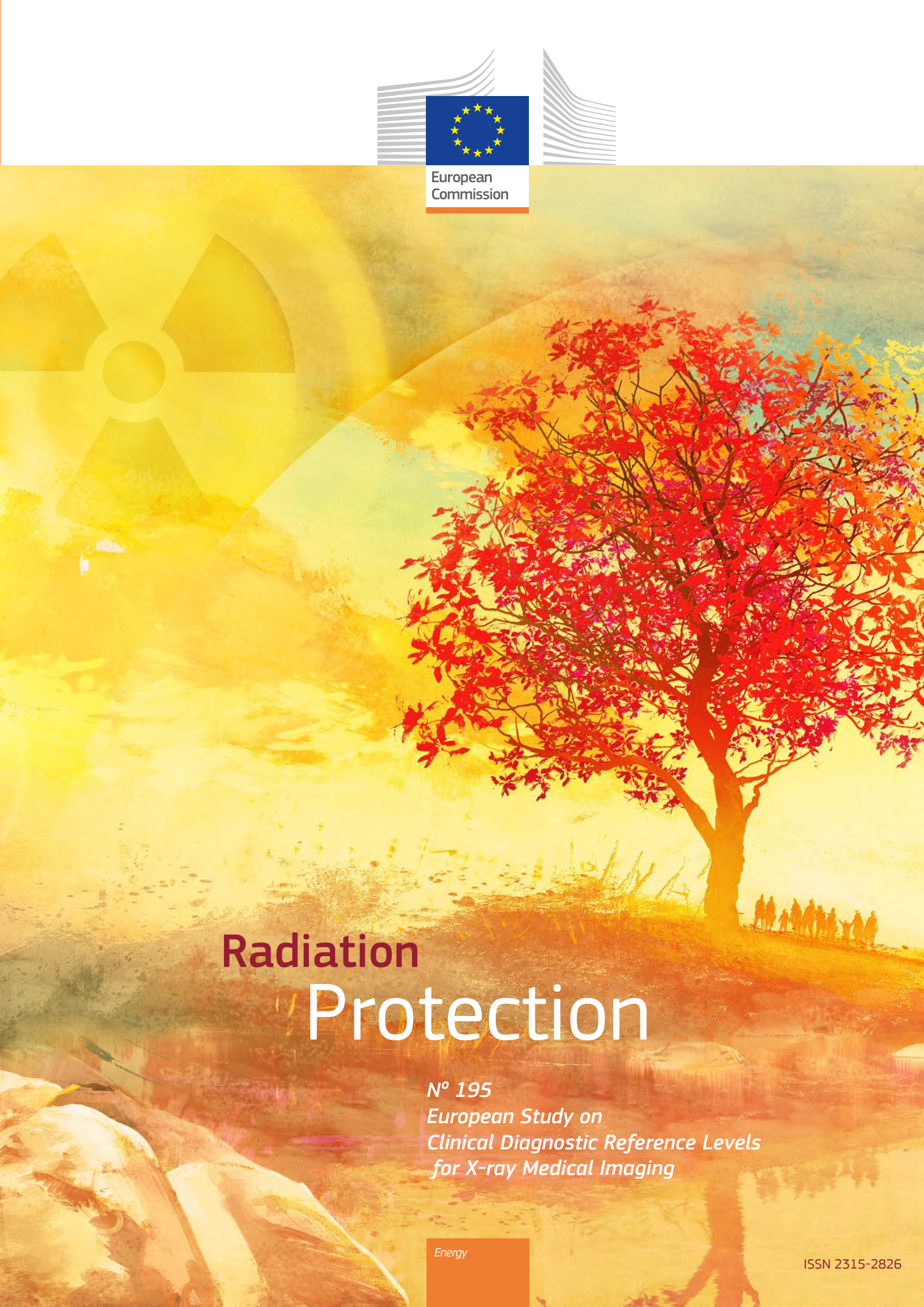

Radiation Protection

Nº 195

European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging

Energy

ISSN 2315-2826

Luxembourg: Publications Office of the European Union, 2021

Print	ISBN 978-92-76-28566-3	ISSN 1681-6803	doi:10.2833/031357	MJ-XA-21-001-EN-C
PDF	ISBN 978-92-76-28565-6	ISSN 2315-2826	doi:10.2833/452154	MJ-XA-21-001-EN-N

EUROPEAN COMMISSION

RADIATION PROTECTION N° 195

European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging

EUCLID

Directorate-General for Energy
Directorate D — Nuclear Energy, Safety and ITER
Unit D3 — Radiation Protection and Nuclear Safety
2021

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This project has received funding from the European Commission under Service Contract N° ENER/2017/NUCL/SI2.759174.

EUCLID | European Study on Clinical DRLs

EC Tender Contract N° ENER/2017/NUCL/SI2.759174

European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging

(EUCLID)

Start date of project: August 1, 2017 Duration: 33 months

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List of Abbreviations

BSSD	Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation
CA	Coronary angiography
CAP	Clinical Indication – Anatomical Location – Procedure
CCTA	Coronary Computed Tomography Angiography
CI	Clinical Indication
CIRSE	Cardiovascular and Interventional Radiological Society of Europe
CT	Computed tomography
$CTDI_{vol}$	Volume Computed Tomography Dose Index [mGy]
$CTDI_{vol,p}$	Average Volume Computed Tomography Dose Index in multiphase CT [mGy]
DLP	Dose Length Product [mGy.cm]
DLP_p	Dose Length Product per Phase [mGy.cm]
DLP_t	Total Dose Length Product [mGy.cm]
DRL	Diagnostic Reference Level
EAP	External Advisory Panel
EFTA	European Free Trade Association
ESC	European Society of Cardiology
EU	European Union
EUCLID	European Study on Clinical Diagnostic Reference Levels for X-ray Medical Imaging (EC Tender Contract N° ENER/2017/NUCL/SI2.759174)
EVAR	Endovascular aneurysm repair
FBP	Filtered back projection
HERCA	Heads of the European Radiological Protection Competent Authorities
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IR	Interventional Radiology
IRA	Iterative Reconstruction Algorithm
$K_{a,r}$	Air kerma at the patient entrance reference point [mGy]
NCA	National competent authority
NI	Number of Images (Total)
NM	Nuclear medicine
PCI	Percutaneous coronary intervention
PAD	Peripheral Artery Disease
P_{KA}	Air kerma-area product [Gy.cm²]
PIDRL	European Guidelines on Diagnostic Reference Levels for Paediatric Imaging
PTA	Percutaneous transluminal angioplasty
PTCA	Percutaneous transluminal coronary angioplasty
SAS	Statistical Analysis System
SB	Scientific Board
SL	Scan length

TACE	Transarterial chemoembolisation
TAVI	Transcatheter aortic valve implantation
TCM	Tube current modulation
TIPS	Transjugular intrahepatic portosystemic shunt
WP	Work Package

1. Abstract

The EUCLID project aimed to study the feasibility of establishing Diagnostic Reference Levels (DRLs) based on clinical indication in the context of Council Directive 2013/59/Euratom.

EUCLID consisted of 1) a literature review of existing national DRLs for computed tomography (CT), interventional radiology (IR) including cardiac procedures and plain radiography, 2) a collection of DRL information from national competent authorities (NCAs) including nuclear medicine and paediatric imaging in 2017, 2019 and early 2020, 3) the establishment of a consensus-based list of 14 clinical indications (10 CT, 4 IR) as candidates for EUCLID DRLs, 4) a Europe-wide data collection survey for these clinical indications (19 hospitals from 14 countries), 5) data analysis (4,299 complete patient datasets were analysed for CT and 1,279 for IR) and the establishment of EUCLID DRLs based on clinical indication, and 6) a European workshop with NCAs and European stakeholders.

Almost all EU countries have DRLs in the various fields which were addressed (12 countries have national DRLs based on clinical indication in CT), however their number and use varies significantly between countries. European DRL values were calculated for plain radiography based on a review of literature on national radiography DRLs. DRLs for nuclear medicine, cardiac procedures, IR and paediatric imaging require further studies and promotion.

The EUCLID DRLs for CT and IR may be used for comparison with local radiological practice. However, significant statistical dispersion of data for most protocols presents a limitation of the study. The EUCLID list of clinical indications will also have to be adapted to local and national settings.

The EUCLID project showed that the establishment of DRLs based on clinical indication is an achievable task. Recommendations are presented for specific areas where the lack of DRLs or the absence of the use of DRLs that have been established is evident, and where collaboration at European level to improve the establishment and use of DRLs and research is needed to support the establishment of DRLs.

2. Executive Summary

The European Union (EU) has introduced the concept of Diagnostic Reference Levels (DRLs) since 1997 (Council Directive 97/43/Euratom), reinforcing the obligation for the establishment and use of DRLs in 2013 (Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, BSSD). According to the BSSD, EU Member States shall ensure that the established DRLs are regularly reviewed and used for optimisation of radiation protection. Moreover, the BSSD expands the application of DRLs to, where appropriate, interventional radiology procedures. The DRLs are among the main tools for optimisation of patient protection in radiological imaging that can be used to identify unusually high patient radiation doses from medical imaging examinations.

In 1999 the European Commission issued Radiation Protection 109 (RP 109) [1]. This document contains examples of DRLs for some of the most common (at the time) plain radiography procedures. The RP 109's DRL values, while still widely used, are considered outdated and not representative of the important developments which have taken place in medical imaging in the past two decades.

In 2018, the European Commission issued Radiation Protection 185 (RP 185) [2] to provide up-to-date guidelines, which help in the practical implementation of the BSSD with respect to DRLs for paediatric imaging. Moreover, the ongoing EU-funded MEDIRAD project[1] will establish DRLs for specific applications of CT in nuclear medicine.

It is well known that clinical indications dictate the main parameters (e.g. image quality, scanning length/collimation, number of phases/projections/images) that affect patient dose. Different image quality is needed for different clinical indications of the same anatomical location.

Usually, DRLs are specified in relation to the body region without specification of the clinical indication. To date, only a few national competent authorities have defined a limited number of DRLs for different clinical indications. Despite a large number of studies available from European countries, there is little information about clinical-indication specific DRLs for x-ray medical imaging.

Objectives of the EUCLID Project

The main objective of the EUCLID project was to establish up-to-date DRLs based on clinical indication for the most important, from a radiation protection perspective, CT and IR procedures in Europe. In order to meet this objective, a survey to collect data from 19 hospitals from 14 European countries was carried out in accordance with a predefined methodology. The project also collected information and provided an overview on the current status of national radiography, CT, IR, cardiac procedures, paediatric and nuclear medicine DRLs in Europe based on literature review and information provided by national competent authorities (NCAs). European DRL values were calculated for plain radiography based on a review of literature on national radiography DRLs. A workshop was organised to disseminate and discuss the results of this project with representatives of European NCAs and the relevant European stakeholders, and to identify the need for further actions on establishing, updating, and using DRLs.

[1] http://www.medirad-project.eu/

Overview of EUCLID Project work programme and structure

This study was carried out by a group of experts under the coordination of the European Society of Radiology (ESR) between August 2017 and April 2020, covering the following areas of expertise: radiology, medical physics, radiography, health policy and regulatory authorities in radiation protection. Two international boards were established: an External Advisory Panel (EAP), consisting of representatives from relevant European and international organisations, that was consulted on the main project activities and outcomes; and, a Scientific Board (SB), consisting of representatives from national regulatory and health authorities, as well as national professional societies (scientific and clinical), to verify the data sources used, and consistency of data collected and analysed for the study.

The project was divided into five work packages (WPs).

WP1 was responsible for the management and general coordination of the project, as well as for dissemination.

WP2 was responsible for the identification of procedures and clinical indications in CT and IR for which a data collection was performed in WP3, as well as for performing a literature review of existing DRLs and DRLs based on clinical indication in CT, IR and radiography and for collecting relevant information from NCAs.

WP3 was responsible for conducting a European DRL survey for CT and IR, following a predefined methodology, in a set of volunteer hospitals.

WP4 was responsible for determining up-to-date DRLs based on clinical indication (EUCLID DRLs) for the protocols and imaging tasks identified under WP2 and through stakeholder consultation; furthermore, WP4 was responsible for validation of the EUCLID project results.

WP5 included the organisation of a workshop to disseminate and discuss the results of the project with representatives from the 28 EU Member States (at the time of the workshop), plus three European Free Trade Association (EFTA) countries: Norway, Iceland, and Switzerland, and relevant national, European and international stakeholders, as well as to identify the need for further national and local actions on establishing, updating and using DRLs.

Review of existing national DRLs and DRLs based on clinical indication in Europe

This part of the study collected information on the status of national DRLs and of DRLs based on clinical indication in Europe from NCAs, from literature, and from the workshop held in December 2019. The methodology for this included contacting NCAs of thirty-one European countries in September 2017 and April 2019 and asking them to provide available national data on CT, IR, and radiography. Information about the status of DRLs in nuclear medicine was also collected during the 2019 survey. Relevant information on DRLs and DRLs based on clinical indication was additionally acquired from NCAs at the workshop (and for those not present in a follow-up email survey in February/March 2020), including paediatric imaging, cardiac procedures and nuclear medicine.

Additionally, a comprehensive literature review was undertaken for CT, IR and radiography procedures for adults in order to identify which clinical indications had already been specifically studied.

Main results: National DRLs and DRLs based on clinical indication in Europe

Almost all countries have put in place a regulatory system for DRLs, in line with the BSSD, and most countries reported the implementation of relatively up-to-date DRLs, with a periodic revision system. However, six countries out of the thirty-one surveyed did not report having any national DRLs in CT. Although some countries have DRLs in all modalities, the relative paucity in IR and in the paediatric sector, as has been already highlighted in the PiDRL study [2], should be noted. DRLs in nuclear medicine and cardiac procedures are either not established or would need a significant update, although the VERIDIC project[2] will address some of this gap for some cardiac procedures.

During literature review, DRLs based on clinical indications for CT were found in twelve countries. The most frequent are for head, cervical spine/neck, chest, coronaries, abdomen, kidney, aorta, tumour staging, and for oncologic follow-up.

The concept of DRLs based on clinical indication for CT has already been adopted by several countries and, furthermore, based on presentations made during the workshop, will be developed in several others in the near future.

DRLs for IR are focussed on some limited clinical indications, such as brain and liver tumours and on some vascular procedures.

DRLs for radiography were comprehensively reported in Dose Datamed 2 [3] and updated in this report on the basis of NCA data.

Detailed results on DRLs and DRLs based on clinical indication were reported per country and per imaging modality (CT, IR, radiography). In general, the reported DRL values were very heterogeneous for CT and IR and, to a less extent, for radiography. In addition, NCA information on DRLs for cardiac procedures, nuclear medicine and paediatric imaging is presented in this report.

Several factors may contribute to the variation in results: Dose Length Product (DLP) values may refer to individual sequences or to a complete examination (total DLP) and in some cases this information was not included in the DRL report, or in any other protocols. In addition, different names have been used for what is likely to be the same indication (e.g. abscess versus acute abdomen). The question of whether these differences are related to various interpretations of the name of the clinical indication or to different practices remains open. A refinement of terminology, with the precise description of the clinical indication, should be encouraged in order to minimise any variation related to the meaning of the clinical indication. This could be initiated by professional organisations.

In IR, the definition of the procedure by reference to various anatomical structures was challenging and there is a need to cover a wider spectrum of clinical indications.

For radiography, the data reflects the analysis of the information obtained from the NCAs and from previous studies (Dose Datamed [3]) and showed that there are no DRLs based on clinical indication.

As regards paediatric imaging, there is little data and few countries have updated their paediatric DRLs.

Establishment of the EUCLID list of clinical indications for CT and IR

The findings from the literature review and the information provided by NCAs have been considered for the definition of the list of clinical indications to be used for the EUCLID data collection among European hospitals.

[2] https://www.researchgate.net/project/VERIDIC-Validation-and-Estimation-of-Radiation-skIn-Dose-in-Interventional-Cardiology

A list of ten clinical indications for CT (1: stroke (detection or exclusion of a haemorrhage); 2: chronic sinusitis (detection or exclusion of polyps); 3: cervical spine trauma (detection or exclusion of a lesion); 4: pulmonary embolism (detection or exclusion); 5: coronary calcium scoring (risk stratification); 6: coronary angiography (vessels assessment); 7: lung cancer (oncological staging / first and follow-up); 8: hepatocellular carcinoma (oncological staging); 9: colic / abdominal pain (exclusion or detection of a stone); and, 10: appendicitis (detection or exclusion)) and four clinical indications for fluoroscopically-guided procedures (1: arterial occlusive disease of iliac arteries (angiographic diagnosis and endovascular treatment of arterial stenosis or occlusion causing intermittent claudication or ischemia); 2: localisation and treatment of hepatocellular carcinoma (TACE: transarterial chemoembolisation); 3: arterial occlusive disease of femoropopliteal arteries (angiographic diagnosis and endovascular treatment of arterial stenosis or occlusion causing intermittent claudication or ischemia); and, 4: biliary drainage (localisation of biliary obstruction and percutaneous treatment of biliary obstruction)) was established by WP2 in several consultation loops with the EAP and the SB. The list is publicly available on the project website[3].

EUCLID data collection from hospitals across Europe

WP3 developed and implemented an EU-wide database tool to collect data from hospitals in order to establish DRLs based on clinical indications across Europe. A panel of hospitals was established to provide data for the EUCLID project. To maximise the geographical coverage of the project, nineteen hospitals from fourteen countries were included in the panel. All hospitals were contacted to review the list of CT and IR clinical indications and provide information about the examinations for which they could provide data for at least twenty average body size adult patients (body mass index 18.5 to 25 kg/m^2 or weight 70+/-15 kg if height is not available) for each CT examination, as well as data for at least thirty average body size adult patients for each IR procedure within the time period of data collection.

Two online surveys, one for CT data collection and one for IR data collection, hosted on a secure electronic data collection platform, were used to collect data from hospitals. Tutorials were organised for data managers of the participating centres to introduce them to the platform and provide information on how to submit survey data. Moreover, bi-weekly teleconferences with the EUCLID data managers were organised with the purpose of discussing limitations and possible issues for hospitals and answering any questions the centres had.

Once collection had been completed, all data was reviewed by the WP4 team to avoid incorrect records being included in the EUCLID database. Individual records were carefully examined to see if the set of predefined criteria was met. If one of the criteria was not met by a patient record, the WP4 team followed up with the hospitals from which the data was obtained in order to correct that particular record or remove it from the EUCLID database. After this, the SB was asked to verify all data collected for the establishment of DRLs based on clinical indication. As the SB members were representatives from the countries in which the data was collected, it was possible to ensure that the data was always checked by a representative of the national authority or professional society of the country from which the data came. SB members checked for data completeness and inconsistencies. In the general instructions for the surveys, data managers were asked to provide the anonymised Radiation Dose Structured Report or any other DICOM report available in their scanner (e.g. DICOM image). These reports proved to be very helpful for the verification of data collected for the establishment of DRLs based on clinical indication. SB members compared selected data (a random sample) with DICOM reports and checked for coherence.

[3] http://www.eurosafeimaging.org/euclid/wp-2

EUCLID data analysis and determination of EUCLID DRLs based on clinical indication values

Once the data had been cleaned, the WP4 team performed data analysis and determination of DRLs based on clinical indication. The data analysis methodology had been discussed and agreed in consultation with the EAP and the SB in advance. This methodology was in line with ICRP good practice recommendations [4].

Analysis of the CT data showed that there are large differences in dose values and in CT techniques between hospitals. CT DRLs based on clinical indication vary between centres or countries mainly due to variable number of phases and/or different scan lengths. Stroke and hepatocellular carcinoma are the two clinical indications with the highest DLP DRL (1291 Gy.cm and 1162 Gy.cm respectively). Hepatocellular carcinoma has the second lowest Volume Computed Tomography Dose Index ($CTDI_{vol}$) of all clinical indications. However, the large number of phases and extensive scan lengths result in high total DLP values. Coronary calcium scoring has the lowest DRL values of all ten clinical indications. Data analysis showed that there is a need to develop knowledge, skills and competences of health professionals involved on the use of CT equipment to improve the use of available dose reduction tools. More efforts are needed towards end user training on dose optimisation, in line with the position of the Heads of the European Radiological protection Competent Authorities (HERCA), which states that "the stakeholders involved in CT imaging are given adequate opportunity to be properly trained and educated on the existence and use of these tools" [5].

Analysis of the IR data showed that, among the four IR procedures, transarterial chemoembolisation (TACE) is associated with the highest DRL value. Biliary drainage procedure had the lowest of all four DRLs. The EUCLID project found that there are large differences in IR dose descriptors and in IR techniques between hospitals. Regarding the experience of operators, 97.40% of operators had performed more than twenty procedures, 1.75% had performed between five and twenty procedures, and only 0.87% had performed fewer than five procedures for each of the four types of fluoroscopically guided procedures examined in the EUCLID project. Therefore, operators who performed IR procedures were, on the whole, experienced interventionalists. Regarding complexity of clinical cases, 43% of procedures were of low complexity, 51% of medium complexity and only 6% of high complexity.

The analysis of collected data allowed "EUCLID DRLs based on clinical indication" (EUCLID DRLs) to be defined for the whole list of ten CT clinical indications and four fluoroscopically guided procedures which were selected for the EUCLID project.

EUCLID European workshop and stakeholder consultation

The results of the EUCLID project were discussed with representatives from 28 EU Member States (at the time of the workshop), plus three EFTA countries: Iceland, Norway, and Switzerland, and the relevant national, European, and international stakeholders at the EUCLID workshop, which was held in Luxembourg in December 2019. The workshop also presented an opportunity to discuss the need for further national and European action on establishing, updating, and using DRLs.

Furthermore, the Draft Final Report, including the EUCLID DRLs and the Publishable Report, was sent to the EAP and SB for stakeholder review.

Key findings, conclusions and recommendations from the EUCLID project

The main findings and recommendations established by the EUCLID project group and supported by discussions and statements at the EUCLID workshop are summarised below.

- The EUCLID project presents DRLs based on clinical indications for ten CT clinical indications and four fluoroscopically guided procedures which were selected for the

project. These findings will enable individual hospitals and clinics to effectively compare their patient doses with data collected from many European countries and optimise their CT and IR protocols, resulting in lower doses at the appropriate image quality. Similarly, NCAs may compare their current DRLs to the EUCLID DRLs, and include that data as an element for their future national DRL reviews, particularly where the intention of establishing DRLs based on clinical indications has been stated.

- The EUCLID project clearly demonstrates the effectiveness and usefulness of a common methodology to document DRL values based on clinical indications on a European scale, by collecting data from a set of hospitals and clinics representative of different practices across countries. However, it appears that a prerequisite for such a development of acceptable European reference values would be to address the root causes of diverging practice in the different countries, as identified above, by stimulating cooperation between all stakeholders concerned, nationally as well as across countries.
- EUCLID survey findings show that the installed base of CT and IR equipment in Europe is old. More than 30% of the CT scanners of the hospitals participating in the EUCLID project were 10 years or older (installation year ≤ 2011, 32.8%). Moreover, a considerable percentage of IR equipment (23%) had an image intensifier instead of a digital detector.
- Most European countries have implemented a national DRL system in line with the BSSD and 12 countries already have DRLs based on clinical indications for CT. It was observed at the workshop that a number of additional countries intend to establish national DRLs based on clinical indications during their next DRL update processes.
- There are, however, many differences from one country to another as regards the status of establishment of DRLs and their use. This highlights the opportunities which could result from closer cooperation between countries, and between the different actors in the health systems to increase information exchange, optimise national DRL systems and address current obstacles. The approach to DRLs needs to be adjusted to the level of expertise and the infrastructure available in each country. DRLs based on clinical indications can improve quality of care and promote safety in medical imaging.
- There is a need for developing guidance for the establishment of DRLs based on clinical indications and in particular for an accepted Europe-wide list of indications and definition of standard protocols.
- Data cleaning and data verification were shown to be vital to the establishment of DRLs, but guidelines are lacking on how this can be done whilst also ensuring that personal data is protected. Guidelines on data protection are also needed to summarise the key points for those establishing DRLs, answer frequently asked questions, and to provide practical checklists to help them comply with regulations.
- There should be a system in place to evaluate image quality. However, grading of image quality is not standardised and European guidance on imaging quality criteria is needed, in particular relative to the indication of the examination.
- Guidance on a common lexicon should be set up to avoid the current difficulties caused by inconsistent use of terminology between and within institutions.
- The establishment of DRLs could benefit from the standardisation of techniques and sequences of multiphase examinations.
- This study shows that CT DRL values are not reported with a similar approach, as some are considering the exposure of the whole examination while some others are considering one scan (phase) only. Information about the number of phases

considered for the determination of DRLs should always be provided (including DLP_p). Establishment of DRL values taking into consideration all phases ($CTDI_{vol}$ and DLP_t) is recommended since they incorporate information about the exposure conditions of the whole CT examination.

