable indicator for early and differential diagnosis of prostate cancer. PET with radiolabeled choline is therefore used for diagnosis of malignant and recurrent tumors and of metastases in prostate cancer patients (Kwee et al., 2006; DeGrado et al., 2002; Schmid et al., 2005; Steiner et al., 2009). A correct evaluation of the patient dose and the optimization of the imaging protocols imply knowledge of the biodistribution and kinetics of the administered compounds. The biokinetics of ^{18}F-choline (^{18}F-FCH) in 4 prostate cancer patients were investigated in a study conducted in the frame of the European Collaborative project MADEIRA (Uusijärvi et al., 2010; Hoeschen et al., 2010). Six new patients were later included in the study. In these investigations, biodistribution and excretion data were collected for up to 4 h after injection of the radiopharmaceutical (Tavola et al., 2012; Janzen et al., 2010; Giussani et al., 2012). Previous human studies with ^{11}C- or ^{18}F-choline were limited up to 1 h after administration (Kwee et al., 2006; DeGrado et al., 2002; Schmid et al., 2005; Steiner et al., 2009; Roivainen et al., 2000).

Please observe that the biokinetics of ^{11}C-choline and of ^{18}F-choline differ, due to the different interactions of carbon and fluorine in the organism. A paper with dosimetric data on ^{11}C-choline has been published by Tolvanen et al. (2010) and the biokinetics and dosimetry of ^{11}C-choline will be subject to further evaluation by ICRP.

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Biokinetic data for ^{18}F-choline

Organ (S)	F_S	T(h)	a	$\tilde{A}/A_0$ (h)
Blood	1.0	0.08	0.5	0.267
		0.35	0.5	
Liver	0.175	0.08	-0.5	0.415
		0.35	-0.5	
		∞	1.0	
Spleen	0.012	0.08	-0.5	0.022
		0.35	-0.5	
		7	1.0	
Kidneys	0.097	0.08	-0.5	0.135
		0.35	-0.5	
		0.5	0.4	
		7	0.6	
Remainder	0.71	0.08	-0.5	1.631
		0.35	-0.5	
		52	1.0	
Urinary bladder	0.825			
≥ 10 y				0.104
5 y				0.093
1 y				0.066

Absorbed doses after intravenous administration of ^{18}F-choline

F-18
1.83 hours

Organ	Absorbed dose per unit activity administered (mGy/MBq)				
	Adult	**15 year**	**10 year**	**5 year**	**1 year**
Adrenals	2.0E-02	2.4E-02	3.8E-02	5.9E-02	1.0E-01
Bladder	5.9E-02	7.5E-02	1.1E-01	1.6E-01	2.2E-01
Bone surfaces	1.2E-02	1.5E-02	2.3E-02	3.7E-02	7.0E-02
Brain	8.7E-03	1.1E-02	1.8E-02	3.0E-02	5.6E-02
Breast	9.0E-03	1.1E-02	1.8E-02	2.8E-02	5.4E-02
Gall bladder	2.1E-02	2.5E-02	3.5E-02	5.4E-02	1.0E-01
GI tract					
Stomach	1.3E-02	1.6E-02	2.5E-02	4.0E-02	7.6E-02
SI	1.3E-02	1.7E-02	2.7E-02	4.2E-02	7.7E-02
Colon	1.3E-02	1.6E-02	2.6E-02	4.0E-02	7.2E-02
(Upper large intestine	1.4E-02	1.7E-02	2.7E-02	4.3E-02	7.8E-02)
(Lower large intestine	1.2E-02	1.5E-02	2.4E-02	3.7E-02	6.4E-02)
Heart	2.0E-02	2.6E-02	4.1E-02	6.3E-02	1.1E-01
Kidneys	9.7E-02	1.2E-01	1.6E-01	2.4E-01	4.3E-01
Liver	6.1E-02	8.0E-02	1.2E-01	1.8E-01	3.3E-01
Lungs	1.7E-02	2.2E-02	3.5E-02	5.6E-02	1.1E-01
Muscles	1.1E-02	1.3E-02	2.1E-02	3.3E-02	6.1E-02
Oesophagus	1.1E-02	1.4E-02	2.1E-02	3.3E-02	6.2E-02
Ovaries	1.3E-02	1.6E-02	2.6E-02	4.0E-02	7.2E-02
Pancreas	1.7E-02	2.2E-02	3.4E-02	5.2E-02	9.3E-02
Red marrow	1.3E-02	1.6E-02	2.4E-02	3.6E-02	6.6E-02
Skin	8.0E-03	9.8E-03	1.6E-02	2.5E-02	4.9E-02
Spleen	3.6E-02	5.0E-02	7.7E-02	1.2E-01	2.2E-01
Testes	9.8E-03	1.3E-02	2.0E-02	3.1E-02	5.7E-02
Thymus	1.1E-02	1.4E-02	2.1E-02	3.3E-02	6.2E-02
Thyroid	1.1E-02	1.4E-02	2.2E-02	3.7E-02	7.0E-02
Uterus	1.5E-02	1.8E-02	2.9E-02	4.4E-02	7.6E-02
Remaining organs	1.1E-02	1.4E-02	2.1E-02	3.4E-02	6.2E-02
Effective dose (mSv/MBq)	2.0E-02	2.4E-02	3.7E-02	5.7E-02	1.0E-01