- The need for DRLs for paediatric CT and IR procedures was stated in the 'European guidelines on DRLs for paediatric imaging' (Radiation Protection No 185) [2] and was further highlighted during the EUCLID workshop. It is encouraging that, during the workshop, representatives from several countries mentioned that the establishment of paediatric DRLs is included in their future plans.
- The development of paediatric DRLs based on clinical indications should be considered as a priority in future European Commission funded projects.
- The establishment of DRLs in interventional radiology and interventional cardiology presents a challenge because of various factors, including procedural complexity, influence patient dose. Further work is necessary to understand the quantification of complexity of fluoroscopically guided procedures and its usefulness in the establishment of DRLs.
- The workshop clearly showed the need to move ahead towards a clarification on the use of DRLs in the field of nuclear medicine.
- The development of DRLs in the field of cardiac procedures was done in a non-coordinated manner and needs to be consolidated.

- Dose management systems can facilitate data collection and help establish, update, and use DRLs and, hopefully, will become widely available in all countries. European recommendations in this regard would facilitate the implementation of dose management systems.
- Dose repositories and dose management systems are considered important tools for supporting the process of optimisation of imaging procedures through the establishment of local DRLs. The use of DRLs in clinical practice has to be revisited in light of the development of local DRLs. Patient dose audits seem to be a vital tool in the optimisation process.
- European guidance would be useful in order to promote the development of interoperable repositories. A review of the methodology for national DRLs and local data collection ought to be considered, including the size of samples, in the light of automatic data collection systems.

EUCLID DRLs based on clinical indication

Tables 1 and 2 show the DRLs based on clinical indication calculated by the EUCLID project.

CI	Clinical indication	$CTDI_{vol,p}$ (mGy)	DLP_p (mGy.cm)	DLP_t (mGy.cm)	scan length (cm)
1	Stroke - Detection or exclusion of a haemorrhage	48	807	1386	18
2	Chronic sinusitis - Detection or exclusion of polyps	11	188	211	16
3	Cervical spine trauma - Detection or exclusion of a lesion	17	455	495	23
4	Pulmonary embolism - Detection or exclusion	9	307	364	35
5	Coronary calcium scoring - Risk stratification	4	72	81	17
6	Coronary angiography - Vessels assessment	25	415	459	17
7	Lung cancer - Oncological staging, First and F-up	8	348	628	47
8	Hepatocellular carcinoma - Oncological staging	9	354	1273	37
9	Colic / abdominal pain - Exclusion or detection of a stone	8	436	480	48
10	Appendicitis - Detection or exclusion	9	498	874	49

Table 1: EUCLID DRLs based on clinical indication for CT

CI	Clinical indication	P_{KA} ($Gy.cm^2$)	T (min)	$K_{a,r}$ (mGy)
1	Arterial occlusive disease of iliac arteries	57	10	251
2	TACE	241	18	1867
3	Arterial occlusive disease of femoropopliteal arteries	26	12	99
4	Biliary drainage	22	10	194

Table 2: EUCLID DRLs based on clinical indication for IR

3. Introduction

The concept of Diagnostic Reference Levels (DRLs) has been introduced as a tool for optimisation of radiation protection of patients exposed to ionising radiation from medical imaging examinations and procedures. The establishment and use of DRLs is required in the Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation (BSSD) [6].

Specifically, the BSSD states that:

"Diagnostic reference levels means dose levels in medical radiodiagnostic or interventional radiology practices, or, in the case of radio-pharmaceuticals, levels of activity, for typical examinations for groups of standard-sized patients or standard phantoms for broadly defined types of equipment" (BSSD, Article 4(20)).

Moreover, the BSSD states that:

"Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, having regard to the recommended European diagnostic reference levels where available, and when appropriate, for interventional radiology procedures, and the availability of guidance for this purpose" (BSSD, Article 56(2)).

Additionally, Member States are required to ensure that:

"appropriate local reviews are undertaken whenever diagnostic reference levels are consistently exceeded and that appropriate corrective action is taken without undue delay." (BSSD, Article 58(f)).

In 1999, the European Commission issued Radiation Protection 109 (RP 109), "*Guidance on diagnostic reference levels DRLs for medical exposure*" [1]. The RP 109's DRL values, while still widely used, are considered outdated and not representative to the important developments which have taken place in medical imaging in the past two decades. In 2018, the European Commission issued Radiation Protection 185 (RP 185) [2] to provide up-to-date guidelines, which help in the practical implementation of the BSSD with respect to DRLs for paediatric imaging. Moreover, the MEDIRAD project[4] funded by the European Union will establish DRLs for specific applications of CT in nuclear medicine.

It is well known that clinical indications dictate the main parameters (e.g. image quality, scanning length/collimation, number of phases/projections/images) that affect patient dose. Different image quality is needed for different clinical indications of the same anatomical location. Kidney stone evaluation, for instance, can be performed by using lower radiation doses than those used in evaluation of appendicitis because detection of high-contrast structures is affected less by high image noise than low-contrast structures. Section collimation affects image noise considerably and, therefore, appropriate selection of collimation is needed on the basis of clinical indication. In a recent survey about CT practice in Germany [7] it was found that scanning lengths realised in many CT examinations are significantly larger than the corresponding clinical indications would specify. Scanning lengths should be reduced as far as possible to avoid unnecessary exposure providing no clinically relevant information. Moreover, the number of scanning phases depends on the clinical indication. Overall, the clinical indication looks to be the main determinant of radiation dose for patients undergoing CT studies and therefore, DRLs should be specified for a given clinical indication. Clinical-indication specific CT protocols have already been developed to help tailor CT dose and image quality on the basis of specific clinical indications [8].

[4] http://www.medirad-project.eu/

Usually, CT DRLs are specified in relation to the body region without specification of the clinical indication. To date, only a few NCAs have defined a limited number of DRLs for different clinical indications but a growing interest was evidenced during the workshop. Despite a large number of studies available from European countries, there is only little information about clinical-indication specific DRLs for medical imaging procedures.

The overall purpose of the EUCLID project was to advance the optimisation of radiation protection of patients in Europe. The project provided up-to-date DRLs based on clinical indication for the most important, from a radiation protection perspective, x-ray imaging tasks in Europe. Furthermore, it stimulated and recommended further action at European, national and local level.

The main objectives of the EUCLID project were to a) collect data needed for the establishment of DRLs based on clinical indication for some CT and IR tasks in Europe b) conduct a European survey in order to specify up-to-date DRLs based on clinical indication for these selected clinical tasks c) collect information on existing national DRLs through a review of the literature and NCA surveys e) organise a workshop to disseminate and discuss the results of the project and to identify the need for further national and local actions on establishing, updating and using DRLs.

The EUCLID project was carried out by a group of experts under the coordination of the ESR from August 2017 until April 2020, covering the following areas of expertise: radiology, medical physics, radiography, health policy and regulatory authorities in radiation protection. Two international boards were established: An External Advisory Panel (EAP), consisting of representatives from relevant European and international organisations (Table 3), that was consulted on the main project activities and outcomes, and a Scientific Board (SB) set up with representatives from national regulatory and health authorities and national scientific and clinical professional societies (Table 4) to verify the used data sources and consistency of data collected and analysed for the study.

The project was divided into five work packages (WPs):

- WP1 was responsible for the management and general coordination of the project, as well as for dissemination.
- WP2 was responsible for the identification of procedures and clinical indications in CT and IR for which a data collection should be performed, as well as for performing a literature review of existing DRLs and DRLs based on clinical indication in CT, IR and radiography for adults. In addition, NCAs were asked to provide information on available national DRLs for CT, IR, radiography, cardiac procedures and paediatric imaging.
- WP3 was responsible for conducting a European DRL survey in a set of volunteering hospitals for CT and IR, following a predefined methodology.
- WP4 was responsible for determining up-to-date DRLs based on clinical indication for the protocols/imaging tasks identified under WP2 and through stakeholder consultation. Furthermore, WP4 was responsible for the validation of the EUCLID project results.
- WP5 organised a workshop to disseminate and discuss the results of the project with the 28 EU Member States, plus Iceland, Norway, and Switzerland, and relevant national, European and international stakeholders, and to identify the need for further national and local actions on establishing, updating, and using DRLs.

European Federation of Organisations for Medical Physics (EFOMP)	Dr Mika Kortesniemi
European Federation of Radiographer Societies (EFRS)	Dr Shane Foley
Cardiovascular and Interventional Radiological Society of Europe (CIRSE)	Prof Efstathios Efstathopoulos
Heads of European Radiological Protection Competent Authorities (HERCA)	Dr Steve Ebdon-Jackson
International Atomic Energy Agency (IAEA)	Prof Jenia Vassileva
International Commission on Radiological Protection (ICRP)	Dr Colin Martin
World Health Organisation (WHO)	Dr María Perez del Rosarío
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)	Ms Nicole Denjoy
ESR Patient Advisory Group (ESR-PAG)	Dr Nicola Bedlington

Table 3: Composition of EUCLID External Advisory Panel

Austrian Society of Radiology (OERG), Austria	Dr Gerald Pärtan
Federal Agency for Nuclear Control (FANC), Belgium	Dr Lodewijk Van Bladel
Radiation and Nuclear Safety Authority (STUK), Finland	Mr Atte Lajunen
Institute for Radiological Protection and Nuclear Safety (IRSN), France	Mr Serge Dreuil
Federal Office for Radiation Protection (BfS), Germany	Dr Alexander Schegerer
Hellenic Association of Medical Physicists (HAMP), Greece	Dr Virginia Tsapaki
Hungarian Society of Radiology, Hungary	Dr Péter Bágyi
Istituto Superiore di Sanità (ISS), Italy	Dr Antonella Rosi
National Institute for Public Health and the Environment (RIVM), the Netherlands	Dr Harmen Bijwaard
Ministerio de Sanidad, Servicios Sociales e Igualdad, Deputy Director General of Quality and Innovation, Spain	Ms Yolanda Agra
Swiss Federal Office of Public Health (FOPH), Switzerland	Ms Barbara Ott
Irish National Population Dose and Optimisation Committee of the Ireland's Health Services, Ireland	Dr Shane Foley
Portuguese Society of Radiology and Nuclear Medicine, Portugal	Dr José Venancio
Polish Medical Society of Radiology, Poland	Prof Katarzyna Karmelita-Katulska

Table 4: Composition of EUCLID Scientific Board

4. Existing national DRLs and DRLs based on clinical indication: Summary of Literature Review & Competent Authority Surveys

The goal of this part of the EUCLID project was to collect information from the European NCAs, from the literature, and from the EUCLID workshop held in December 2019 in order to get an overview of the current status of DRLs and DRLs based on clinical indication across Europe. It was agreed that DRLs update for plain radiography would be based on the literature review and that the concept of clinical indication should not be applied to plain radiography because the impact on dose exposure would be only marginal and feasibility questionable in the framework of this project.

The methodology was based on data collection with three approaches:

1. The NCAs of thirty-one European countries were contacted two times, in September 2017 and in April 2019, and asked to provide available national data on CT, interventional radiology and radiography for adults. The second outreach to national competent authorities also included a question on national nuclear medicine DRLs for adults and on DRLs for paediatric imaging.
2. A comprehensive literature review was undertaken in order to identify which clinical indications should be specifically studied in the EUCLID project. The list of clinical indications was based on consensus among consortium members, EAP and SB members. In addition, a literature review was performed for plain radiography and cardiology procedures (with the support of the European Society of Cardiology, ESC).
3. The country reports presented at the EUCLID workshop in December 2019 also informed the final version of this part of the study. They included information on national DRLs for CT, plain radiography, IR, interventional cardiology, nuclear medicine and paediatric imaging, including information on the availability of DRLs based on clinical indication for each modality. An email follow-up was carried out with NCAs from countries not represented at the workshop in February/March 2020.

4.1 Status of existing DRLs at national level

This section provides an overview of existing DRLs at national level as per the information provided by the NCAs.

An overview of the situation per modality in Europe based on the country reports given by the NCAs at the EUCLID workshop in December 2019 and additional information provided in February and March 2020 is summarised in Table 5 below.

Modality	Number of Countries	(of which Paediatric)
CT	25	9
Interventional Radiology	11	4
Interventional Cardiology	20	Data not collected as part of EUCLID project
Plain radiography	26	9
Nuclear Medicine	22	5

Table 5: Number of countries with DRLs per modality

4.1.1 Computed Tomography (CT) DRLs for adults

This section provides an overview of existing DRLs for CT at national level as per the information provided by the NCAs.

	CT		
Country	**No. DRLs**	**Last Update**	**DRLs based on clinical indication**
AT	7	2018	Y
BE	10	2018	N
BG	12	2018	N
CH	15	2018	Y (partially)
CY	-	-	-
CZ	6	2016	N
DE	20	2016	Y (partially)
DK	7	2015	Y
EE	-	-	-
ES	6	2015	N
FI	13	2013	Y
FR	11	2019	Y
GR	7	2014	N
HR	7	2018	N
HU	-	-	-
IE	13	2017	Y
IS	-	-	-
IT	4	2017	Y
LT	11	2018	N
LU	9	2019	N
LV	3	2019	N
MT	-	-	-
NL	4	2012	Y (partially)
NO	11	2017	Y
PL	9	2011	N
PT	-	-	-
RO	7	Under approval for publication	N
SE	6(4)	2018	Y
SI	6	2019	N
SK	6	2018	Y
UK	13	2011, 2018	Y

Table 6: Status of CT DRLs and DRLs based on clinical indication per country

It should be highlighted that the number of DRLs per country varies greatly, ranging from three to twenty (the mean being around nine).

Overall, it is evident that most countries have relatively up-to-date DRLs for CT.

4.1.2 Interventional Radiology (IR) DRLs for adults

This section provides an overview of existing DRLs for IR at national level as per the information provided by the NCAs.

Country	IR (adults)		
	No. DRLs	Last Update	DRLs based on clinical indication
AT	6	2018	Y (partially)
BE	-	-	-
BG	-	-	-
CH	22	2016	Y
CY	-	-	-
CZ	-	-	-
DE	10 (+6 fluoroscopy)	2018	Y
DK	-	-	-
EE	-	-	-
ES	-	-	-
FI	-	-	-
FR	10	2019	Y
GR	-	-	-
HR	-	-	-
HU	-	-	-
IE	11	2017	N
IS	-	-	-
IT	-	2017	Y
LT	-	-	-
LU	4	2019	Y
LV	-	2016	N
MT	-	-	-
NL	-	-	-
NO	1	2017	Y
PL	5	2011	N
PT	-	-	-
RO	-	-	-
SE	-	2018	Y
SI	4	2017	N
SK	20	2018	Y
UK	5 (+19 fluoroscopy)	2010	Y

Table 7: Status of IR DRLs and DRLs based on clinical indication per country

Interventional radiology is generally not comprehensively covered, as only eleven countries established DRLs in IR. The number of IR DRLs per country varies between one and twenty-four (the mean being around eleven).

- Some countries are on the way to developing national DRLs for IR but have not implemented them yet. Some countries are just evaluating ongoing studies to define national DRLs.
- Belgium was found to have a DRL for IR in literature, but no information was provided by the NCA.
- Denmark, Italy, Latvia, Lithuania, Malta, Portugal, Romania do not have national DRLs for IR. However, some of these countries (Italy, Portugal and Romania) plan to establish DRLs for IR in the near future.

4.1.3 Interventional Cardiology DRLs for adults

This section provides an overview of existing DRLs for interventional cardiology at national level as per the information provided by the NCAs.

Country	Interventional Cardiology (adults)		
	No. DRLs	Last Update	DRLs based on clinical indication
AT	2	2018	N
BE	-	-	-
BG	2	2018	N
CH	14	2016	Y
CY	-	-	-
CZ	2	2016	N
DE	3 (1 fluoroscopy)	2018	Y
DK	-	-	-
EE	-	-	-
ES	2	2015	N
FI	5	2016	Y
FR	2	2019	Y
GR	4	2014	N
HR	1	2018	Y
HU	-	-	-
IE	3	2017	N
IS	-	-	-
IT	-	2017	Y
LT	3	2018	N
LU	3	2019	Y
LV	-	2016	N
MT	-	-	-
NL	-	-	-
NO	4	2017	Y
PL	2	2011	N
PT	-	-	-
RO	2	Under approval for publication	N
SE	1	2018	Y
SI	2	2019	N
SK	10	2018	Y
UK	2	2010	Y

Table 8: Status of interventional cardiology DRLs and DRLs based on clinical indication per country

- Many countries have DRLs for coronary angiography (CA), usually without giving the number of vessels and projections. Cardiac interventions are summarised as percutaneous transluminal coronary angioplasty (PTCA) and percutaneous coronary interventions (PCI) without further specifications (number of vessels/lesions; number of stents; stenosis or occlusion).
- Four countries have DRLs for percutaneous transluminal angioplasty (PTA): Germany, Luxembourg, Poland, and Switzerland (PTA pelvis/PTA femur/PTA lower leg).
- Eleven countries have DRLs for PTCA: Austria, Cyprus, Czech Republic, Greece, Ireland, Luxembourg, Poland, Slovenia, Spain, Switzerland and UK.
- Seven countries have DRLs for PCI or PCI+CA: Bulgaria, Czech Republic, Finland, France, Germany, Sweden and Switzerland.
- Nineteen countries have DRLs for cardiac diagnostics such as CA and cardiac interventions (PTCA and PCI): Austria, Belgium, Bulgaria, Cyprus, Czech Republic,

Finland, France, Germany, Greece, Ireland, Luxembourg, The Netherlands, Norway, Poland, Slovenia, Spain, Sweden, Switzerland and UK.

- The number of interventional cardiology DRLs per country varies greatly, between one and fourteen (the mean being around 3.5).

4.1.4 Plain Radiography (PX) DRLs for adults

The last update on plain radiography DRL values in Europe was provided in the Dose Datamed 2 report [3].

During the EUCLID project, data was collected from the NCAs, which can be considered as an update of the values from Dose Datamed 2. The project team requested the NCAs to send up to date information about DRLs for plain radiography, which allowed the creation of tables per country and anatomical region, with up to date DRLs, giving an overview of the situation in Europe. Table 9 provides an overview of existing DRLs for plain radiography at national level as per the information provided by the NCAs.

	Plain x-rays (adults)		
Country	**No. DRLs**	**Last Update**	**DRLs based on clinical indication**
AT	8	2018	N
BE	5 +1 mammography	2017	N
BG	17	2018	N
CH	7	2011	N
CY	-	-	-
CZ	14 +7 mammography	2016	N
DE	8	2018	Y (partially)
DK	5	2012	N
EE	2	2018	Y
ES	2 +1 mammography	2015	N
FI	9	2017	N
FR	12	2019	N
GR	12	2014	N
HR	15	2018	N
HU	-	-	-
IE	19	2017	N
IS	-	-	-
IT	20	2017	Y
LT	27	2018	N
LU	10	2019	N
LV	10 (2 mammography)	2019	N
MT	-	-	-
NL	7	2012	N
NO	7	2017	Y (partially)
PL	24	2011	N
PT	-	-	-
RO	18	Under approval for publication	N
SE	7	2018	Y
SI	17	2019	N
SK	12	2018	Y
UK	19 +1 mammography	2010	N (Y for mammography)

Table 9: Status of plain radiography DRLs and DRLs based on clinical indication per country

DRLs for plain radiography were reported in twenty-six European countries. The number of radiography DRLs per country varies greatly, from two to twenty-seven (the mean being around thirteen). From the thirteen anatomical regions with DRLs established, the top five were: Chest PA (nineteen countries); Pelvis AP (nineteen countries); Lumbar spine AP (seventeen countries); Abdomen AP (fifteen countries); Lumbar spine lateral (fourteen countries).

Table 10 provides an overview of the replies received from the NCAs to the email invitations sent in September 2017 and in April 2019 to provide available national DRL data.

Country	Cervical spine AP		Cervical spine LAT		Thoracic spine AP		Thoracic spine LAT		Lumbar spine AP		Lumbar spine LAT	
	ESD (mGy)	P_{KA} (Gy.cm²)	ESD (mGy)	P_{KA} (Gy.cm²)	ESD (mGy)	P_{KA} (Gy.cm²)	ESD (mGy)	P_{KA} (Gy.cm²)	ESD (mGy)	P_{KA} (Gy.cm²)	ESD (mGy)	P_{KA} (Gy.cm²)
AT									7.4	2.0	9.6	3.2
BG						1.1		2.2		2.4	12.0	4.0
CH	3.1				7.0		21.0		8.7		26.0	
CZ	1.7	0.3	1.3	0.3	4.4	1.1	5.7	1.2	6.2	1.7	12.0	3.1
DE						1.1		1.4		2.0		3.5
DK										5.5		
ES										4.1		
FI									3.5	1.0	10.0	2.1
FR		0.4		0.4		1.2		1.5		3.0		4.5
GR	1.8								7.0		16.0	
IE		0.2		0.2		1.0		2.0		1.6		2.7
IT									6.2		15.0	
LT					3.5	1.6	8.0	2.2	10.0	1.5	20.0	5.0
LU		0.6		0.6		1.3		1.7	8.0	2.6	20.0	3.5
LV									10.0		30.0	
MT		0.2						2.5				5.5
NL												
NO		0.7				2.5				6.0		
PL					5.2	2.2	9.0	3.2	7.4	3.2	22.0	8.0
RO		0.5		0.5		1.4		1.9		2.0		3.1
SE										5.1		
SI		0.3		0.4		1.0		1.3		0.1		0.2
SK					7.0		20.0		10.0		30.0	
UK		0.2		0.2	3.5	1.0	7.0	1.5	5.7	1.5	10.0	2.5

Table 10: Existing national DRLs for plain radiography *(continued on next page)*

Country	Skull AP/PA		Skull LAT		Chest PA		Chest LAT		Abdomen AP		Pelvis AP		Hip AP	
	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)
AT	1.8	0.6	1.1	0.5	0.1	0.2	0.5	0.5	3.9	2.1	2.9	2.1		
BE						0.3				2.8		3.5		
BG	2.5	0.8	2.5	0.8	0.5	0.5	1.5			3.0	4.0	4.0		
CH	5.4		3.5		0.2		0.4		7.0		7.8		4.7	
CZ	2.8	0.7	2.2	0.6	0.3	0.2	1.1	0.6	5.2	2.9	4.5	2.0		
DE		0.6		0.5		0.15		0.4		2.3		2.5		1.1
DK						0.3						1.5		
ES												2.9		
FI					0.1	0.1	0.5	0.2	3.5	1.6				
FR						0.2		0.6		4.0		4.5		
GR	3.7		2.8		0.4		1.4				6.0			
IE						0.2				2.3		2.6		1.5
IT	2.7		2.0		0.3		1.1		4.7		4.5			
LT	3.0	0.7	3.0	0.7	0.3	0.2	1.2	0.3	5.0	3.0	5.0	2.5	5.0	1.4
LU	5.0	0.6	3.0	0.6	0.3	0.2	1.2	0.5		3.0	6.0	2.5		
LV					0.4		1.5		10.0		10.0		10.0	
MT						0.1				2.5		1.5		
NL						0.1						3.0		
NO						0.5						1.7		2.0
PL	3.7	1.1	2.3	1.0	0.2	0.2	1.1	1.0	7.0	5.5	7.0	5.0		
RO		0.7		0.6		0.5		1.1		2.2		2.2		
SE						0.3						1.6		
SI						0.1		0.4		2.6		2.0		
SK					0.4		1.5		10.0		10.0			
UK	1.8		1.1		0.2	0.1	0.5		4.0	2.5	4.0	2.2		

Table 10: Existing national DRLs for plain radiography *(continued)*

The survey of the NCAs gave the EUCLID project the possibility to create tables with official data from the participating European countries and to establish EUCLID DRLs for plain radiography. National DRLs were accepted for the calculation of EUCLID DRLs if values from at least three countries were available. From the twenty-seven countries that replied, only two do not have national DRLs for plain radiography (although Cyprus uses the ones from Greece).

The information provided by the NCAs clearly demonstrates the need to harmonise plain radiography practices in Europe. At this point in time, where the technology used across European countries is essentially based on computed or digital radiography, evidence shows that there are still huge differences between radiation doses for the same radiographic procedure. Although these procedures are considered low-dose, they are very frequently used, especially chest, lumbar spine and pelvis, thus contributing to the increase of the collective dose in the population.