Annex 4

^{11}C-raclopride

^{11}C

Biokinetic model

Raclopride is a synthetic compound of the salicylamide series with high selectivity and affinity for central D $_2$-dopamine receptors. It can be labeled with ^{11}C and used in positron emission tomography (PET). The neurotransmitter dopamine may be involved in various neuropsychiatric diseases. ^{11}C-raclopride is rapidly cleared from both plasma and whole blood, and crosses the blood-brain barrier. After intravenous administration, ^{11}C-raclopride localizes in the basal ganglia, a region with a high density of dopamine receptors. PET images show concentration of ^{11}C-raclopride in the region of the putamen relative to the rest of the brain. Images can be taken immediately after injection and continued for approximately 60 minutes (Glatting et al., 2004; Slifstein et al., 2007).

The proposed biokinetic model is mainly based on experimental data from Ribeiro et al. (2005) (11 measurements from 2 to 112 min after application). The source organs have been grouped according to 3 retention half-times. Slifstein et al. (2011) have also LLI and cortical bone, but not muscle, as source regions. They also report a lower kidney uptake.

References for ^{11}C-raclopride

Glatting, G., Mottaghy, F. M., Karitzky, J., Baune, A., Sommer, F. T., Landwehrmeyer, G.B., Reske, S.N., 2004. Improving binding potential analysis in [^{11}C] raclopride PET studies using cluster analysis Med. Phys. 31(4), 902-906.

Ribeiro, M.-J., Ricard, M., Bourgeois, S., Lièvre, M.-A., Bottlaender, M., Gervais, P., Dollé, F., Syrota, A., 2005. Biodistribution and radiation dosimetry of [^{11}C]raclopride in healthy volunteers. Eur.J. Nucl. Mol. Imag. 32(8), 952-958.

Slifstein, M., Lawrence, S. Kegeles, L. S., Gonzales, R., Frankle, W. G., Xu, X., Laruelle, M., Abi-Dargham, A., 2007. [^{11}C]NNC 112 selectivity for dopamine D_1 and serotonin 5-HT_{2A} receptors: a PET study in healthy human subjects. J.Cerebr. Blood Flow & Metab. 27, 1733–1741.

Slifstein, M., Suckow, R. F., Javitch, J. A., Cooper, T., 2011. Characterization of in vivo pharmacokinetic properties of the dopamine D1 receptor agonist DAR-0100A in nonhuman primates using PET with [^{11}C] NNC112 and [^{11}C] raclopride. J. Cerebr. Blood Flow & Metab. 31(1), 293-304.

Biokinetic data for ^{11}C-raclopride

Organ (S)	F_S	T(h)	a	$\tilde{A}/A_0$ (h)
Liver	0.18	4.00		0.081
Kidneys	0.06	1.00		0.023
(from excretion proc.)				0.0054
Brain	0.03	1.00		0.011
Red marrow	0.02	∞		0.0098
Lungs	0.02	1.00		0.0073
Heart wall	0.01	1.00		0.0037
Small intestine wall	0.08	0.33		0.019
Gallbladder contents	0.16			0.0062
Gastrointestinal tract contents				
Small intestine	0.40			0.023
Upper large intestine	0.40			0.0027
Lower large intestine	0.40			0.00010
Urinary bladder content	0.31			
Adults, 15 and 10 year old				0.029
5, 1 year old				0.028
Other tissues	0.60	0.33	0.1	0.27
		4.00	0.45	
		∞	0.45	

Comments to the biokinetic data table regarding assumed excretion routes: Activity in liver is excreted according to ICRP 53 gall bladder model (90 % passes the gallbladder). Activity in the SI wall and half of the activity in other tissues with the long half-time goes directly to the GI tract contents. Remaining activity with finite biological half-time is excreted via the urinary bladder.

Absorbed doses after intravenous administration of ^{11}C-raclopride

C-11

20.38 minutes

Organ	Absorbed dose per unit activity administered (mGy/MBq)				
	Adult	**15 year**	**10 year**	**5 year**	**1 year**
Adrenals	3.6E-03	4.5E-03	7.0E-03	1.1E-02	2.0E-02
Bladder	2.2E-02	2.8E-02	4.2E-02	6.5E-02	1.2E-01
Bone surfaces	2.6E-03	3.2E-03	5.1E-03	8.3E-03	1.7E-02
Brain	2.8E-03	2.9E-03	3.2E-03	3.7E-03	5.4E-03
Breast	1.8E-03	2.3E-03	3.8E-03	6.2E-03	1.2E-02
Gall bladder	1.8E-02	2.1E-02	2.7E-02	4.9E-02	1.7E-01
GI tract					
Stomach	2.8E-03	3.4E-03	5.7E-03	9.1E-03	1.8E-02
SI	1.4E-02	1.8E-02	3.2E-02	4.7E-02	9.2E-02
Colon	4.1E-03	5.1E-03	8.3E-03	1.2E-02	2.2E-02
(Upper large intestine	5.2E-03	6.4E-03	1.1E-02	1.5E-02	2.8E-02)
(Lower large intestine)	2.7E-03	3.3E-03	5.3E-03	7.9E-03	1.4E-02)
Heart	4.5E-03	5.9E-03	9.1E-03	1.4E-02	2.5E-02
Kidneys	2.6E-02	3.1E-02	4.4E-02	6.6E-02	1.2E-01
Liver	1.5E-02	1.9E-02	3.0E-02	4.4E-02	8.3E-02
Lungs	3.1E-03	4.4E-03	6.3E-03	9.6E-03	1.9E-02
Muscles	2.3E-03	2.9E-03	4.6E-03	7.4E-03	1.4E-02
Oesophagus	2.1E-03	2.7E-03	4.3E-03	6.9E-03	1.4E-02
Ovaries	3.6E-03	4.5E-03	7.1E-03	1.1E-02	2.0E-02
Pancreas	3.5E-03	4.3E-03	7.1E-03	1.1E-02	2.0E-02
Red marrow	3.1E-03	3.6E-03	5.6E-03	9.0E-03	1.8E-02
Skin	1.7E-03	2.1E-03	3.5E-03	5.8E-03	1.2E-02
Spleen	2.7E-03	3.5E-03	5.6E-03	9.1E-03	1.7E-02
Testes	2.1E-03	2.7E-03	4.6E-03	7.4E-03	1.5E-02
Thymus	2.1E-03	2.7E-03	4.3E-03	6.9E-03	1.4E-02
Thyroid	1.9E-03	2.5E-03	4.1E-03	6.9E-03	1.4E-02
Uterus	3.9E-03	4.9E-03	8.0E-03	1.2E-02	2.3E-02
Remaining organs	2.7E-03	3.6E-03	5.9E-03	9.2E-03	1.8E-02
Effective dose (mSv/MBq)	5.0E-03	6.4E-03	9.8E-03	1.5E-02	3.0E-02

Annex 5

^{18}F-fluoride

^{18}F

Biokinetic model

Considering the high uptake in mineral bone and since the skeleton model has been considerably improved since the ICRP Publication 53 (ICRP, 1988) was published, ICRP has again reviewed the literature and proposes a new biokinetic model and a new dose table for this substance.

^{18}F-fluoride is a highly effective bone-seeking PET tracer used for detection of skeletal abnormalities (Fair et al., 2010). The uptake mechanism of ^{18}F-fluoride resembles that of ^{99m}Tc-methylene diphosphonate (MDP), but has better pharmacokinetic characteristics, including faster blood clearance and 2-fold higher uptake in bone. Uptake of ^{18}F-fluoride reflects blood flow and bone remodeling. The proposed biokinetic model is mainly based on the compartment model of Blake et al. (2001) and Park-Holohan et al. (2001), Additional information was extracted from Hawkins et al. (1992) and Doot et al. (2010).