European DRLs for plain radiography were calculated based on the median (P50) of the national DRL values provided by the NCAs (Tables 11 and 12).

EUCLID DRLs	Cervical spine AP		Cervical spine LAT		Thoracic spine AP		Thoracic spine LAT		Lumbar spine AP		Lumbar spine LAT	
	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)
min	*1.7*	*0.2*	*-*	*0.2*	*3.5*	*1.0*	*5.7*	*1.2*	*3.5*	*0.1*	*9.6*	*0.2*
max	*3.1*	*0.7*	*-*	*0.6*	*7.0*	*2.5*	*21.0*	*3.2*	*10.0*	*6.0*	*30.0*	*8.0*
median	*1.8*	*0.3*	*-*	*0.4*	*4.8*	*1.2*	*8.5*	*1.8*	*7.4*	*2.0*	*16.0*	*3.4*

Table 11: European DRLs for plain radiography

EUCLID DRLs	Skull AP /PA		Skull LAT		Chest PA		Chest LAT		Abdomen AP		Pelvis AP		Hip AP	
	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)	ESD (mGy)	P_{KA} (Gy.cm^2)
min	*1.8*	*0.6*	*1.1*	*0.5*	*0.1*	*0.1*	*0.4*	*0.2*	*3.5*	*1.6*	*2.9*	*1.5*	*4.7*	*1.4*
max	*5.4*	*1.1*	*3.5*	*1.0*	*0.5*	*0.5*	*1.5*	*1.1*	*10.0*	*5.5*	*10.0*	*5.0*	*10.0*	*2.0*
median	*2.9*	*0.7*	*2.4*	*0.6*	*0.3*	*0.2*	*1.1*	*0.5*	*5.1*	*2.6*	*5.5*	*2.5*	*5.0*	*1.5*

Table 12: European DRLs for plain radiography

4.1.5 Paediatric DRLs

The EUCLID project was mainly focused on adults. However, the NCAs were additionally invited to provide an overview of national DRLs for paediatric imaging as part of the update in April 2019 and also within the framework of the EUCLID workshop held in December 2019. Table 13 provides an overview of existing DRLs for paediatric imaging at national level as per the information provided by the NCAs.

Country	Paediatric Imaging		
	No. DRLs	Last Update	DRLs based on clinical indication
AT	2 CT, 4 PX	2018 (CT), 2017 (PX)	N
BE	4 CT, 3 PX	2019	N
BG	-	-	-
CH	5 CT, 25 NM, 15 PX	2018	N
CY	-	-	-
CZ	-	-	-
DE	3 CT, 1 fluoroscopy, 4 PX	2016	N
DK	-	-	-
EE	-	-	-
ES	3 CT, 1 IR, 4 PX	2015	N
FI	5 CT, 3 PX	2015 (CT), 2018 (PX)	Y (CT), N (PX)
FR	4 CT, 4 NM, 8 PX	2019	Y (fluoroscopy only)
GR	-	-	-
HR	-	-	-
HU	-	-	-
IE	10	-	-
IS	-	-	-
IT	-	-	-
LT	-	-	-
LU	7CT, 28NM, 6PX	2019	N
LV	23 NM, 4 PX	-	-
MT	-	-	-
NL	1 CT, 3 PX	2012	N
NO	-	-	-
PL	-	-	-
PT	-	-	-
RO	-	-	-
SE	-	-	-
SI	-	-	-
SK	8 Cardio, 4 CT, 8 IR, 70 NM, 6 PX	2018	Y
UK	3 CT, 15 fluoroscopy, all NM procedures	2011 (CT), 2010 (fluoroscopy), 2020 (NM)	Y

(PX = plain radiography)

Table 13: Status of paediatric DRLs and DRLs based on clinical indication per country

Table 13 summarises the current status of paediatric DRLs per modality. Although some countries have DRLs in all modalities including for paediatric imaging, the relative paucity of DRLs in paediatric imaging should be noted, as has been already highlighted in the PiDRL study [2]. In countries that have paediatric DRLs for CT, the number of DRLs is very low, with three DRLs on average (compared to a mean of nine CT DRLs for adults). Paediatric DRL values are provided in the PiDRL publication [2].

4.1.6 Nuclear Medicine DRLs for adults

The EUCLID project was mainly focused on CT, IR and plain radiography. To complement this information, the NCAs were also invited to provide an overview of national DRLs nuclear medicine in April 2019 and in the course of the EUCLID workshop in December 2019.

This section provides an overview of existing DRLs for nuclear medicine at national level as per the information provided by the NCAs (Table 14).

Country	Nuclear Medicine (adults)		
	No. DRLs	Last Update	DRLs based on clinical indication
AT	28	2010	N
BE	8	2019	Y
BG	5	2018	N
CH	17	2019	Y (partially)
CY	-	-	-
CZ	83	2016	N
DE	18	2012	Y
DK	20	2016	N
EE	-	-	-
ES	-	-	-
FI	15	2015	Y
FR	12	2019	Y (partially)
GR	12	2007	N
HR	64	1999	N
HU	-	-	-
IE	14	2017	N
IS	-	-	-
IT	50	2000	Y
LT	72	2018	N
LU	38	2019	Y
LV	36	2002	N
MT	-	-	-
NL	-	-	-
NO	-	-	-
PL	32	2011	N
PT	-	-	-
RO	5	Under approval for publication	N
SE	12	2018	Y
SI	26	2013	N
SK	70	2018	Y
UK	82	2020	Y

Table 14: Status of nuclear medicine DRLs and DRLs based on clinical indication per country

The number of nuclear medicine DRLs per country varies greatly, between five and eighty-three (the mean being around thirty-three).

4.2 Status of DRL values based on clinical indication at national level

This section provides an overview of existing DRL values based on clinical indication at national level as identified by the literature review performed within the project and as provided by the NCAs. Some literature from countries outside Europe was considered for CT.

4.2.1 Existing values of CT DRLs based on clinical indication in Europe

For CT, data from sixty-five papers, articles, and reports from NCAs was considered, including some from countries outside Europe (USA, Japan and Egypt). Among them, twenty-three include DRLs based on clinical indication for one or several anatomical locations. It is important to note that some of the DRLs based on clinical indication sent by European NCAs are still in the process of implementation.

Based on the two surveys among the NCAs and the literature review, DRLs based on clinical indication for CT were found in twelve countries:

- Austria, Denmark, Finland, France, Germany, Ireland, Italy, Norway, Sweden, Switzerland, the Netherlands, and the United Kingdom

The anatomical locations, for which DRLs based on clinical indication were found in the literature (and their frequency), are: head (eleven); cervical (eight); chest (twenty-four); abdomen (twelve); abdomino-pelvis (five), chest-abdomen-pelvis (three).

The clinical indications considered by the NCAs and/or in the literature are listed in Table 15.

Head: ▪ Acute stroke ▪ Haemorrhage/aneurysms/arteriovenous malformations ▪ Metastases/cerebral abscess ▪ Trauma ▪ Cholesteatoma ▪ Sinusitis
Cervical (spine and neck): ▪ Fracture ▪ Disk Pathology ▪ Adenopathy/abscesses
Chest: ▪ Lung cancer ▪ Interstitial lung disease ▪ Pulmonary embolism ▪ Coronaries (CTC angiography) ▪ Coronaries (calcium scoring)
Abdomen ▪ Liver metastases ▪ Abscess ▪ Kidney stones/colic ▪ Kidney tumour/colic ▪ Acute abdomen ▪ Pancreas Adenocarcinoma
Abdomen-Pelvis: ▪ Abscess/lymphadenopathy ▪ Virtual colonoscopy (polyps/tumour) ▪ Abdominal aorta angiography ▪ Colic ▪ Occlusion
Chest-Abdomen-Pelvis: ▪ Tumour ▪ Infectious ▪ Oncologic follow-up

Table 15: CT clinical indications

Considering that the concept of DRLs based on clinical indications has been developed only recently, some discrepancy and inconsistency was found in the classification of the clinical indications.

4.2.1.1. Head CT

In head CT, trauma is the clinical indication with the highest number of studies (seven out of ten). The DLP values range from 90mGy.cm to 1000mGy.cm (see Table 16)

Head CT																		
Reference	**acute stroke/post fossa**		**acute stroke/cerebrum**		**acute stroke/brain (whole)**		**acute stroke/all sequences**		**Haemorrhage, aneurysms, arteriovenous malformations**		**metastases, cerebral abscess**		**Trauma, sinusitis***		**cholesteatoma**		**sinusitis**	
	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)
Danish Health Authority (DK) 2015 [14]	-	-	-	-	-	-	-	-	58	930	-	-	-	-	-	-	-	-
Public Health England (UK) 2016 [15]	80	-	60	-	60	-	-	970	-	-	-	-	-	-	-	-	-	-
Schegerer et al (DE) 2017 [7]	-	-	-	-	-	-	-	-	-	-	-	-	9	120	-	-	-	-
Treier et al (CH) 2010 [16]	-	-	-	-	-	-	-	-	65	1000	65	1000	25	350	50	250	-	-
Van der Molen et al (NL) 2013 [17]	-	-	-	-	-	-	-	-	-	936	-	-	-	133	-	-	-	-
Wachabauer et al (AT) 2017 [18]	-	-	-	-	-	-	-	-	-	-	-	-	-	90	-	-	-	-
Geryes et al (FR) 2019 [19]	-	-	-	-	-	-	-	-	44	1010	44	790	43	920	-	-	-	-
Ireland (IE) MERU 2017 [20]	26 (a)	469 (a)	-	-	-	-	-	-	-	-	-	-	62 (a)	918 (a)	-	-	21 (a)	183 (a)
	31 (b)	477 (b)	-	-	-	-	-	-	-	-	-	-	64 (b)	927 (b)	-	-	21 (b)	210 (b)
Norway (NO) 2018 [21]	-	-	-	-	-	-	60	950	60	950	-	-	-	-	-	-	-	-
Sweden (SE) 2019 [22]	-	-	-	-	-	-	60	1000	60	1000	-	-	60	1000	-	-	-	-

(a) for female patients; (b) for male patients
*as combined in original papers

Table 16: DRLs based on clinical indication for head CT

4.2.1.2 Cervical CT

In cervical CT the clinical indication of fracture was the most frequent (seven out of eight studies). The DLP values range from 300 mGy.cm [22] to 640 mGy.cm [15]. Note that for the clinical indication adenopathy/abscesses, the DRLs presented by Switzerland [16] and Sweden [22] are the same (DLP value 600 mGy.cm). See Table 17.

Cervical CT						
Reference	**Fracture**		**Disk Pathology**		**Adenopathy, abscesses**	
	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)
German Federal Office for Radiation Protection (DE) 2016 [23]	20	300	25	-	-	-
Public Health England (UK) 2016 [15]	26	600	-	-	-	-
Treier et al (CH) 2010 [16]	-	-	-	-	30	600
Geryes et al (FR) 2019 [19]	31	640	-	-	-	-
Ireland (IE) MERU 2017 [20]	26 (a)	469 (a)	-	-	-	-
	31 (b)	477 (b)	-	-	-	-
Norway (NO) 2018 [21]	15	350	-	-	-	-
Sweden (SE) 2019 [22]	13	300	-	-	30	600
Public Health England (UK) 2018 [15]	21	440	-	-	-	-

(a) for female patients; (b) for male patients

Table 17: DRLs based on clinical indication for cervical CT

4.2.1.3 Chest CT

Chest CT is the anatomical location with most studies (twenty-four). Coronary Computed Tomography Angiography (CCTA) is the clinical indication with the highest number of proposed DRLs (eleven out of twenty-four). The DLP values range from 170mGy.cm [15] to 1510mGy.cm [24]. See Table 18.

Chest CT												
Reference	**Lung cancer**		**Interstitial lung disease (axial)***		**Interstitial lung disease (helical)***		**Pulmonary embolism**		**CCTA**		**Calcium Scoring**	
	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)
Castellano et al (UK) 2017 [25]	-	-	-	-	-	-	-	-	-	173	-	-
Danish Health Authority (DK) 2015 [14]	16	620	-	-	13	500	-	-	29	230	-	-
Foley et al (IE) 2012 [26]	-	-	7	276	-	-	13	432	-	-	-	-
Fukushima et al (JP) 2012 [24]	-	-	-	-	-	-	-	-	-	1510	-	
German Federal Office for Radiation Protection (DE) 2016 [23]	-	-	-	-	-	-	-	-	20 (d)	330 (d)	-	
Hausleiter et al 2009 (Protection I; worldwide) [27]	-	-	-	-	-	-	-	-	69,6	1152	-	
Japan Network for Research on Medical Exposures (JP) 2015 [28]	-	-	-	-	-	-	-	-	90	1400	-	-
Kanal et al (USA) 2017 [29]	-	-	-	-	-	-	19	557	-	-	-	-
Mafalanka et al (FR) 2015 [30]	-	-	-	-	-	-	-	-	-	870	-	-
Palorini et al (IT) 2014 [31]	-	-	-	-	-	-	-	-	-	1208	-	131
Public Health England (UK) 2016 [15]	12	610	4	140	12	350	13	440	-	-	-	-

(a) for female patients; (b) for male patients; (c) prospective, no padding; (d) prospective, with padding; (e) retrospective, with gating; *as listed in the original publications

Table 18: DRLs based on clinical indication for chest CT *(continued on next page)*

Chest CT												
Reference	**Lung cancer**		**Interstitial lung disease (axial)***		**Interstitial lung disease (helical)***		**Pulmonary embolism**		**CCTA**		**Calcium Scoring**	
Radiation and Nuclear Safety Authority (FI) 2013 [32]	11	430	-	-	-	-	-	-	-	-	-	-
Salama et al (EG) 2017 [33]	-	-	-	-	22	421	-	-	-	-	-	-
Schegerer et al (DE) 2017 [7]	-	-	-	-	-	-	15	300	20 (d)	-330 (d)	8	119
									45 (e)	702 (e)		
Treier et al (CH) 2010 [16]	-	-	-	-	-	-	-	-	-	1000	-	150
Van der Molen et al (NL) 2013 [17]	-	-	-	-	-	276	-	371	-	671	-	51
Wachabauer et al (AT) 2017 [18]	-	-	-	-	-	-	-	400	-	-	-	-
Habib Geryes et al (FR) 2019 [19]	-	-	-	-	-	-	8	310	-	-	-	-
Ireland (IE) MERU 2017 [20]	7 (a)	241 (a)	-	-	7 (a)	210 (a)	9 (a)	234 (a)	-	-	-	-
	7 (b)	272 (b)	-	-	7 (b)	249 (b)	12 (b)	278 (b)	-	-	-	-
Norway (NO) 2018 [21]	9	350	-	-	9	300	-	-	-	-	-	-
Sweden (SE) 2019 [22]	9	350	-	-	-	-	-		-	-	-	-
Public Health England (UK) 2018 [15]	-	-	-	-	-	-	-	-	-	170 (c)	-	-
	-	-	-	-	-	-	-	-	-	280 (d)	-	-
	-	-	-	-	-	-	-	-	-	380 (e)	-	-
Netherlands (NL) 2012 [34]	-	-	-	-	-	-	10	350	-	-	-	-

(a) for female patients; (b) for male patients; (c) prospective, no padding; (d) prospective, with padding; (e) retrospective, with gating;
*as listed in the original publications

Table 18: DRLs based on clinical indication for chest CT *(continued)*

4.2.1.4 Abdominal CT

In abdominal CT, liver metastases and kidney stones/ colic are the clinical indications with most proposed DRLs. The DLP values for liver metastases range from 400mGy.cm [16], [18] to 1423mGy.cm [33] and for kidney stones/colic from 200mGy.cm [16] to 460mGy.cm [18]. See Table 19.

Abdomen (epigastrium)												
Reference	**Liver Metastases**		**Abcess**		**Kidney stones/colic**		**Kidney tumor/colic**		**Acute Abdomen**		**Pancreas Adeno CA**	
	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)
Danish Health Authority (DK) 2015 [14]	-	-	-	-	-	-	-	-	17	700	-	-
Public Health England (UK) 2016 [15]	14	910	15	745	10	460	13	1150	-	-	-	-
Radiation and Nuclear Safety Authority (FI) 2013 [32]	-	-	-	-	7	330	-	-	-	-	-	-
Salama et al (EG) 2017 [33]	31	1423	-	-	-	-	-	-	-	-	-	-
Treier et al (CH) 2010 [16]	15	400	-	-	-	-	-	-	-	-	-	-
Van der Molen et al (NL) 2013 [17]	-	-	-	-	-	329	-	1371	-	-	-	1000
Wachabauer et al (AT) 2017 [18]	-	400	-	-	-	-	-	-	-	-	-	-
Ireland (IE) MERU 2017 [20]	9 (a)	554 (a)	-	-	6 (a)	254 (a)	-	-	-	-	-	-
	10 (b)	515 (b)	-	-	8 (b)	291 (b)	-	-	-	-	-	-
Norway (NO) 2018 [21]	-	-	-	-	5	250	13	1300	-	-	-	-
Sweden (SE) 2019 [22]	11	550	-	-	5	200	12	1000	-	-	-	-
Netherlands (NL) 2012 [34]	-	-	-	-	-	-	-	-	15	700	-	-

(a) for female patients; (b) for male patients

Table 19: DRLs based on clinical indication for abdominal CT

4.2.1.5 Abdomino-pelvic CT

In abdomino-pelvic CT, abscess/lymphadenopathy is the clinical indication with the highest number of proposed DRLs (four out of five). The DLP values range from 650mGy.cm [16], [18], [19] to 745mGy.cm [15]. It is interesting to note the same DLP value for this clinical indication in Austria, France and Switzerland. See Table 20.

Abdomino-pelvic CT										
Reference	**Abscess lymphadenopathy**		**VC - polyps/tumor**		**CT angiography (AAA)**		**Colic**		**Occlusion**	
	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)
Public Health England (UK) 2016 [15]	15	745	11	950	-	-	-	-	-	-
Treier et al (CH) 2010 [16]	15	650	-	-	15	650	-	-	-	-
Van der Molen et al (NL) 2013 [17]	-	-	-	-	-	727	-	-	-	-
Wachabauer et al (AT) 2017 [18]	-	650	-	-	-	-	-	-	-	-
Habib Geryes et al (FR) 2019 [19]	-	650	-	-	-	-	8	400	12	880

Table 20: DRLs based on clinical indication for abdomino-pelvis CT

4.2.1.6 Chest-abdomino-pelvic CT

In chest-abdomino-pelvic CT, DRLs based on clinical indication were found for tumour, infections and oncologic follow-up. The DLP values range from 870mGy.cm [19] to 950mGy.cm [21] for tumour and from 605mGy.cm [20] to 970mGy.cm [19] for oncologic follow-up. See Table 21.

Chest Abdomen Pelvis						
Reference	**Tumour**		**Infectious**		**Oncologic follow-up**	
	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)	$CTDI_{vol}$ (mGy)	DLP (mGy.cm)
Habib Geryes et al (FR) 2019 [19]	10	870	11	970	11	970
Ireland (IE) MERU 2017 [20]	-	-	-	-	8 (a)	605 (a)
	-	-	-	-	8 (b)	643 (b)
Norway (NO) 2018 [21]	15	950	-	-	-	-

(a) for female patients; (b) for male patients

Table 21: DRLs based on clinical indication for chest-abdomen-pelvis CT

4.2.2 Existing values of IR DRLs based on clinical indications in Europe

This section is based on clinical indication data from the NCAs and literature review.

Approximately twenty papers and studies were considered for the data collection of existing or proposed DRLs related to clinical indications in IR. Only European studies were considered for IR. Tables 22 and 23 summarise the findings. A comparison between these studies is quite difficult due to their inconsistency in the description of the performed procedure and the missing information of complexity levels during the intervention. Some of the articles provide P_{KA} mean values only instead of mean, median and quartile values or interquartile ranges (i.e. 75^{th} percentile for DRL estimation).

Due to this lack of consistent information regarding the type of procedure and the lack of specification of complexity levels, a wide range of dose and fluoroscopy time values is found in the publications.

The use of multiple DRL quantities (P_{KA}, $K_{a,i}$, fluoroscopy time and number of acquired images) for interventional fluoroscopy is discussed in the ICRP Publication 135 [4]. These quantities may help to identify the cause of overexposure and they could simplify the investigation thereafter. Therefore, it is recommended that all available data suitable for DRL quantities should be tracked.

The complexity of the procedure affects the applied dose much more than the patient's weight or fluoroscopy time and should thus also be part of the data collection and analysis. Ruiz-Cruces [10] classified three levels of complexity for common interventional procedures – these complexity indicators could be used as multiplicators for DRL quantities or to divide each procedure into subgroups of simple, medium and complex cases. This information of the complexity level should also be a part of the data acquisition for DRL quantities.

Country	Cerebral embolisation	PTA	Embolisation bronchial arteries	TIPS (liver)	Hepatic embolisation
	P_{KA} (Gy.cm^2)				
Austria *)	---	100	----	----	----
Belgium +)	175 (monoplan) 240 (biplan)	----	----	330	----
Bulgaria °)	----	----	----	----	----
France *) +) °)	190 (58 min)	----	135 (38 min)	190 (39 min), 186	240 (27 min), 249 (TACE)
Germany *) +)	180 (thrombus aspiration); 250 (coiling cerebral aneurysm)	90 (pelvis) 40 (femur) 25 (lower limb)		----	230 (TACE), 224 (TACE)
Ireland *) +)	62	70	----	186	300 (TACE)
Luxembourg *)	----	50	----	----	----
Norway °)	----	----	----	----	----
Poland *)	----	100 (18 min)	----	----	----
Spain +) °)	----	----	----	----	170, 303, 881
Switzerland*)	350 (50 min)	350 (cerebral or lower limbs, 14min)	150 (30 min)	350 (40 min)	300 (20 min)

*) DRLs reported by the NCAs; +) DRLs from other publications; °) These countries plan to establish national DRLs in near future.
(some fluoroscopy times are indicated in brackets)

Table 22: Existing DRLs for interventional procedures

Country	Vertebroplasty	Embolisation pelvic arteries	Upper limbs embolisation	All IV lines, Hickman line	All thoracic procedures	All abdominal procedures	All pelvic procedures	All peripheral procedures
	P_{KA} (Gy.cm^2)							
Austria *)	----	----	----	----	----	----	----	100 66
Finland *)	----	----	----	----	----	----	----	----
France *)	60 (9 min)	----	----	----	----	----	----	----
Germany *) +)		90	40		230 (EVAR)	230 (EVAR), 203 (EVAR)		
Greece	----	----	----	----	----	----	----	----
Ireland *)	----	----	----	3	8	70	70	30
Switzerland *)	80 (15 min)	300 (30 min)	150 (30 min)	----	----	----	200	----
UK	----	----	----	3 (1.5 min)	----	----	----	----

*) DRLs reported by the NCAs; +) DRLs from other publications
(some fluoroscopy times are indicated in brackets)

Table 23: Existing DRLs interventional procedures (part 2)

One country reported P_{KA} reference values for eleven procedures; all others reported values for between one and three procedures only. This paucity highlights the reluctance of European countries to establish DRLs in IR. The lack of IR DRLs may, at least partly, be attributed to the fact that the number of examinations for certain IR procedures is too low for DRLs to be established.

The names of the procedures do not clearly specify clinical indications but are related to a clinical indication. As an example, all peripheral PTA procedures could be considered in relation with limb ischemia symptoms. However, in some procedures, like cerebral embolisation there would be a need for clarification of the clinical background.

Few multi-centre studies have been published on IR DRLs (outside interventional cardiology). Vano et al. [35] collected dose data for twenty procedures for about 1,300 patients in thirteen European countries. Because of the limited number of patients, preliminary reference levels were proposed only for a few procedures. A retrospective study of nine interventional neuroradiology departments was published by Kien et al. [36] in 2011. Seven diagnostic (cerebral and spinal angiography) and therapeutic (embolisation and vertebroplasty) procedures were reviewed. For each procedure, three dosimetric parameters were recorded: P_{KA}, fluoroscopy time, and number of images. Results showed interdepartmental variations, up to four-fold for diagnostic procedures and seven-fold for therapeutic procedures. DRLs were proposed for six types of procedures. Bleeser et al. [37] established DRLs for common angiographic and interventional procedures in Belgium. P_{KA} measurements were performed on twenty-one systems. DRLs were based on about 3,200 procedures performed in seventeen centres.

A conclusion of all the above studies is that, for the same procedure, reported P_{KA} and fluoroscopy times show a wide range of values, which is most likely caused by different complexity levels of the procedure. This is very critical and should be carefully considered in future European guidance.