References for ^{18}F-fluoride

Blake, G.M., Park-Holohan, S., Cook, G. J. R., Fogelman, I., 2001. Quantitative studies of bone with use of ^{18}F-fluoride and ^{99m}Tc-methylene diphosphonate. Sem. Nucl. Med. 31, 28-49.

Doot, R.K., Muzi, M., Peterson, L.M., Schubert, E.K., Gralow, J.R., Specht, J.M., Mankoff, D.A., 2010. Kinetic analysis of ^{18}F-fluoride PET images of breast cancer bone metastases. J. Nucl. Med. 51, 521-527.

Fair, J., Sajdak, R., Smith, G. T., 2010. SNM practice guideline for sodium ^{18}F-fluoride PET/CT bone scans. J. Nucl. Med. 51(11), 1813-1820.

Hawkins, R. A., Choi, Y., Huang, S.-C., Hoh, C. K., Dahlbom, M., Schiepers, C., Satyamurthy, N., Barrio, J. R., Phelps, M. E., 1992. Evaluation o the skeletal kinetics of fluorine-18-Fluoide ion with PET. J. Nucl. Med. 33, 633-642. (contains a compartment model without excretion)

ICRP, 1988. Radiation dose to patients from radiopharmaceuticals. ICRP Publication 53, Ann. ICRP 18 (1-4).

Park-Holohan, S.-J., Blake, G. M., Fogelman, I., 2001. Quantitative studies of bone using ^{18}F-fluoride and ^{99m}Tc-methylene diphosphonate: evaluation of renal and whole-blood kinetics. Nucl. Med. Commun. 22(9), 1037-1044.

Biokinetic data for ^{18}F-fluoride

Organ	F	t½ (h)	a	$\tilde{A}/A_0$ (h)
Remainder	0.4	0.25	0.75	0.33
		13	0.25	
Bone surf	0.6	0.25	-1	1.4
		∞	1	
Trabecular bone				
Adults, 15, 10 y				0.83
5, 1 y				0.97
Cortical bone				
Adults, 15, 10 y				0.55
5, 1 y				0.42
Urinary bladder	0.24			
Adult, 15 y				0.29
10 y				0.26
5, 1 y				0.19

Absorbed doses after intravenous administration of ^{18}F-fluoride

F-18

1.83 hours

Organ	Absorbed dose per unit activity administered (mGy/MBq)				
	Adult	**15 year**	**10 year**	**5 year**	**1 year**
Adrenals	6.7E-03	8.8E-03	1.3E-02	2.0E-02	3.9E-02
Bladder	1.5E-01	1.9E-01	2.8E-01	3.9E-01	5.4E-01
Bone surfaces	9.4E-02	7.5E-02	1.2E-01	2.1E-01	4.8E-01
Brain	6.6E-03	7.5E-03	1.1E-02	1.6E-02	2.5E-02
Breast	2.9E-03	3.7E-03	6.0E-03	9.5E-03	1.8E-02
Gall bladder	4.2E-03	5.1E-03	8.2E-03	1.2E-02	2.3E-02
GI tract					
Stomach	3.7E-03	4.6E-03	7.9E-03	1.1E-02	2.0E-02
SI	5.8E-03	7.5E-03	1.1E-02	1.7E-02	3.0E-02
Colon	6.8E-03	8.4E-03	1.3E-02	1.9E-02	3.0E-02
(Upper large intestine	5.1E-03	6.3E-03	1.0E-02	1.5E-02	2.6E-02)
(Lower large intestine	9.1E-03	1.1E-02	1.7E-02	2.5E-02	3.7E-02)
Heart	4.2E-03	5.1E-03	7.9E-03	1.2E-02	2.2E-02
Kidneys	1.3E-02	1.6E-02	2.4E-02	3.6E-02	6.7E-02
Liver	4.0E-03	5.2E-03	7.8E-03	1.2E-02	2.3E-02
Lungs	4.5E-03	5.8E-03	8.6E-03	1.3E-02	2.6E-02
Muscles	5.8E-03	7.1E-03	1.1E-02	1.6E-02	2.8E-02
Oesophagus	3.7E-03	4.8E-03	7.2E-03	1.1E-02	2.2E-02
Ovaries	8.3E-03	1.1E-02	1.5E-02	2.2E-02	3.6E-02
Pancreas	5.0E-03	6.1E-03	9.2E-03	1.4E-02	2.7E-02
Red marrow	3.7E-02	3.9E-02	7.6E-02	1.8E-01	4.4E-01
Skin	4.1E-03	4.9E-03	7.7E-03	1.2E-02	2.2E-02
Spleen	4.2E-03	5.5E-03	8.4E-03	1.3E-02	2.6E-02
Testes	6.1E-03	8.3E-03	1.4E-02	2.0E-02	3.2E-02
Thymus	3.7E-03	4.8E-03	7.2E-03	1.1E-02	2.2E-02
Thyroid	4.9E-03	5.7E-03	8.1E-03	1.2E-02	2.0E-02
Uterus	1.3E-02	1.5E-02	2.4E-02	3.5E-02	5.0E-02
Remaining organs	5.9E-03	7.3E-03	1.1E-02	1.7E-02	2.8E-02
Effective dose (mSv/MBq)	1.7E-02	2.0E-02	3.3E-02	5.6E-02	1.1E-01