Ruiz-Cruces et al. [10] developed national DRLs for IR, to propose complexity criteria for seven common therapeutic IR procedures, and evaluated their impact on patient doses.

For each procedure, the authors established criteria to evaluate the complexity. As expected, the increase in complexity is associated with an increase in the mean P_{KA} values. In a very recent French study [11], complexity was assessed for four types of procedures: cerebral angiography (according to the number of cerebral vessels examined), biliary drainage (with or without endoprosthesis insertion), lower limbs arteriography (with or without aortography, without stenting) and vertebroplasty (according to the number of vertebra treated). Dose estimators increase with the complexity of the procedure. These studies show that for IR DRLs, an assessment of the level of complexity is important. Scaling of DRLs by complexity may be useful for some procedures.

Tuthill et al. [12] established reference levels for EVAR for five European centres and proposed an interim European reference level for EVAR procedures based on data from those centres. For the same procedure (abdominal EVAR), fluoroscopy time ranges from ten to thirty minutes. Similarly, with other studies, the authors found that radiation exposure levels vary greatly between individual patient examinations, hospitals, and countries.

Few research groups have also established local DRLs for angiography and interventional neuroradiology [38], abdominal interventional radiology procedures [39] and EVAR [40].

4.2.3 Existing DRLs based on clinical indications in Europe for interventional and nuclear medicine cardiac procedures

As the radiology departments recruited for data collection are not performing interventional and nuclear cardiology procedures, the European Society of Cardiology. (ESC) kindly provided a literature list and brief analysis for these exams. In addition, the NCAs were invited to report on national DRLs in interventional cardiology at the EUCLID workshop in December 2019.

Table 24 shows DRL values for interventional coronary and aortic procedures collected from the NCAs and from the literature.

Country	PTCA		PCI		PCI+ CA	CA	TAV I	Pacemakers
	P_{KA} (Gy.cm²)	FT (min)	P_{KA} (Gy.cm²)	FT (min)				
Austria		----	130	----	----	45	----	----
Belgium +)	125	----	----	----	----	60	----	----
Bulgaria °)	----	----	----	----	140 (8.9-18.1 min)	40 (3.8-6.5 min)	----	----
Cyprus (from Greece)	130	18	----	----	----	55 (6 min)	----	----
Czech Republic	91	----	----	----	91	49	----	----
Finland *)	----	----	75	15	----	30 (4 min)	90 (19 min)	3.5
France +)°)	----	----	80	15	----	38 (6 min)	----	----
Germany	----	----	48	13	55	28	80 (18 min)	----
Greece	130	18	----	----	----	55 (6 min)	----	35
Ireland *)	75	----	----	----	----	----	----	12
Luxembourg *)	44	----	----	----	----	23	----	----
Netherlands	----	----	----	----	----	80	----	----
Norway +) °)	----	----	----	----	----	20.3	46.6	----
Poland *)	120	20	----	----	----	60	----	----
Slovenia	100		----	----	----	50	----	----
Spain +) °)	67	16	----	----	----	32 (6.7 min)	----	----
Sweden (DRLs from 2008)	----	----	----	----	80	---	----	----
Switzerland	130	26	----	----	100	50 (8 min)	100 (30 min)	30
UK	40	11.3	----	----	----	31 (4.3 min)	----	7

*) DRLs reported by the NCAs at the workshop; +) DRLs from other publications; °) These countries plan to establish national DRLs in near future.

Table 24: Interventional cardiology DRLs based on clinical indications

DRLs for interventional cardiology procedures (invasive) and CCTA (non-invasive coronary angiography) are implemented in some countries (Siiskonen T et al. [41]). In addition, there are several multi-centre reports on radiation exposure during invasive and non-invasive CA. The inter-site variability for CCTA is 37-fold as reported from a dose survey performed in 2017. Overall, dose for CA decreased significantly over the last 10 years. For example, in Germany dose for invasive coronary angiography decreased by 24% from 2008-2015 [42]. Registries (for example, EURECA Imaging Registry[5]) were implemented to assess adherence to ESC guidelines for non-invasive cardiac imaging and to assess the current radiation dose exposure in the different imaging techniques.

4.2.3.1 Nuclear Cardiology DRLs

Based on the literature review, a very large variation exists in the reported dose. Based on the analysis of these data, it will be difficult to propose a solid DRL for different kinds of procedures.

4.2.3.2 Cardiac Electrophysiology Procedures (Electrophysiologic Study and Ablation Procedures) and Cardiac Device Implantations

The literature review showed a very large variation in the reported PKA (DRL/mean/median) for device implantations and ablation procedures/electrophysiology studies (EPS). Based on the analysis of these data, it will be difficult to propose a solid DRL for different kinds of procedures such as ablation of atrial fibrillation, implantation of cardiac resynchronization therapy (CRT) or non-CRT devices. It was pointed out that there is a large variety of interventional electrophysiology procedures. The heterogeneity of dose data between procedures and institutions is large, which can be partially explained by technical and operator-dependent factors. The VERIDIC project[6] tried to overcome problems with maximum skin dose (MSD) measurements and 2D presentation of skin dose distribution.

4.2.4 Existing Plain Radiography DRLs based on clinical indication in Europe

European plain radiography DRLs were published in the Dose Datamed 2 report [3]. These values are mostly based on anatomical region protocols. An overview of the current situation regarding plain radiography DRLs in Europe can be found in section 4.1.4.

4.2.5 Existing Paediatric imaging DRLs based on clinical indication in Europe

The last update on paediatric imaging DRLs can be found in the PiDRL report [2]. The few existing DRLs are mostly based on anatomic regions. An overview can be found in section 4.1.5.

4.2.6 Existing Nuclear Medicine DRLs based on clinical indication in Europe

The last update is in the EC report RP 180 [3]. According to the presentation by European Association of Nuclear Medicine (EANM) during the EUCLID workshop, DRLs in nuclear medicine exist in Europe, but are not applied in clinical practice. Nuclear medicine physicians at the workshop called for more efforts to harmonise diagnostic procedures (and injected activities) in nuclear medicine.

[5] https://www.escardio.org/Research/Registries-&-surveys/Observational-research-programme/eureca-registry

[6] https://www.researchgate.net/project/VERIDIC-Validation-and-Estimation-of-Radiation-skIn-Dose-in-Interventional-Cardiology

5. EUCLID List of Clinical Indications

5.1 Definition of DRLs based on clinical indication: the CAP approach

Until now, DRLs are defined for an anatomical location (A), with lacking information on the clinical indication (C) and on the procedure (P). According to the EUCLID approach, including all this information (C+A+P) strengthens the significance of DRLs, as they correspond to a better specified setting and would ultimately provide a stronger tool for optimisation and comparisons between centres or countries.

Therefore, the definition of clinical indication-based DRLs should be a combination of disease and symptoms, anatomical location and of the used technique. The CAP concept is applicable for CT and IR but is not considered to be well suited for plain radiography.

Given the above considerations, the EUCLID team decided to define the EUCLID list of clinical indications and the EUCLID DRLs on the basis of the CAP concept.

5.2 Development process of EUCLID clinical indications

The EUCLID list of clinical indications (see sections 5.2.1 and 5.2.2) is in line with the clinical indications found in literature, but has been updated to take into consideration the suggestions from the NCAs, the SB and the EAP. The SB and EAP were asked to provide feedback on the initial proposal of clinical indications before setup of the data collection survey to ensure agreement on the final list of EUCLID clinical indications. Consensus on the final EUCLID list of clinical indications was reached among the SB, EAP and steering committee. In addition, the centres participating in the data collection survey reviewed and agreed on the list prior to the launch of the survey.

5.2.1 List of clinical indications for CT

The list of clinical indications for CT was established according to two major criteria: the indication name should be clear and unambiguous (this was tested with the centres before launching the survey) and selected procedures should be frequent. Another parameter that was taken into consideration was radiation exposure by prioritising CT procedures associated with considerable patient dose.

In addition, alignment with existing clinical indications in the literature and a consensus with the EAP and the SB were sought.

Finally, ten clinical indications were proposed according to the CAP concept (Table 25). It was checked whether the corresponding procedure was considered appropriate by the ESR iGuide[7], the European Society of Radiology's Clinical Decision Support (CDS) tool for imaging referral guidelines. The Dutch study [17], which covered twenty-one hospitals and was published in 2013, was used to assess the frequency of the examinations and examples of exposure contributions were taken from both the Dutch study and the last DRL report from Public Health England [15].

Two clinical indications (stroke and sinusitis) from the list correspond to almost 35% of the examinations. Most other examinations are much less frequent but represent a significant dose contribution. It should be pointed out that there are several different clinical indications for the same anatomical location (e.g. three for head and neck, four for thorax, three for abdomen).

For the protocol specification, the approach of Public Health England was followed and "all phases" instead of detailed protocols were used considering the entire exam (provided the number of phases was provided by the participating centres).

[7] https://www.myesr.org/esriguide

	Clinical Task (C)	Anatomical Location (A)	Procedure (P)
CT 1	Stroke Detection or exclusion of a haemorrhage	Head	All Phases
CT 2	Chronic sinusitis Detection or exclusion of polyps	Neck	All Phases
CT 3	Cervical spine trauma Detection or exclusion of a lesion	Spine	All Phases
CT 4	Pulmonary embolism Detection or exclusion	Thorax	All Phases
CT 5	Coronary calcium scoring Risk stratification	Coronary Arteries	All Phases
CT 6	Coronary angiography Vessels assessment	Coronary Arteries	All Phases
CT 7	Lung Cancer Oncological staging First and F-up	Brain Thorax Liver	All Phases
CT 8	Hepatocellular carcinoma Oncological staging	Liver	All Phases
CT 9	Colic /abdominal pain Exclusion or detection of a stone	Abdomen	All Phases
CT 10	Appendicitis Detection or exclusion	Abdomen	All Phases

Table 25: Final CT clinical indications for the EUCLID project

5.2.2 List of clinical indications for IR

DRLs based on clinical indication for interventional procedures should primarily be defined for procedures, which are clinically well established, contribute significantly to patient care and involve a rather high radiation exposure for the patient and operator. The reasons for choosing initially arterial occlusive disease of iliac arteries, biliary drainage, arterial occlusive disease of femoropopliteal arteries and TACE are given below:

- Endovascular treatment of arterial occlusive disease (stenosis and occlusion) is one of the most frequently performed endovascular procedures in iliac and femoro-popliteal arteries. The iliac vessels are located in the pelvis; imaging of stenosis and occlusion frequently requires angled views and magnification. Both factors contribute to high radiation doses for the patient and the operator. Thus, DRLs are relevant for clinical practice. In contrary, endovascular treatment of occlusive lesions in the lower extremities involves a much lower dose for the patient and the operator. However, more complex procedures such as recanalization of long occlusions or treatment of complex lesions below the knee, especially in diabetic patients, may involve a relevant radiation dose to the patient's skin.
- Biliary drainage is frequently performed to relieve mechanical biliary obstruction caused by benign or malignant disease. The term "biliary drainage" is not exactly defined since it may imply drainage by an indwelling transhepatic catheter or a percutaneously / endoscopically placed biliary stent. In rare cases, additional procedures are performed to remove stones or ablate tumours. Complexity depends on the site and nature of biliary obstruction.
- TACE is the most common abdominal embolisation procedure for treatment of hepatic tumours, especially hepatocellular carcinoma. Complexity can be graded according

to the number and size of tumours (for hepatocellular carcinoma the Barcelona staging system can be applied) and the anatomy of the access vessels (aberrant / accessory hepatic arteries). Patients with left sided tumours and Michels Type 2,4,5 hepatic arterial anatomy are usually more difficult to catheterise.

Clinical Indication Number	Clinical task	Anatomical location	Procedure
IR 1	Arterial occlusive disease of iliac arteries Angiographic diagnosis and endovascular treatment of arterial stenosis or occlusion causing intermittent claudication or ischemia	Pelvis	Recanalisation & Stenting
IR 2	Localisation and treatment of hepatocellular carcinoma TACE: transarterial chemoembolisation	Liver	Transarterial (chemo)embolisation of tumor vasculature and feeding hepatic arteries
IR 3	Arterial occlusive disease of femoropopliteal arteries Angiographic diagnosis and endovascular treatment of arterial stenosis or occlusion causing intermittent claudication or ischemia	Lower extremity	Recanalisation and angioplasty +- stenting
IR 4	Biliary drainage Localisation of biliary obstruction and percutaneous treatment of biliary obstruction	Abdomen	Percutaneous transhepatic cholangiography and biliary drainage

Table 26: Final IR clinical indications for the EUCLID project

6. Methodology for DRL Survey among European Hospitals

6.1 Introduction

As previously described, EUCLID WP2 created the list of CT and IR clinical indications for which EUCLID DRLs should be established. EUCLID WP3 developed and implemented an EU-wide survey to collect data from hospitals in order to establish DRLs for these clinical indications across Europe following a methodology predefined by the project team. The data collected was continuously reviewed for accuracy and then analysed according to the methodology set out below.

6.2 Network of hospitals

A network of nineteen hospitals from fourteen European countries was established to provide data for the EUCLID project and to maximise the geographical distribution. Table 27 shows the list of hospitals and centres participating in the EUCLID project.

Abbreviation	Hospital/Centre	Country
APH	European Georges Pompidou Hospital	France
BMC	Bravis Medical Centre	Netherlands
CHUC	Centro Hospitalar e Universitário de Coimbra	Portugal
EMC	Erasmus MC	Netherlands
FCB	Fundació Clínic per a la Recerca Biomèdica	Spain
GVA	La Fe Health Research Institute	Spain
HHH	H.-Hart Hospital	Belgium
HRH	Humanitas Research Hospital, Rozzano	Italy
IRS	Institut de Radiologie de Sion	Switzerland
KUH	Kuopio University Hospital, Diagnostic Imaging Centre	Finland
LUX	Lux Med, Warsaw	Poland
MUH	Mercy University Hospital	Ireland
MUI	Medical University Innsbruck	Austria
PSH	Affidea Hungary Péterfy Sándor Hospital and Trauma Center	Hungary
UMM	Johannes Gutenberg University Mainz University Med Center	Germany
UoC	Panepistimio Kritis - University of Crete	Greece
UOR	University of Rome "A. Gemelli"	Italy
USB	University Hospital Basel	Switzerland
UZA	Antwerp University Hospital	Belgium

Table 27: List of hospitals or centres participating in the study

All hospitals were contacted to provide a representative sample of at least twenty average body size adult patient data for each CT examination, as well as at least thirty average body size adult patient data for each IR procedure. Tables 25 and 26 (above) show the list of examinations for which data was requested. Hospitals submitted data only on the clinical indications that were performed within their departments.

6.3 Training on data submission

Two online questionnaires, one for CT data collection and the other for IR data collection as well as a secure data collection electronic platform were used to collect data from the participating hospitals. Four tutorials (webinars) were organised for data managers of the participating centres to introduce the data collection server and provide information on how to submit survey data. Moreover, bi-weekly teleconferences with the EUCLID data managers were organised with the purpose to discuss limitations and possible issues for hospitals, provide clarifications and answer any questions. The teleconferences also aimed at motivating centres to submit data. In each teleconference, at least one representative of the EUCLID team of experts was present to lead the discussion. Moreover, emails were sent to all centres encouraging them to send any questions related to data submission to EUCLID experts. A question and answer document on the most frequently asked questions was drafted and provided to all participating hospitals.

6.4 Data protection

The European Parliament and the Council of the European Union issued data protection regulation 2016/679 [43] on the protection of natural persons with regards to the processing of personal data and on the free movement of such data. To maintain confidentiality, unauthorised third parties must be prevented from accessing and viewing medical data, an issue central to the EUCLID project. It was also important to maintain data integrity when transferring information by verifying that the information arrived as it was sent and was not modified in any way. The European Institute for Biomedical Imaging Research (EIBIR) has established a professional platform for data collection, REDCap[8]. This platform was used to collect EUCLID information from the network of hospitals. Anonymised data was stored on servers located in Austria, with continuous data protection and daily, off-site full backups.

6.5 Survey results per hospital

6.5.1 CT

Table 28 shows the amount of data submitted by the hospitals for CT compared to what was initially agreed.

Hospital/Centre	Initial number of patients	Submitted number of patients	%
APH	200	187	94
BMC	180	165	92
CHUC	200	208	104
EMC	140	208	149
FCB	200	200	100
GVA	180	166	92
HHH	200	1258	629
HRH	200	201	101
IRS	120	103	86
KUH	140	140	100
LUX	200	70	35
MUH	180	131	73
MUI	200	238	119
PSH	180	180	100
UMM	180	213	118
UoC	200	209	105
UOR	200	194	97
USB	120	121	101
UZA	200	200	100
Total	**3420**	**4392**	

Table 28: Summary statistics of data submitted compared to data initially agreed for CT

[8] https://www.eibir-edc.org/

6.5.2 IR

Table 29 shows the amount of data submitted by the hospitals for IR compared to what was initially agreed.

Hospital/Centre	Initial number of patients	Submitted number of patients	%
APH	90	62	69
BMC	0	0	0
CHUC	120	134	112
EMC	120	85	71
FCB	120	79	66
GVA	120	90	75
HHH	0	0	0
HRH	120	42	35
IRS	0	0	0
KUH	60	64	107
LUX	120	60	50
MUH	60	63	105
MUI	120	135	113
PSH	90	90	100
UMM	120	96	80
UoC	90	95	106
UOR	120	96	80
USB	60	69	115
UZA	60	60	100
Total	**1560**	**1320**	

Table 29: Summary statistics of data submitted compared to data initially agreed for IR

6.6 Analysis of data collected

The steps below were followed in order to ensure complete and accurate data for defining DRLs in the EUCLID project.

6.6.1 Review and plausibility tests of survey data

All data was continuously reviewed during the data collection period in an attempt to avoid incorrect records. Data was then prepared for cleaning in order to be sure that it was in the correct format and was "logical" and correct. Individual records were carefully examined if any of the following criteria were met:

- Body weight did not match the weight interval of 70±15 kg that was indicated within the CT and IR questionnaires and represented the reference person. This was done for all body examinations in CT and IR.
- Body mass index did not match the indicated range of 18.5-25 kg/m2 within the questionnaire. This was done for all body examinations in CT and IR.
- The phase name provided by the participating centre was not compatible with the CT procedure.
- Modern technical features used for dose reduction (e.g., tube voltage adaption) were reported to have been used in devices that were more than ten years old as, prior to that time, these features were not offered in the device configuration.
- Data values did not correspond to the values provided in the DICOM report.

If any of the above criteria were met by a patient record, follow-up with the concerned hospitals was done as specified below.

6.6.2 Follow-up with hospitals

If mistakes were noticed in the data submitted in the survey, participating centres were contacted individually by e-mail or by phone to clarify the discrepancies. This was done not

only during the collection period but also during the cleaning process. Data was discarded if the discrepancy could not be clarified or removed.

Additionally, bi-weekly teleconferences with the EUCLID data managers were organised from October 2018 onwards with the purpose of discussing limitations and possible issues for hospitals, providing clarifications, and answering any questions.

6.6.3 Missing data

Only examinations with complete patient information, dose quantities and indices, and other information for the DRLs determination were included. Data sets where patient weight did not fit to specified weight range were replaced by data sets which fitted within the specific weight range.

An exception to this methodology was made for the LUXMED hospital in Poland. Although data submitted by LUXMED was not complete for all dosimetric quantities (either in CT and IR procedures) and, therefore, did not meet the criteria for inclusion according to the agreed methodology, following discussion, the EUCLID consortium agreed that P_{KA} and fluoroscopy times for CIs IR 1 and IR 3, and DLP for CIs CT 1 and CT 2, should be included and analysed in order to provide as much information as possible. For the same reason, a similar exception was made for MUH hospital for CI IR 4, where only twenty-five cases were submitted.

6.6.4 Data cleaning

Once the collection period ended, data was checked and discussed in virtual meetings. If mistakes were again noticed, participating centres were once more contacted individually by e-mail for clarifications. Again, data was discarded if the discrepancy could not be clarified or removed.

6.6.5 Data verification from the Scientific Board

Once the cleaning process finished, data was sent to SB members for verification purposes. SB members were representatives of national regulatory authorities and national scientific/professional societies from the countries in which data was collected. Each SB member received by email two excel files with clean data: one for CT and one for IR (only data from hospitals in his/her country were sent). They were also provided with the CT and IR questionnaires used in data collection for their information. Any other information to check for data completeness and inconsistencies requested by the SB members was provided to them where available, including DICOM and RDSR reports. The SB members then provided their verification of the data to the project team.

6.7 Defining DRL quantities

6.7.1 Computed Tomography

Based on the feedback from European countries, and taking into consideration the ICRP Report 135 [4] the EUCLID consortium decided to define CT DRLs in terms of:

- $CTDI_{vol,p}$: Average Volume Computed Tomography Dose Index in multiphase CT
- DLP: Dose Length Product
- SL: Scan Length

In order to investigate the effect of scan phase (series) the DLP per phase (DLP_p) was also considered. DLP_p was required to clarify excessive DLP values because large DLP values can result either from large $CTDI_{vol,p}$ and/or large scan lengths. DLP_t represents the total dose received in a study but this quantity is affected by different other parameters: $CTDI_{vol,p}$, scan lengths, number of phases. For easier identification of the cause of excessive values, all these DRL values, including scan length, are necessary tools.

6.7.2 Interventional Radiology

The initial proposal of the EUCLID project consortium was to define IR DRLs in terms of:

- P_{KA}: Air kerma-area product
- $K_{a,r}$: Cumulative air kerma at the patient entrance reference point
- T: Fluoroscopy time
- NI: Total number of images

The consortium also considered the possibility of defining IR DRLs in terms of complexity of clinical case [4],[10]. The consortium decided this would only be considered if there were enough patient cases per category (at least thirty patients) to ensure statistical power. In order to evaluate complexity of case the paper of Ruiz-Cruces et al. [10] was followed and IR procedures were graded as one of the following categories: easy, medium, and high difficulty. The criteria considered included: anatomical characteristics, type and/or location of injury, and type of treatment.

6.7.3 Determination of DRLs based on clinical indication

For the definition of DRLs, ICRP 135 recommendation for estimating regional DRLs was followed:

"*A 'DRL value' is a selected numerical value of a DRL quantity, set at the 75th percentile of the medians of DRL quantity distributions observed at healthcare facilities in a nation or region*" (page 41, paragraph 48) [4].

Therefore, the following steps were followed:

- Estimation of the median of each hospital for each clinical indication.
- Estimation of the 75th percentile of all the medians for each clinical indication. This ensures effective recognition of the "outliers" i.e. the centres, which have unusually high patient dose levels.
- The rounded values of these 3rd quartile (75th) values were defined as DRLs.

7. Survey Results and Determination of DRLs based on Clinical Indication

7.1 Results of statistical analysis

CT

The hospitals reported four different manufacturing companies: Philips (15.5%), Siemens (56.0%), Canon (3.0%), and General Electric (15.5%).

CT machines were installed during the period 2003-2019. Most of the scanners were installed during the period 2011-2014. More than 30% of the scanners were 10 years or older and only 12.3% were installed in the years 2017-2018. As far as the number of detector rows was concerned, the range reported was 4-256 (60% being 64-row, 22% being 128-row and the remaining 18% being 4-row, 16-row, 256-row and others).

As far as dose measurement and verification were concerned, 91% of scanners had a display of CTDI/DLP quantities and 90% of data managers (medical physicists) reported annual or biannual CTDI measurements. In 94% of data, the CTDI display was verified by measurements and in that case, verification showed 0.5-10.3% accuracy. DRLs were taken into consideration during the design of a protocol in 84% of cases.

Image quality was adequate to answer the diagnostic question in 99.5% of samples. Various iterative algorithms were applied in 83% of samples. Tube current modulation was activated in 87% of samples. Data analysis based on phase name was impossible as numerous different nomenclatures were used for CT multi-phase examinations of the same CI. One-phase exams were reported in 77.2% of samples, followed by two-phase exams (10.9%) and equally represented three-phase (5.9%) and four-phase exams (6.0%). Investigation of stroke (head examination) and oncological staging for hepatocellular carcinoma (abdominal examination) were the most frequent three- and four-phase examinations.

Strong radiation safety culture is dictated by routine dose display verification measurements, routine quality control testing and applying DRLs concept during CT protocol design and active use in clinical routine.

IR

The hospitals reported two manufacturing companies: Siemens (86.0%) and Philips (14.0%). The machines were installed during the period 2003-2018 and 77.0% of them were biplane and only 23.0% were monoplane. Most of the X-ray machines had a flat panel detector (77.0%) and only 23.0% had an image intensifier. All fluoroscopy systems of EUCLID participating hospitals complied with article 60.3 of the BSSD regarding image intensifiers or equivalent devices. The installation year was evenly distributed between years; 39.8% during the period 2003-2011, 27.9% between 2011-2014 and 32.3% after 2014.

The PKA meter was calibrated in 86% of samples. Data managers reported verification of PKA values through measurements with annual (61.7%), biannual (12.3%), quarterly (10.6%) measurements and a small percentage reporting either monthly (8.3%) or daily (7.1%) tests. Verification of measurements and dose display varied up to 25%.

Image quality was adequate to answer the diagnostic question in 99.9% of samples.

As far as technical protocol is concerned, data managers reported using pulsed fluoroscopy in almost all cases (90%). Automatic exposure control was activated in 93% of samples. Cine mode was used only in 30% of samples and there was no change in the cine mode in 85% of cases. If the cine feature was used then four images per second were applied in 67.5% of cases, 7.5 images per second were applied in 26.3% of cases, fifteen images per second were used in 5.7% of cases and thirty images per second were applied in less than 1% of cases.

The experience of most operators was rather high with 97.4% having executed more than 20 procedures of this type, 1.8% having executed between 5 and 20 procedures, and only

0.8% fewer than five procedures. The complexity of procedure was mainly low (43.0%) or middle (51.0%), and only 6% of procedures were complex. Results did not permit any firm conclusions to be drawn or DLRs based on complexity of case or operator experience to be derived (almost all operators were highly experienced physicians).

7.1.1 CT DRLs based on clinical indication

The figures shown below present the main parameters that were considered for defining DRLs for the ten CT CIs separately (Figures 1-10). Apart from $CTDI_{vol,p}$, DLP per phase (DLP_p) and total DLP (DLP_t) per examination, the consortium also considered the possibility to define DRLs in terms of SL. All these quantities were provided by data managers.

The figures below show our results in each indication separately. The figures contain varying number of hospitals depending on the procedure and/or the dose quantity. The variation is due to the fact that not all hospitals supplied data for all the clinical indications.

All ten figures are semi-logarithmic box and whisker plots where solid horizontal lines are the 5th, 25th, 50th, 75th, and 95th percentiles. Dotted lines are the arithmetic means.

a) Top figure: Volume CT dose index ($CTDI_{vol,p}$*),*
b) 2nd figure: Dose length product per phase (DLP_p*),*
c) 3rd figure: Total DLP (DLP_t*),*
d) bottom figure: scan length in cm (SL).

Figure 1: Data results for CI CT 1 (Stroke - Detection or exclusion of a haemorrhage)

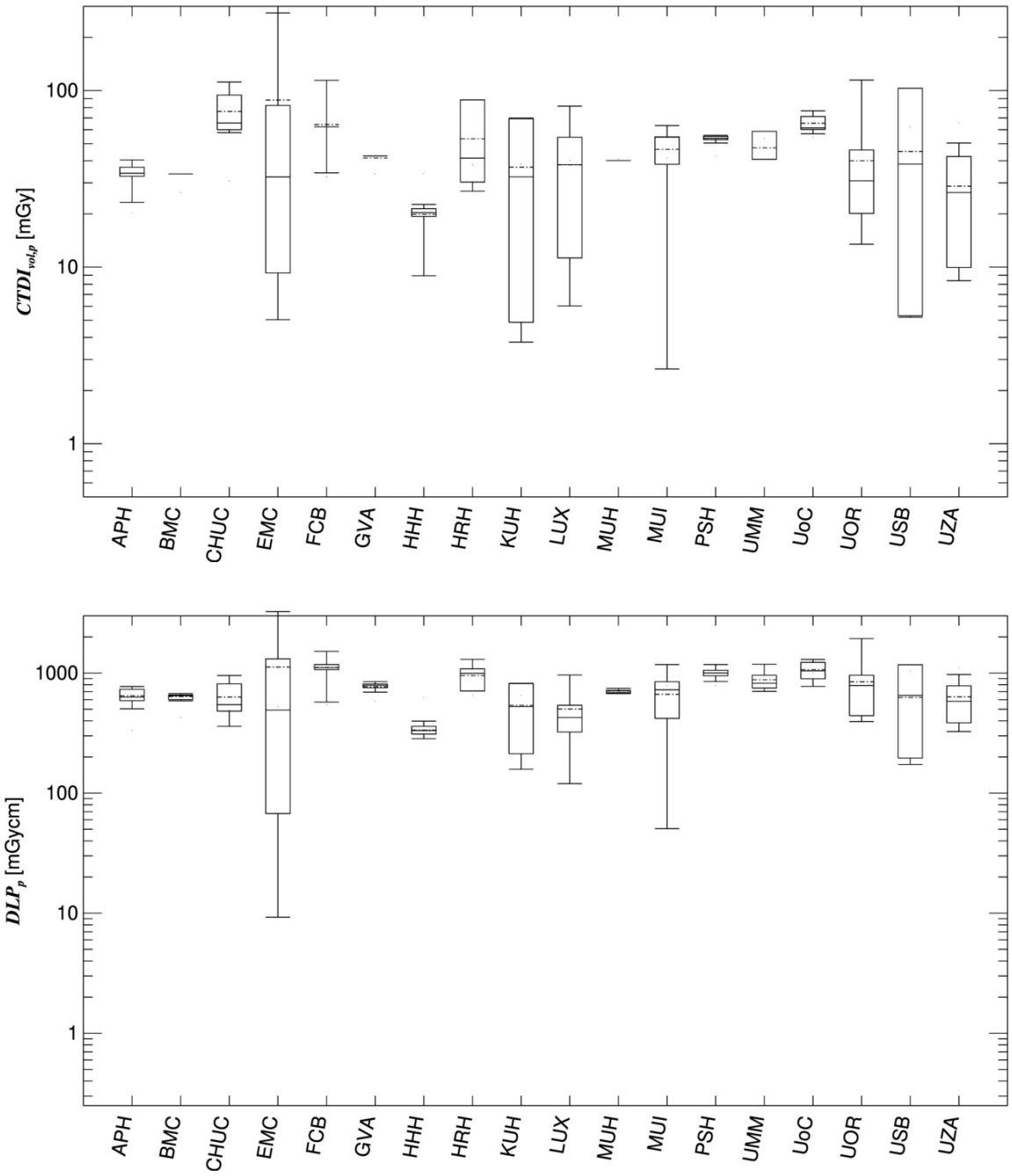


Figure 1 *(continued)*

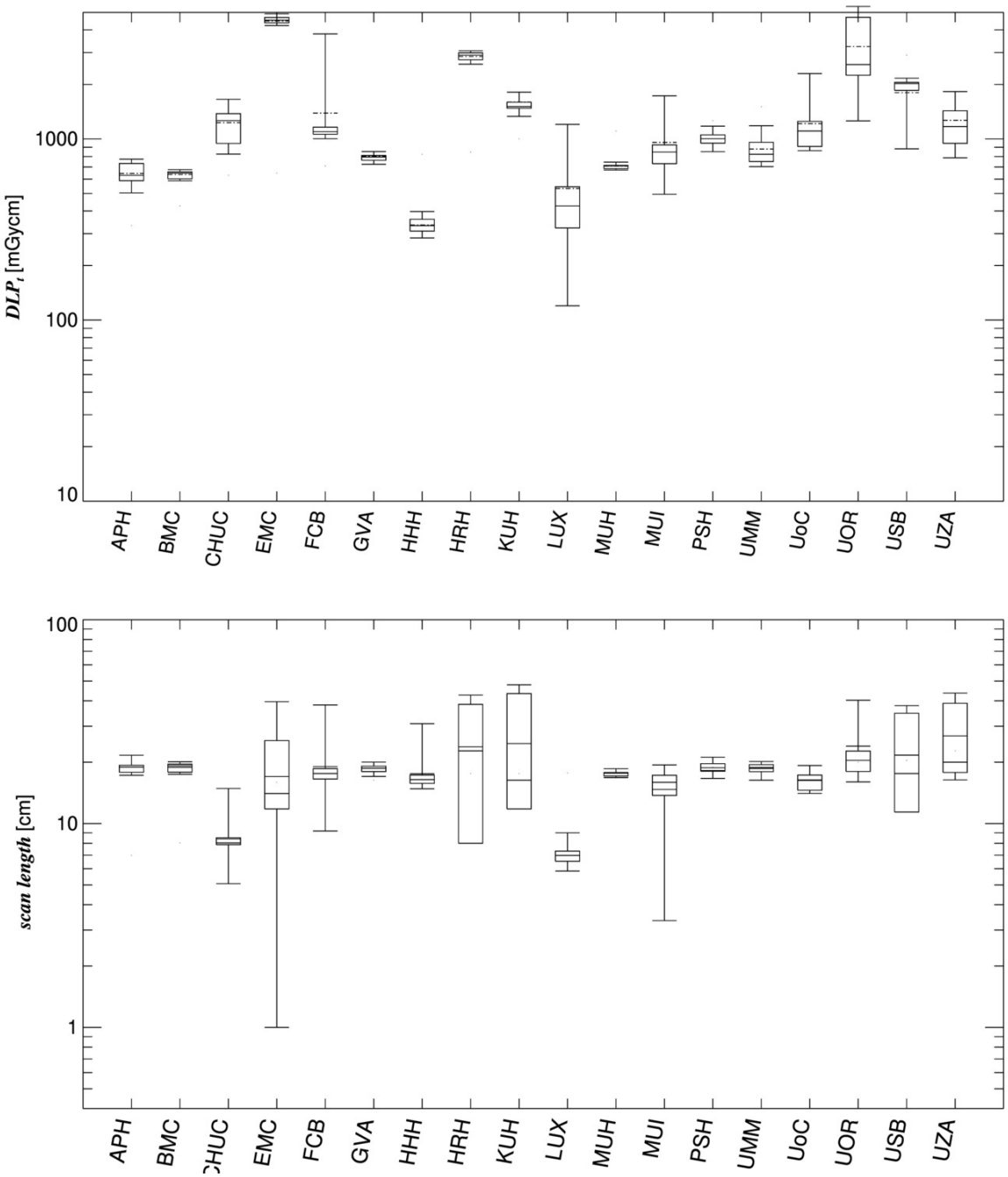
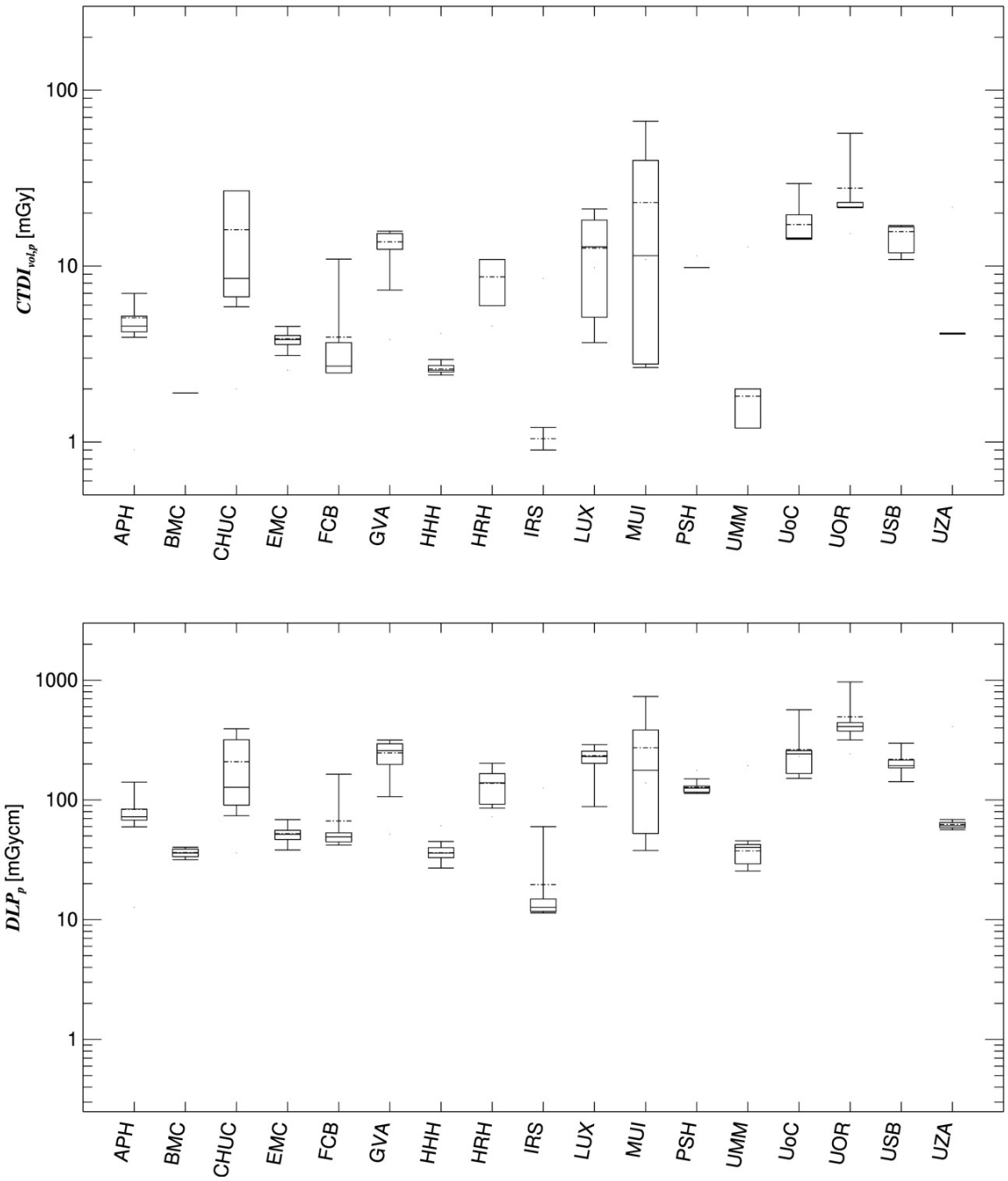


Figure 2: Data results for CI CT 2 (Chronic sinusitis - Detection or exclusion of polyps)



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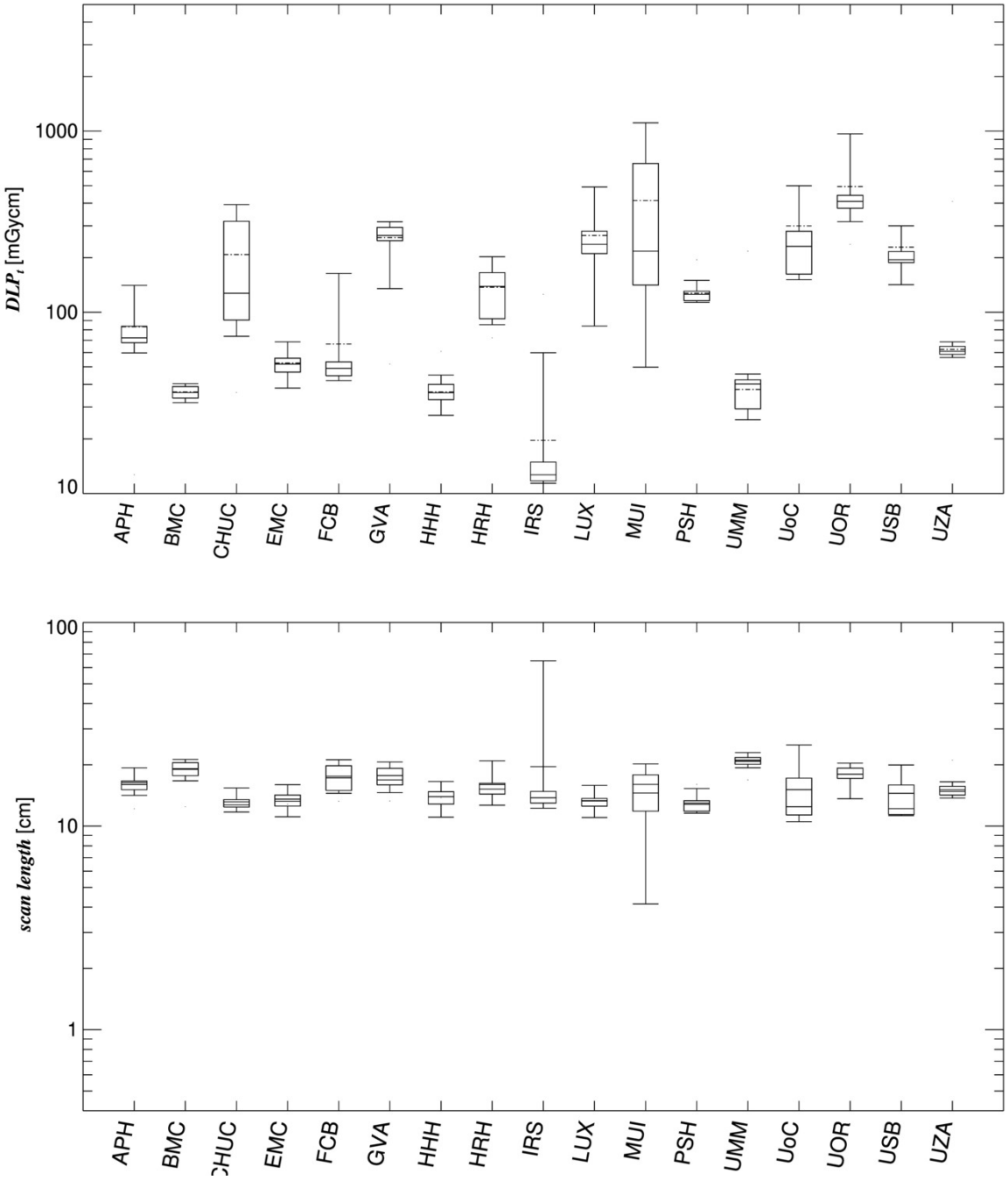


Figure 3: Data results for CI CT 3 (Cervical spine trauma - Detection or exclusion of a lesion)

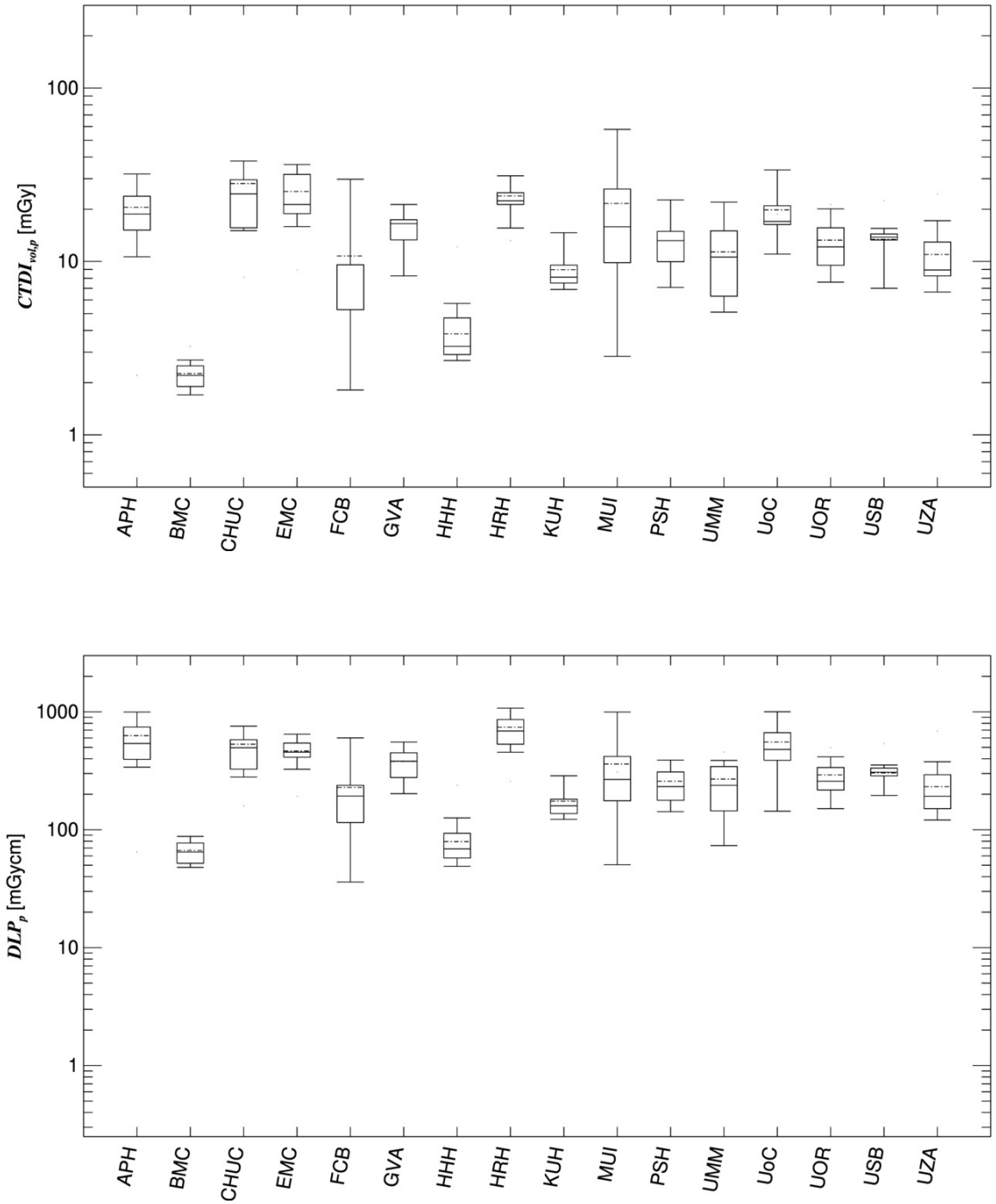


Figure 3 *(continued)*

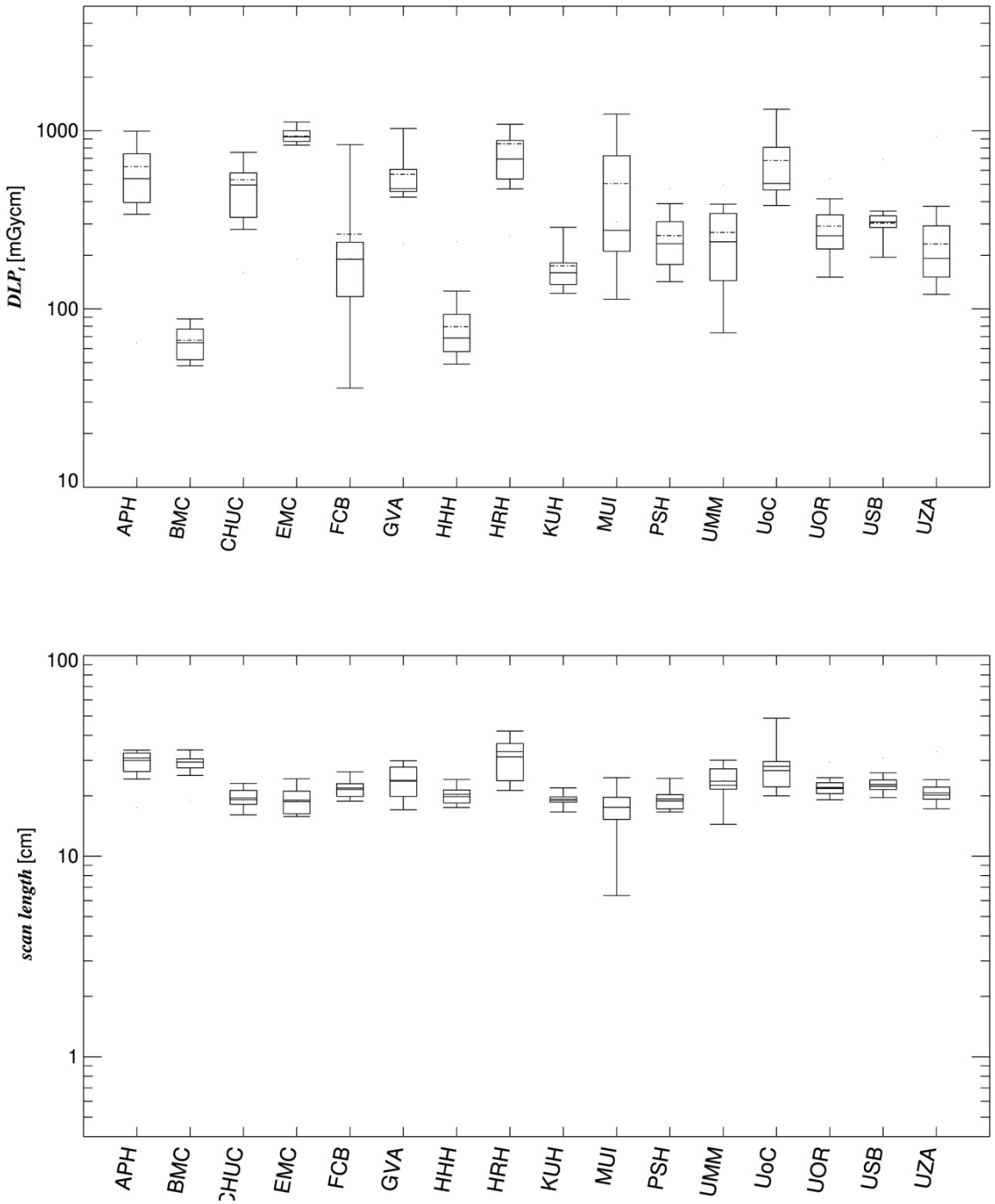


Figure 4: Data results for CI CT 4 (Pulmonary embolism - Detection or exclusion)