Annex 6

Tc-99m tetrofosmin, at rest (corrections).

Tc-99m

6.02 hours

Organ	Absorbed dose per unit activity administered (mGy/MBq)				
	Adult	**15 year**	**10 year**	**5 year**	**1 year**
Adrenals	4.2E-03	5.3E-03	8.1E-03	1.2E-02	2.2E-02
Bladder	1.7E-02	2.2E-02	3.2E-02	4.2E-02	5.6E-02
Bone surfaces	5.8E-03	6.9E-03	1.0E-02	1.5E-02	2.7E-02
Brain	2.3E-03	2.9E-03	4.6E-03	7.4E-03	1.3E-02
Breast	2.0E-03	2.5E-03	3.7E-03	6.1E-03	1.2E-02
Gall bladder	3.6E-02	4.1E-02	5.3E-02	9.3E-02	3.0E-01
GI tract					
Stomach	4.5E-03	6.0E-03	9.7E-03	1.4E-02	2.4E-02
SI	1.5E-02	1.8E-02	2.9E-02	4.6E-02	8.1E-02
Colon	2.4E-02	3.1E-02	5.0E-02	7.9E-02	1.5E-01
(Upper large intestine	2.7E-02	3.5E-02	5.6E-02	8.9E-02	1.6E-01)
(Lower large intestine	2.0E-02	2.6E-02	4.2E-02	6.6E-02	1.2E-01)
Heart	4.7E-03	5.9E-03	8.9E-03	1.3E-02	2.3E-02
Kidneys	1.3E-02	1.6E-02	2.2E-02	3.2E-02	5.5E-02
Liver	4.0E-03	5.0E-03	7.7E-03	1.1E-02	2.0E-02
Lungs	2.8E-03	3.7E-03	5.5E-03	8.5E-03	1.6E-02
Muscles	3.3E-03	4.1E-03	6.2E-03	9.4E-03	1.7E-02
Oesophagus	2.8E-03	3.6E-03	5.4E-03	8.5E-03	1.6E-02
Ovaries	8.8E-03	1.1E-02	1.6E-02	2.4E-02	4.0E-02
Pancreas	4.9E-03	6.2E-03	1.0E-02	1.5E-02	2.5E-02
Red marrow	3.8E-03	4.6E-03	6.8E-03	9.5E-03	1.6E-02
Skin	2.0E-03	2.4E-03	3.8E-03	6.0E-03	1.1E-02
Spleen	3.9E-03	5.0E-03	7.8E-03	1.2E-02	2.1E-02
Testes	3.1E-03	3.9E-03	6.2E-03	9.6E-03	1.7E-02
Thymus	2.8E-03	3.6E-03	5.4E-03	8.5E-03	1.6E-02
Thyroid	5.5E-03	8.2E-03	1.3E-02	2.6E-02	4.7E-02
Uterus	7.8E-03	9.7E-03	1.5E-02	2.2E-02	3.5E-02
Remaining organs	3.8E-03	4.9E-03	7.6E-03	1.2E-02	2.0E-02
Effective dose (mSv/MBq)	8.0E-03	1.0E-02	1.5E-02	2.4E-02	4.6E-02