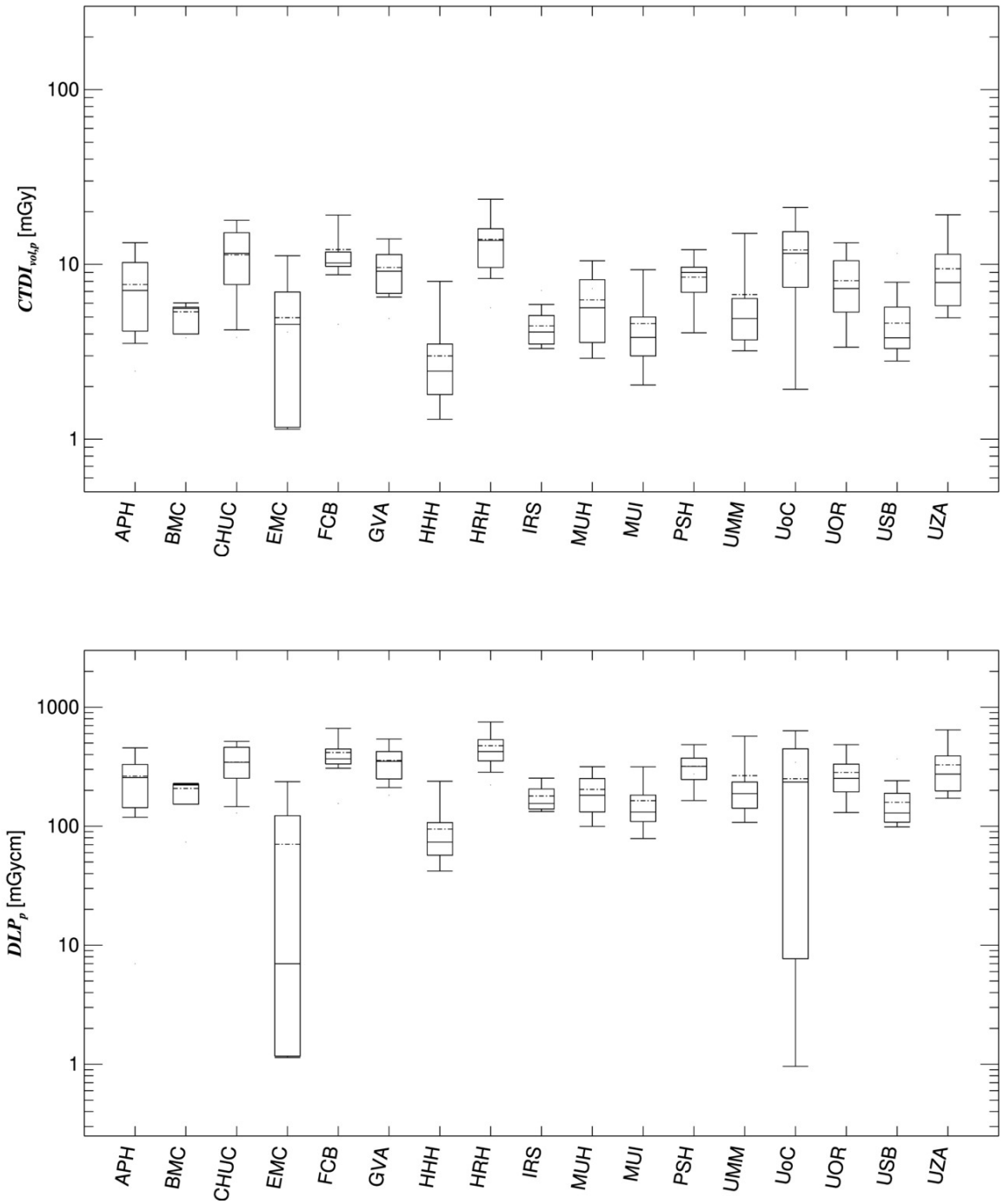


Figure 4 *(continued)*

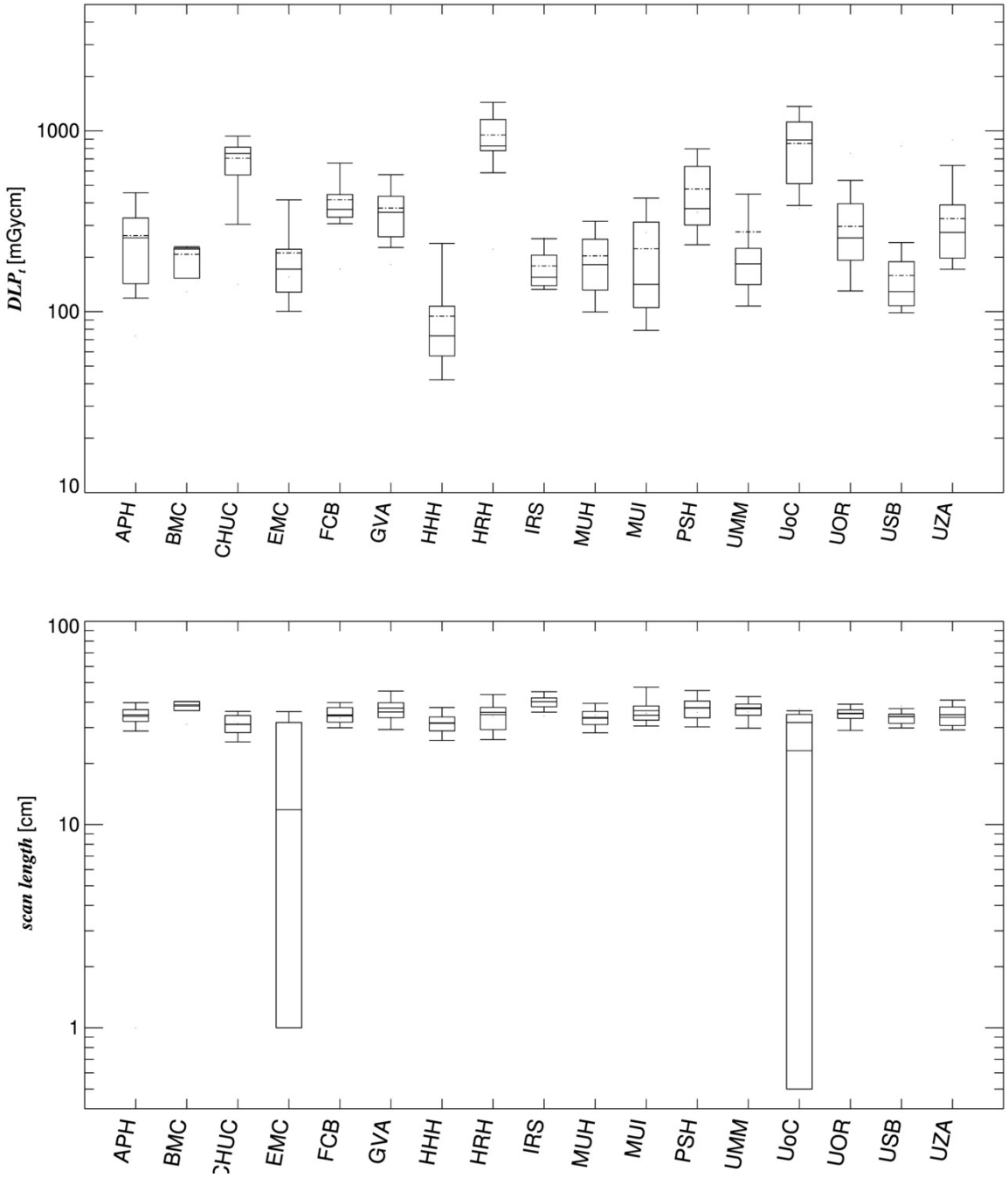
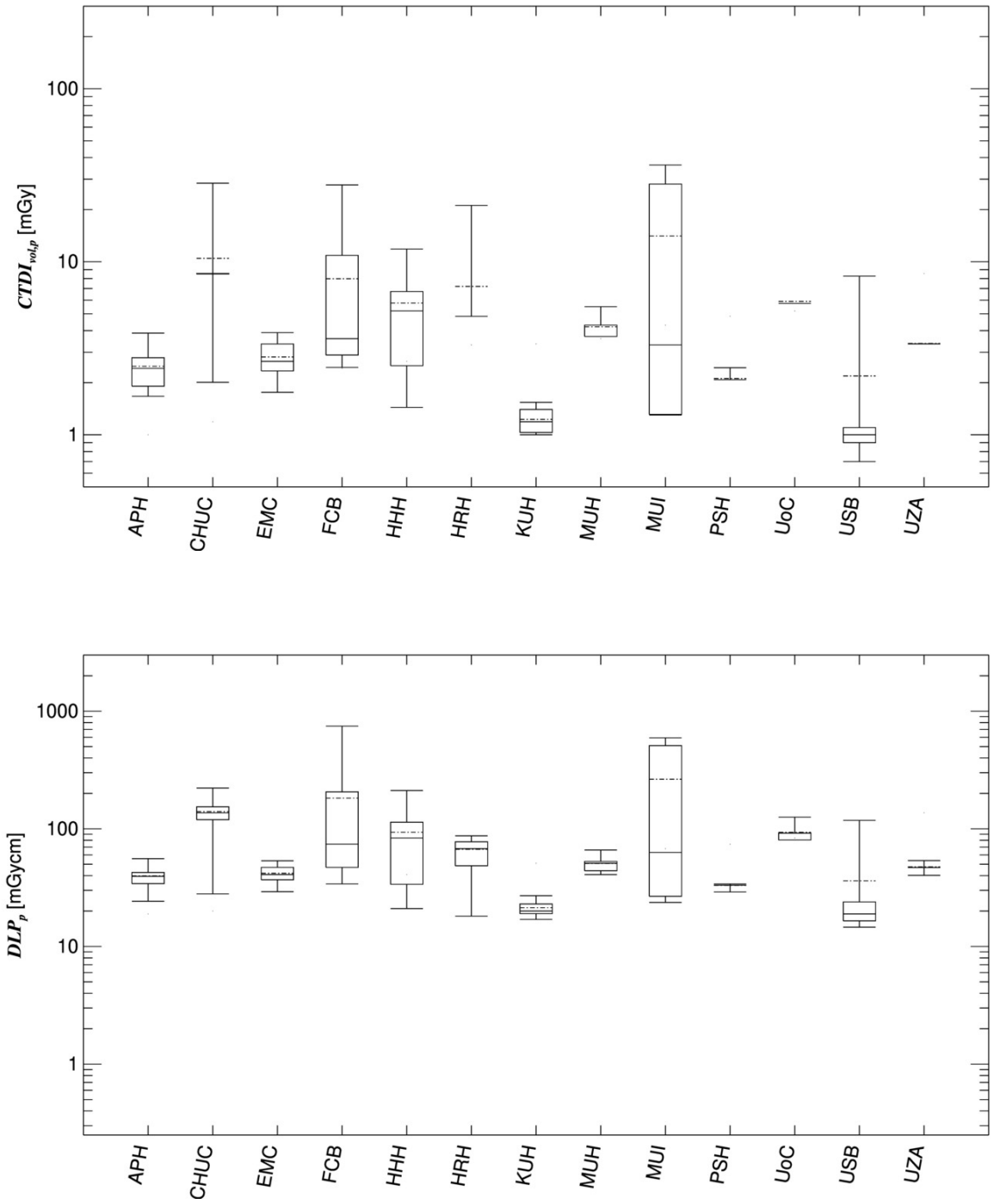


Figure 5: Data results for CI CT 5 (Coronary calcium scoring - Risk stratification)



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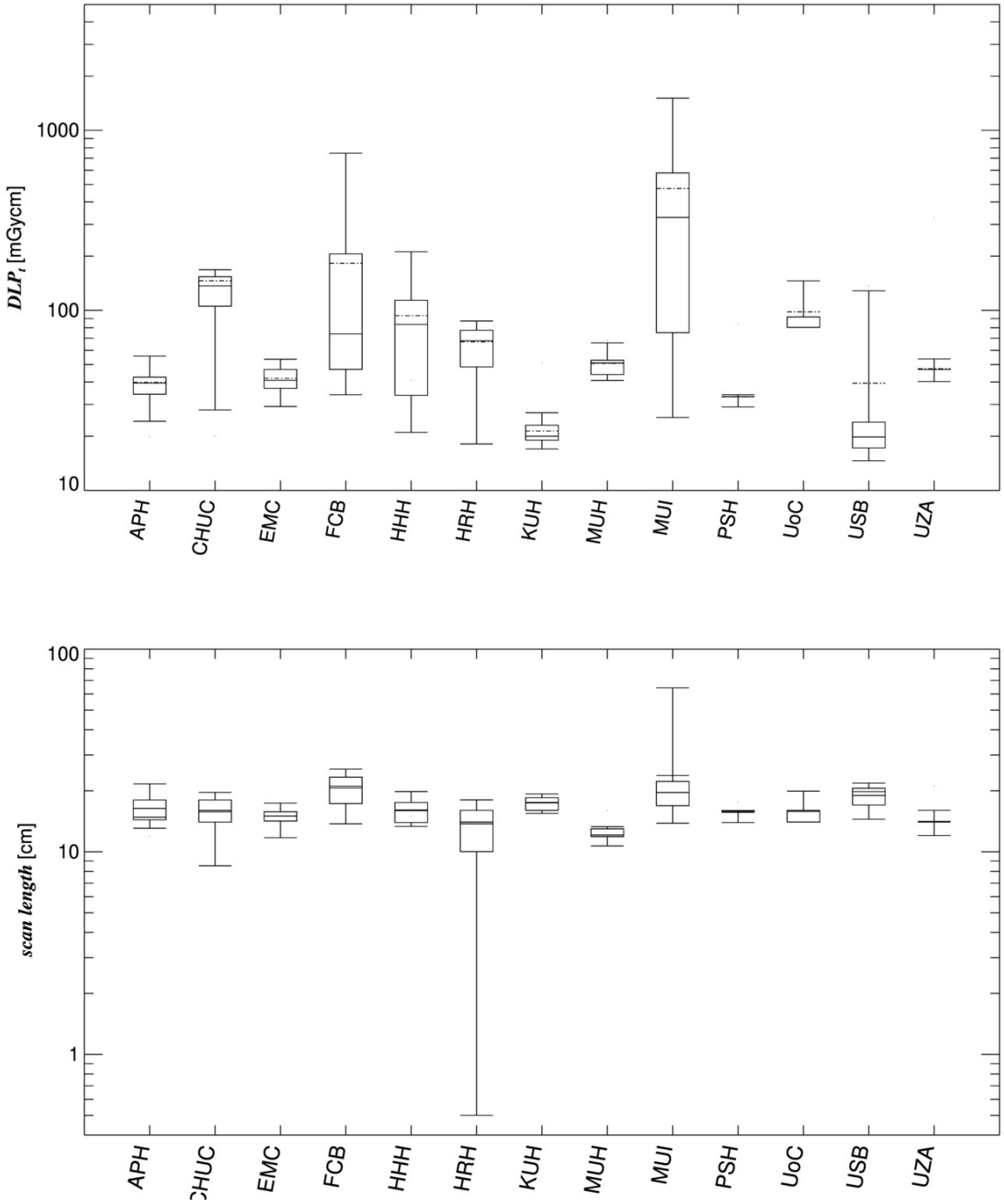
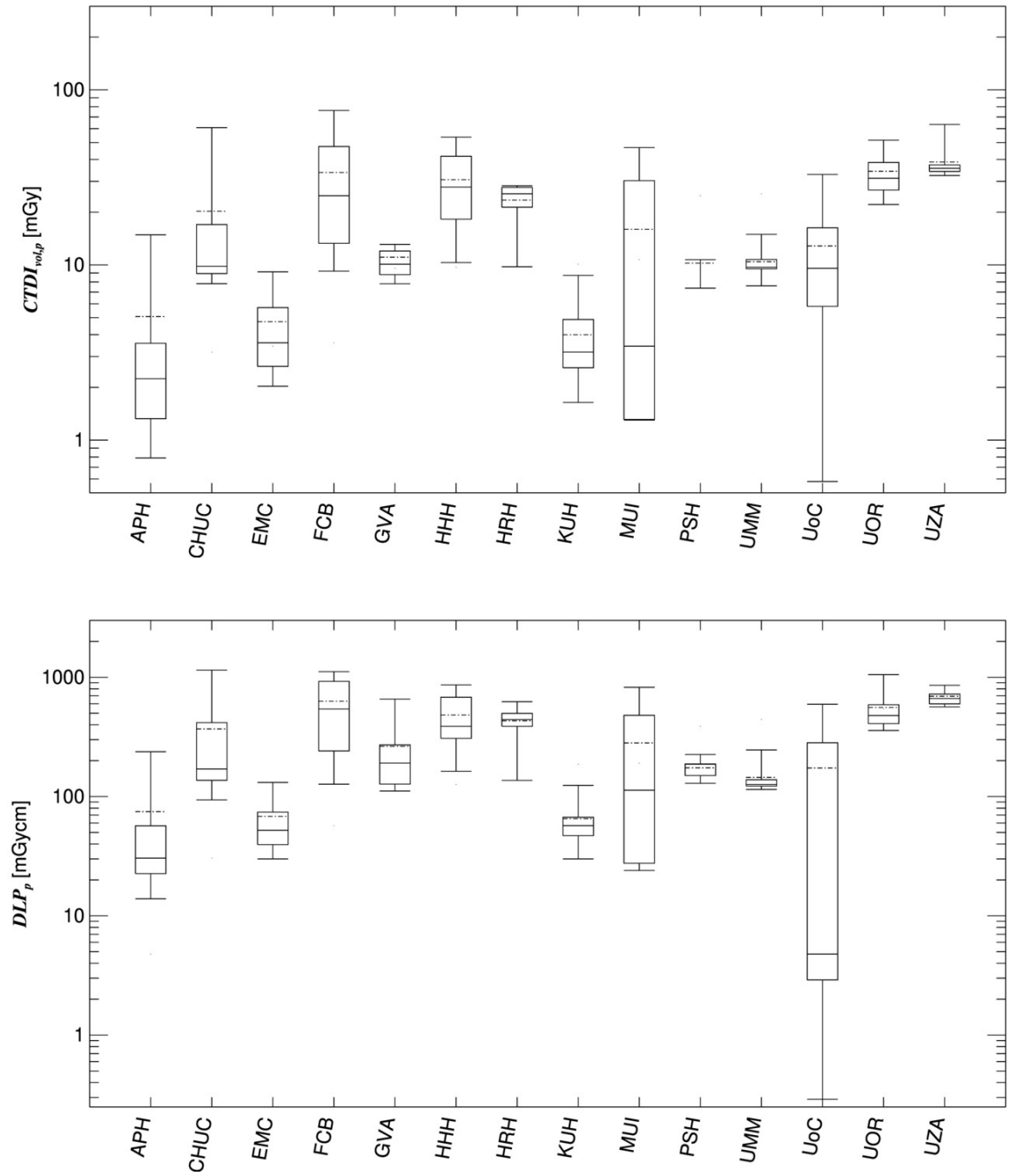


Figure 6: Data results for CI CT 6 (Coronary angiography - Vessels assessment)



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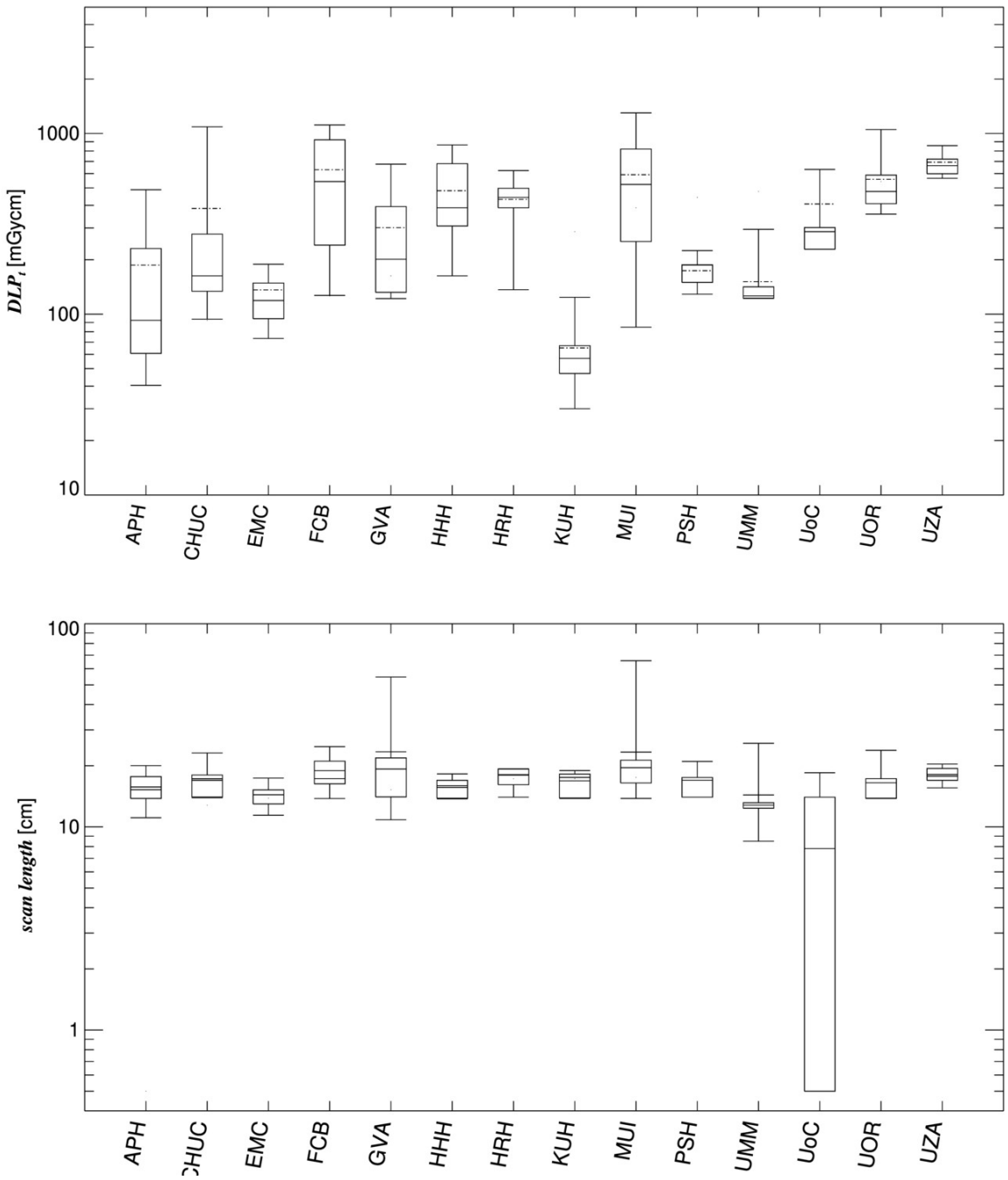


Figure 7: Data results for CI CT 7 (Lung cancer - Oncological staging, First and F-up)

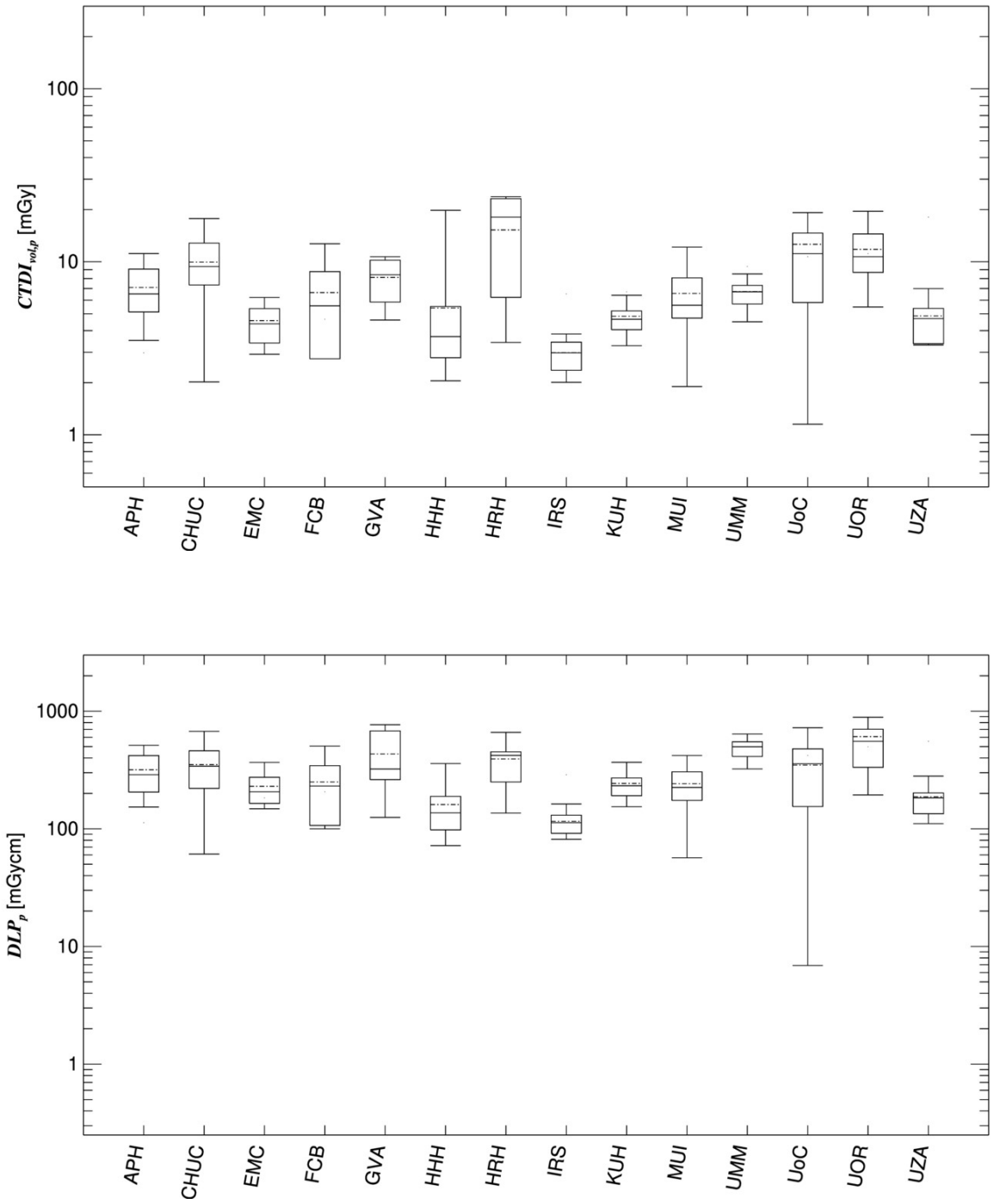


Figure 7 *(continued)*

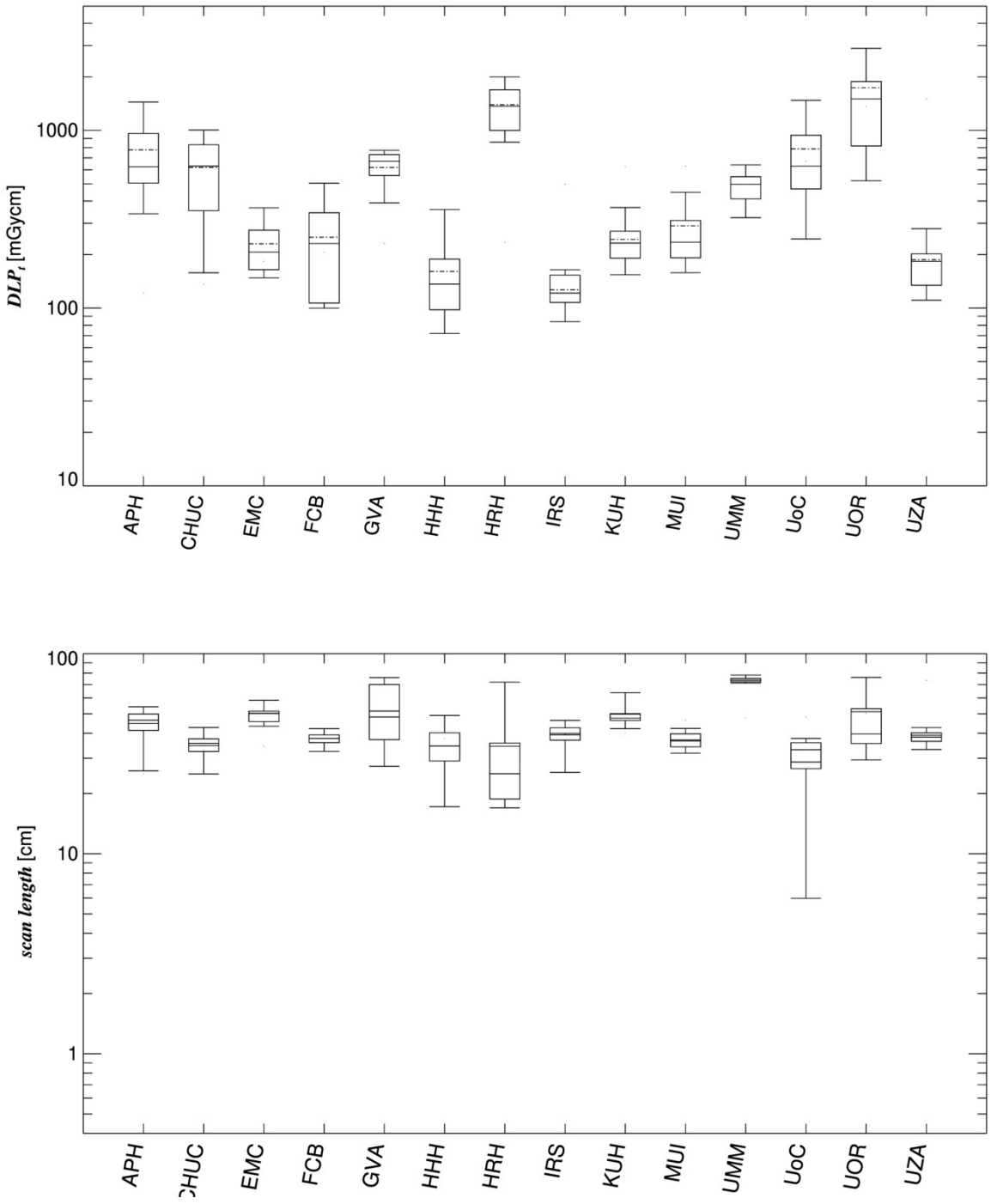


Figure 8: Data results for CI CT 8 (Hepatocellular carcinoma - Oncological staging)

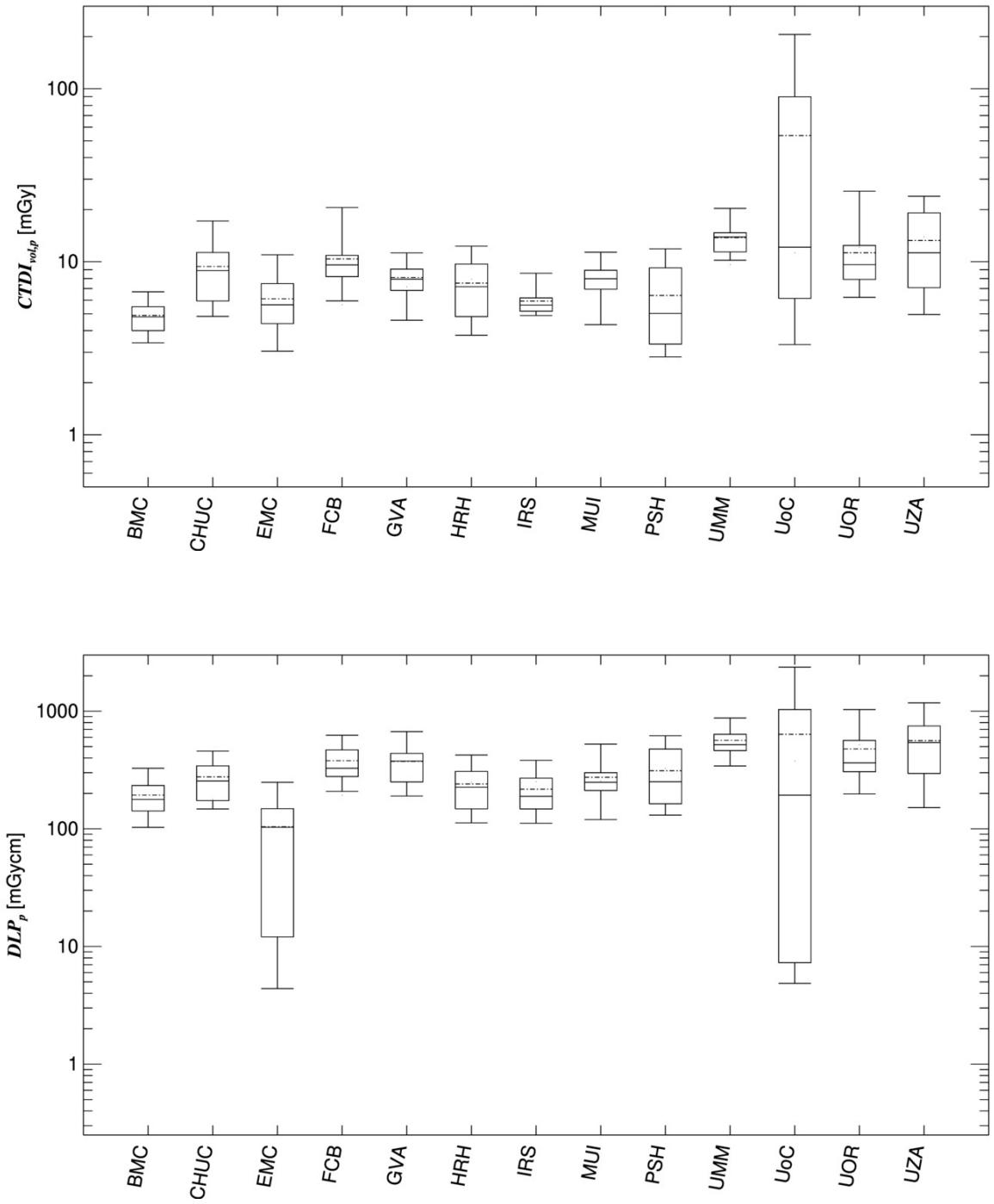


Figure 8 *(continued)*

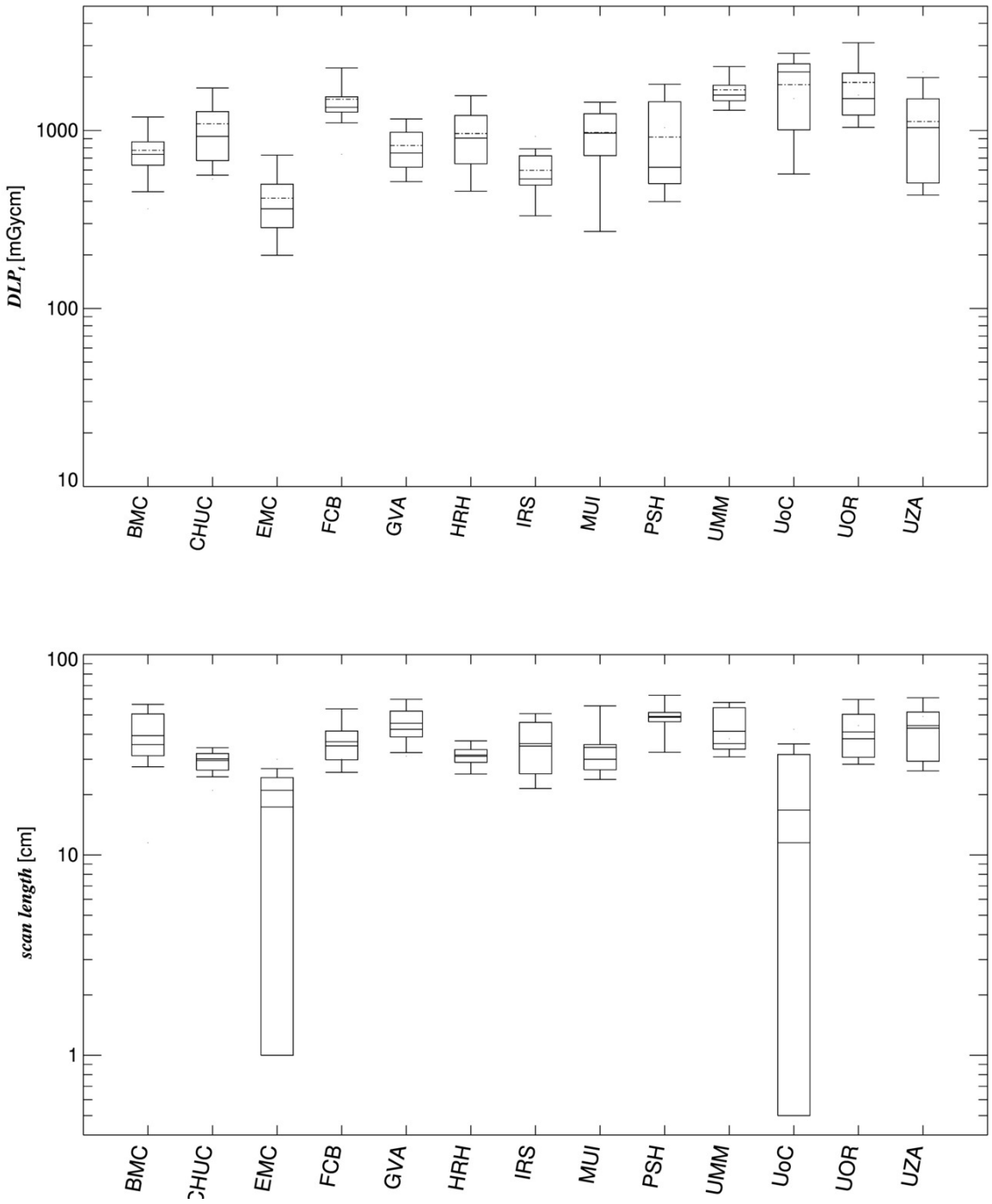


Figure 9: Data results for CI CT 9 (Colic / abdominal pain - Exclusion or detection of a stone)

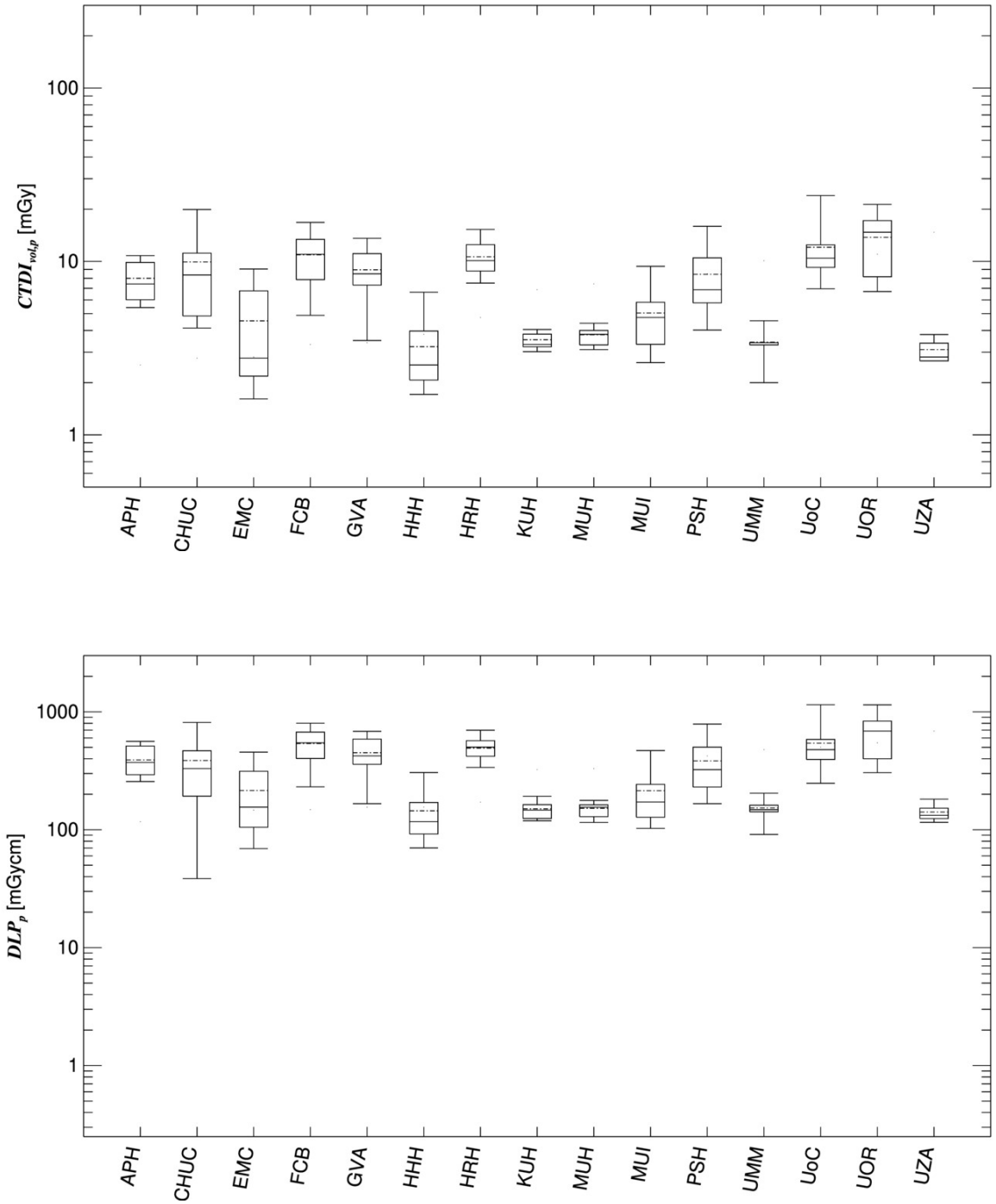


Figure 9 *(continued)*

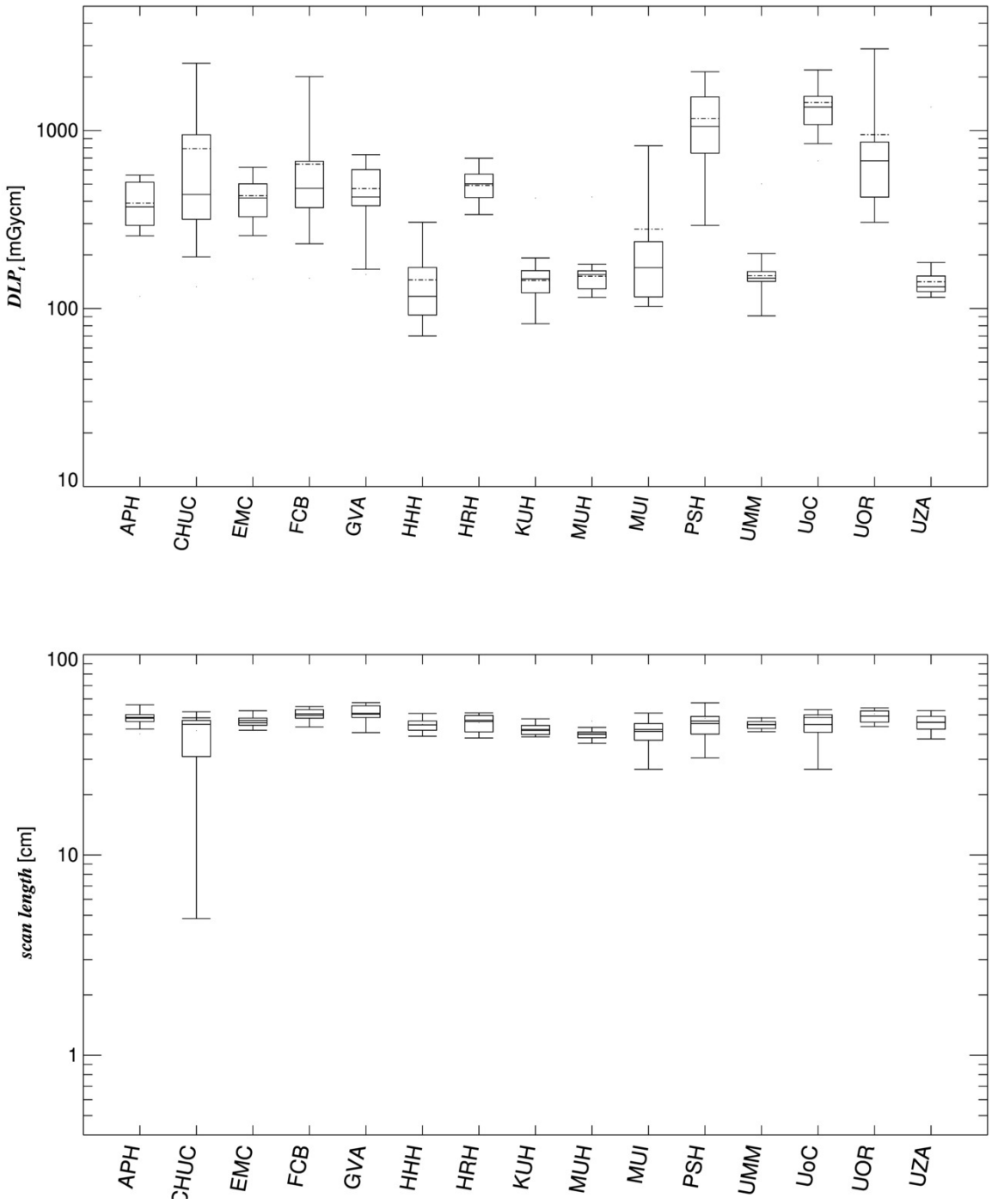


Figure 10: Data results for CI CT 10 (Appendicitis - Detection or exclusion)

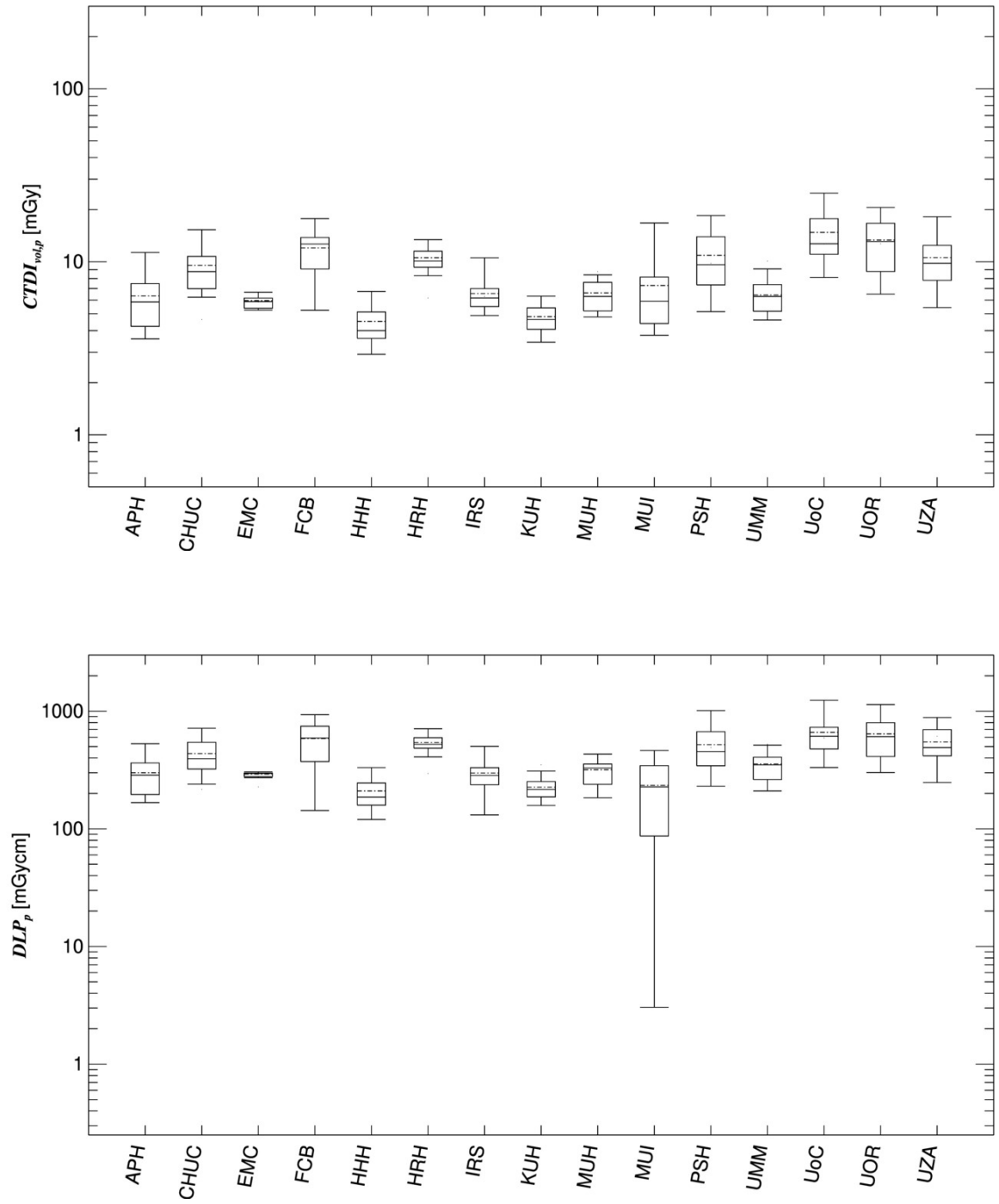


Figure 10 *(continued)*

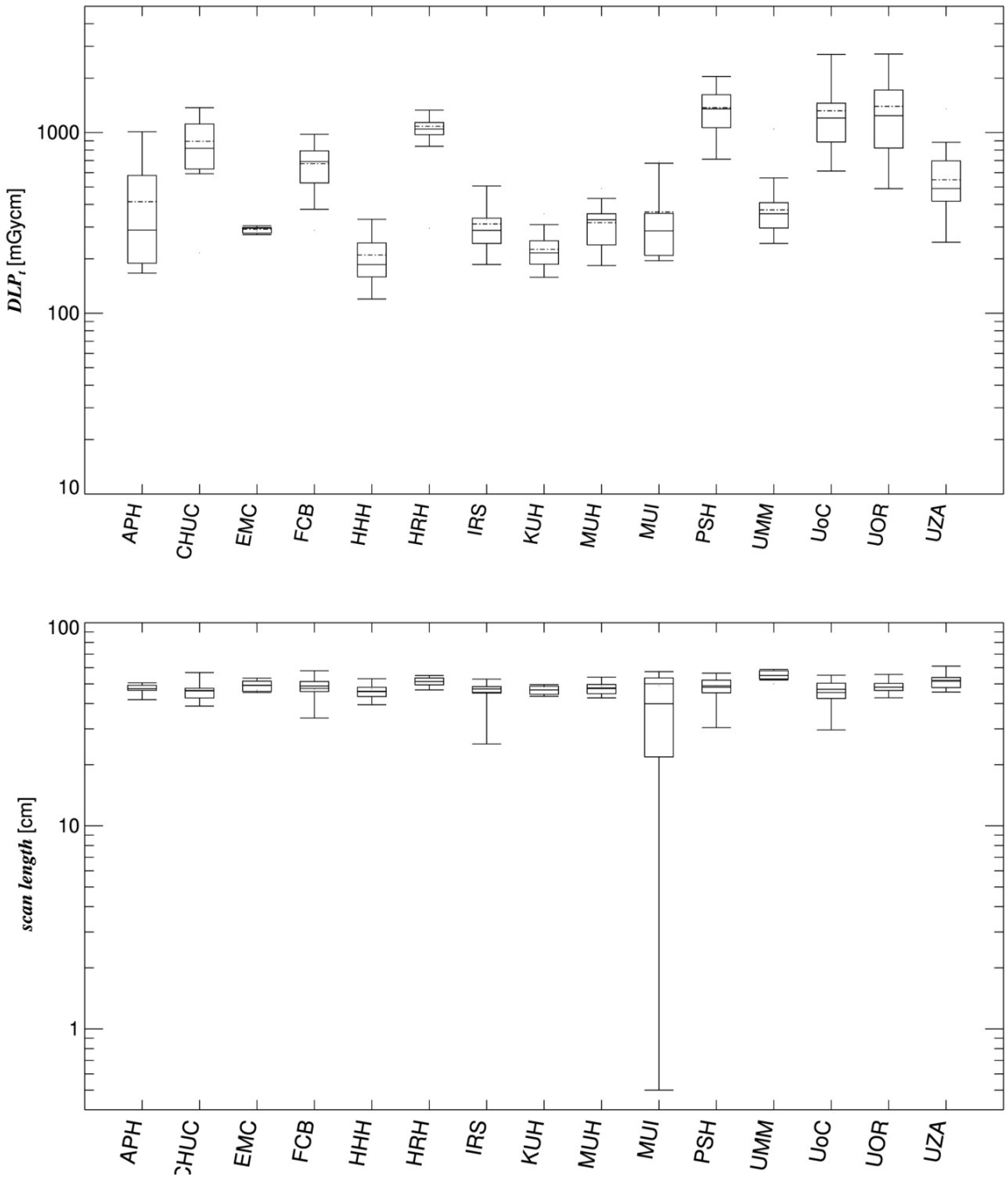


Table 30 presents the CT DRLs for the ten clinical indications investigated in the survey.

CI	clinical indication	$CTDI_{vol,p}$ (mGy)*	DLP_p (mGy.cm)	DLP_t (mGy.cm)	scan length (cm)
1	Stroke - Detection or exclusion of a haemorrhage	48	807	1386	18
2	Chronic sinusitis - Detection or exclusion of polyps	11	188**	211	16
3	Cervical spine trauma - Detection or exclusion of a lesion	17	455	495	23
4	Pulmonary embolism - Detection or exclusion	9	307	364	35
5	Coronary calcium scoring - Risk stratification	4	72	81	17
6	Coronary angiography - Vessels assessment	25	415	459	17
7	Lung cancer - Oncological staging, First and F-up	8	348	628	47
8	Hepatocellular carcinoma - Oncological staging	9	354	1273	37
9	Colic / abdominal pain - Exclusion or detection of a stone	8	436	480	48
10	Appendicitis - Detection or exclusion	9	498	874	49

**$CTDI_{vol,p}$ represents the mean $CTDI_{vol}$ of all phases*
*** Chronic sinusitis DLP_p reflects data coming from small number of patients (14 patients in total) with more than 1 phase and DLP values much higher than those with only 1-phase protocol*

Table 30: DRL values for the ten CT clinical indications

Data analysis showed that:

- Stroke and hepatocellular carcinoma are the two CIs with the highest DLP_t DRL, 1386 mGy.cm and 1273 mGy.cm respectively.
- Stroke $CTDI_{vol,p}$ DRL is the highest of all CIs.
- Coronary calcium scoring has the lowest DRL values of all ten CIs.
- There are large differences in patient dosimetric values between hospitals. This is shown both in individual analysis and in comparing all countries and hospitals together.
- There are large differences between DRLs for clinical indications that were referring to the same anatomical region. An example is CI CT 9 and CI CT 10, with DLP_t 480 and 874 mGy.cm respectively (abdomen area). Another example is CI CT 5 and CI CT 6, with DLP_t 81 and 459 mGy.cm respectively (coronary arteries investigation).
- Scan lengths of 1 cm were observed. These values were discussed and confirmed with data managers and members of the SB. They result from "pre-monitoring", "monitoring", or "bolus tracking" phases considering the names of the corresponding phases provided by the participating centres. These phases are used to highlight the arrival of (a bolus of) injected contrast media in the vessel being imaged. For this examination, the visualisation of a small body layer (with a length of approx. 1 cm) is sufficient.

Further statistical analysis was performed in the attempt to understand the influence of scanner age, reconstruction algorithms, tube current modulation (TCM) and other variables on scanner output acknowledging the fact that data are limited and also highly variable. The statistical analysis was performed by subgrouping radiation dose in terms of $CTDI_{vol,p}$ according to the CIs and the following criteria:

A Year of installation: based on the year of installation of the scanner operated in the reporting facilities, scanners were grouped as follows: <2011, 2011-2014, >2014;
B Use of spiral or sequential mode;
C Availability and use of tube current modulation;
D Availability and use of iterative reconstruction algorithms;
E Manufacturer: the four manufacturers (GE, Philips, Siemens, and Toshiba);

The statistical significance of differences of radiation dose between the defined subgroups was tested using either the Mann-Whitney or the Kruskal-Wallis test depending on how many subgroups were considered. All statistical tests were performed at a significance level of p=0.05.

As shown for A, C, and D in detail in Tables 31-33, statistical significance was found for the following CIs:

A 1,2,3,7,8,10;
B 1,2,3,6,8;
C 1,2,3,5,6,8,9,10;
D 1,2,3,4,6,7,8,9,10;
E 1,2,3,4.

Examples are shown in Tables 31-33. Despite the use of some dose reduction tools in daily routine, the heterogeneity found in the dose descriptor values suggests that there is a need for practitioners to make their use more efficiently. $CTDI_{vol,p}$ values in some CIs are higher for newer CT systems (installation after 2014), for equipment with iterative reconstruction algorithm (IRA) compared to the conventional filtered back projection (FBP) and examinations with activated TCM compared with cases where TCM was not activated.

CI	N before 2011	N 2011-2014	N after 2014	$CTDI_{vol,p}$ before 2011	$CTDI_{vol,p}$ 2011-2014	$CTDI_{vol,p}$ after 2014	p
1	168	628	68	50	34	42	<1.0e-8
2	87	301	100	11	8	7	2,10E-02
3	66	286	93	20	19	13	7,30E-03
4	157	350	81	9	6	11	<1.0e-8
5	134	156	76	9	5	4	2,80E-01
6	155	192	143	20	22	10	2,50E-12
7	110	296	250	8	6	15	<1.0e-8
8	371	158	374	10	8	14	3,60E-11
9	159	380	95	8	5	11	<1.0e-8
10	89	276	157	10	8	9	1,20E-06

N number of patients, CI: clinical indication, p: computed probability

Table 31: Correlation of mean $CTDI_{vol,p}$ with year of installation

CI	N (IRA)	N (FBP)	$CTDI_{vol,p}$ (IRA)	$CTDI_{vol,p}$ (FBP)	p
1	706	154	34	55	1,20E-19
2	432	48	8	11	6,00E-05
3	387	56	17	25	1,50E-03
4	434	151	7	8	1,30E-02
5	272	93	7	6	5,10E-01
6	400	88	21	6	4,20E-29
7	585	70	10	8	1,20E-01
8	656	229	12	9	7,40E-04
9	562	63	6	10	2,00E-07
10	479	37	9	11	2,70E-04

N number of patients, CI: clinical indication, p: computed probability

Table 32: Correlation of mean $CTDI_{vol,p}$ with use of reconstruction algorithms (IRA or FBP)

CI	N (TCM on)	N (TCM off)	$CTDI_{vol,p}$ (TCM on)	$CTDI_{vol,p}$ (TCM off)	p
1	671	193	35	49	5,40E-15
2	319	169	6	12	5,00E-05
3	415	30	17	23	1,50E-02
4	563	25	7	8	7,90E-01
5	241	125	8	3	4,20E-08
6	378	112	21	8	6,00E-29
7	652	4	10	8	2,40E-01
8	876	27	11	14	7,40E-03
9	597	37	7	4	6,80E-07
10	500	22	9	8	1,10E-01

N number of patients, CI: clinical indication, p: computed probability

Table 33: Correlation of mean $CTDI_{vol,p}$ with use of TCM

Comparison with recent literature is shown in Tables 34 and 35 for $CTDI_{vol}$ and DLP.

N		$CTDI_{vol}$				
	CI	EUCLID 2020	Oldenburg et al. 2019 [44]	Habib Geryes et al. 2019 [19]	PHE 2011 [45]	Schegerer et al. 2017 [7]
1	Stroke	50	53	44	60	
2	Chronic sinusitis	11	21			
3	Cervical spine trauma	11	30	31		
4	Pulmonary embolism	9	15	8	13	15
5	Coronary calcium scoring	4	7			8
6	Coronary angiography	25	31			20
7	Lung cancer, First and F-up	8	15			
8	Hep carcinoma - Onc. staging	9	14			
9	Colic (det of stone)	8	14	8	10	
10	Appendicitis	9	16	9		

Table 34: Comparison of EUCLID $CTDI_{vol,p}$ DRLs with recent literature

N		DLP_t				
	CI	EUCLID 2020	Oldenburg et al. 2019 [44]	Habib Geryes et al. 2019 [19]	PHE 2011 [45]	Schegerer et al. 2017 [7]
1	Stroke	1386	1076	1010	1000	
2	Chronic sinusitis	181	373			
3	Cervical spine trauma	490	962	640		
4	Pulmonary embolism	364	558	310	440	
5	Coronary calcium scoring	81	102			120
6	Coronary angiography	459	915			328
7	Lung cancer, First and F-up	628	858			
8	Hep carcinoma - Onc. staging	1273	2016			
9	Colic (det of stone)	480	773	400	460	
10	Appendicitis	874	1059	610		

Table 35: Comparison of EUCLID DLP_t DRLs with recent literature

Comparison shows the large variability between DLP_t for some clinical indications such as stroke, oncological staging or appendicitis. For stroke, all DRL $CTDI_{vol}$ values reported are comparable. However, this is not shown for DRL DLP_t; the three studies report comparable results whereas EUCLID DLP_t DRL is about 1.3 times more (possibly due to number of phases, scan length or perfusion part). For appendicitis, the EUCLID $CTDI_{vol,p}$ DRL value is comparable to the $CTDI_{vol}$ reported by Habib Geryes et al. [19] and half of the value reported by Oldenburg et al. [44]. One would then expect that DRL DLP_t would follow the same pattern. This is not shown in the EUCLID results, pointing to differences in number of phases or scan length.

Summary points on CT results:

1. The analysis of the data obtained from the surveys shows that there is a need to develop knowledge, skills and competences of health professionals involved in the use of CT equipment to improve the use of dose reduction tools available in CT equipment. The results imply that more efforts are needed towards training end users on using low-dose features and taking an active part in CT optimisation. As HERCA clearly stated in the respective position paper:

   "*CT dose optimisation through the use of dose reduction and dose management tools can only be made possible if radiologists and other imaging specialists, medical physicists, CT technologists and CT manufacturers work together as a team*" [5].

   Specifically, for CT manufacturers the HERCA paper mentioned explicitly that they are responsible for providing the CT end user not only with just the tools dose optimisation and management but equally important the extensive education and training on the use of these tools.

2. DRLs based on clinical indication vary between centres or countries possibly also due to variable number of phases or scan length.

   Apart from stroke, EUCLID CT DLP values are in general lower than those reported in the recent literature.

7.1.2 IR DRLs based on clinical indication

The figures shown below (11-14) present the main technical parameters that were considered for defining DRLs (P_{KA}, T, $K_{a,r}$) for the four clinical indications separately. The figures contain a varying number of hospitals depending on the procedure and/or the dose quantity. The variation is due to the fact that not all hospitals supplied data for all the clinical indications.

Although initially number of images (NI) was considered as one of the four quantities for DRL definition, the findings showed a large variability of data that could not justify the use of NI for DRL definition. During the data cleaning process and the extensive discussion with hospital data managers, the following conclusions were made:

1) Certain modern X-ray machines included in the survey provided the possibility to record either radiographic images or fluoroscopic images.
2) The operators chose to record either using the radiography or the fluoroscopic function during the procedure or depending on the features of the X-ray machine. It was therefore subject to the choice of the operator.
3) NI comparison between hospitals and countries showed that operators in certain hospitals used the radiography function for recording and reported low NI, in the order of tens of images (for example CHUC median NI value was seven with 5%-95% of 5-14 images for CI IR 1). Operators in other hospitals that utilised fluoroscopic feature for archiving reported NI in the order of thousands of images (FCB median NI was 17244 images with 5%-95% of 1600-62140 images for CI IR 1).
4) Despite the extensive follow up of hospitals, some participating centres did not understand what NI means (e.g. they provided the number of fluoroscopic images).

For figures 11-14: Solid horizontal lines: 5^{th}, 25^{th}, 50^{th}, 75^{th}, 95^{th} percentiles, dotted: arithmetic mean.
top figure: Air kerma-area product (P_{KA})
2nd figure: Fluoroscopy Time (T)
3rd figure: Air kerma at the patient entrance reference point ($K_{a,r}$)

Figure 11: Data results for CI IR 1 (Arterial occlusive disease of the iliac arteries - Angiographic diagnosis and endovascular treatment of arterial stenosis or occlusion causing Intermittent claudication or ischemia)

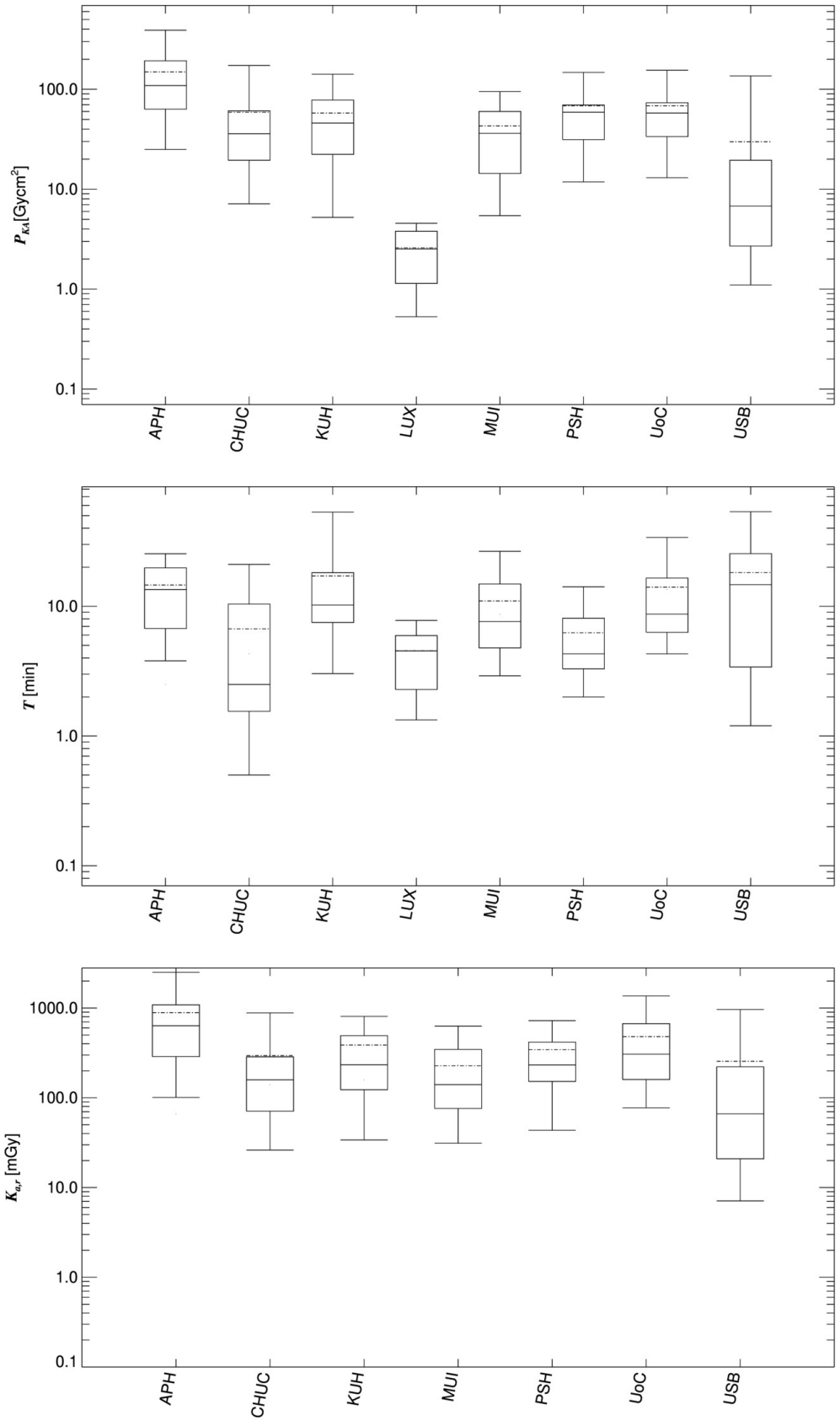


Figure 12: Data results for CI IR 2 (Localisation and treatment of hepatocellular carcinoma - Transarterial chemoembolisation (TACE))

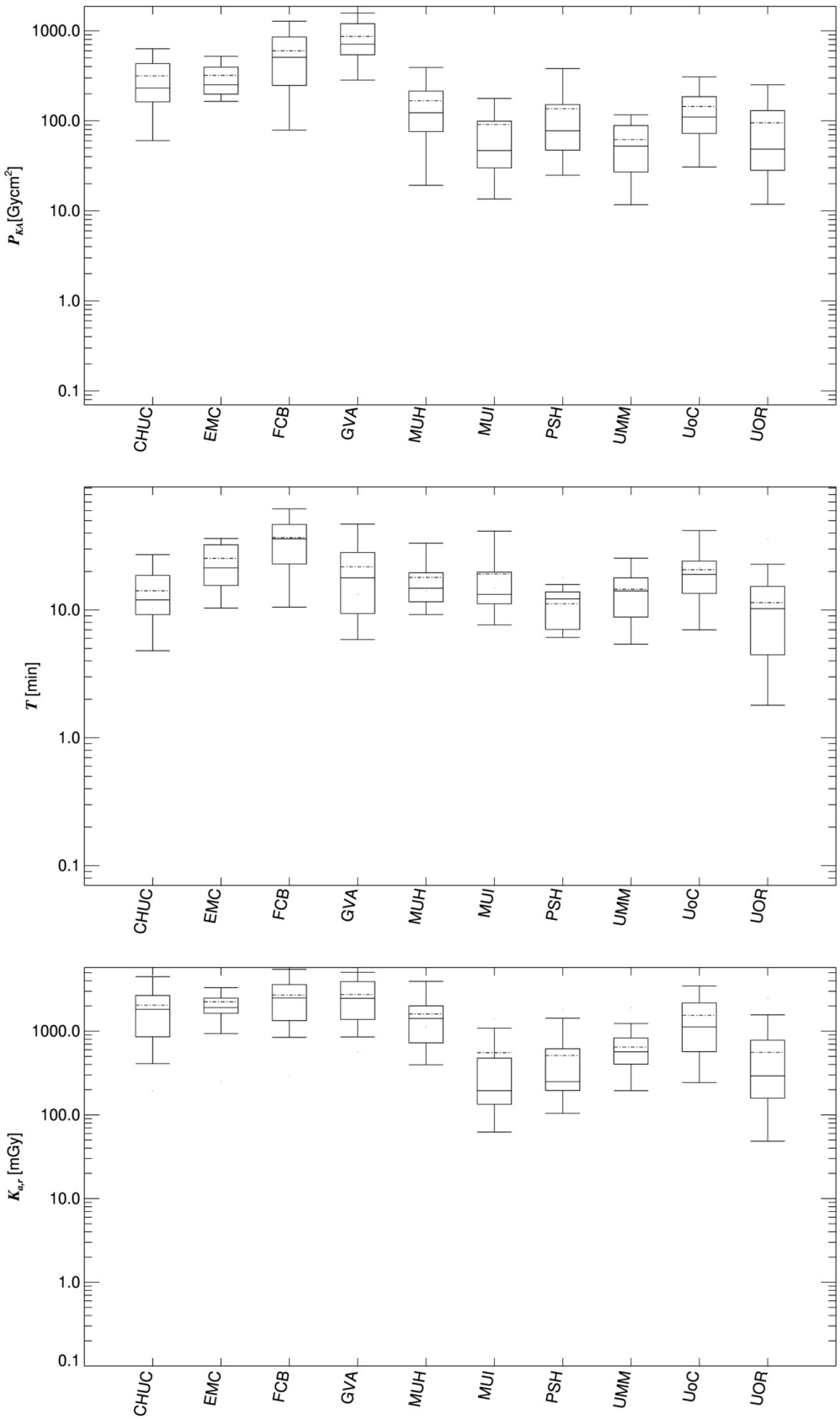


Figure 13: Data results for CI IR 3 (Arterial occlusive disease of femoropopliteal arteries - Angiographic diagnosis and endovascular treatment of arterial stenosis or occlusion causing intermittent claudication or ischemia)

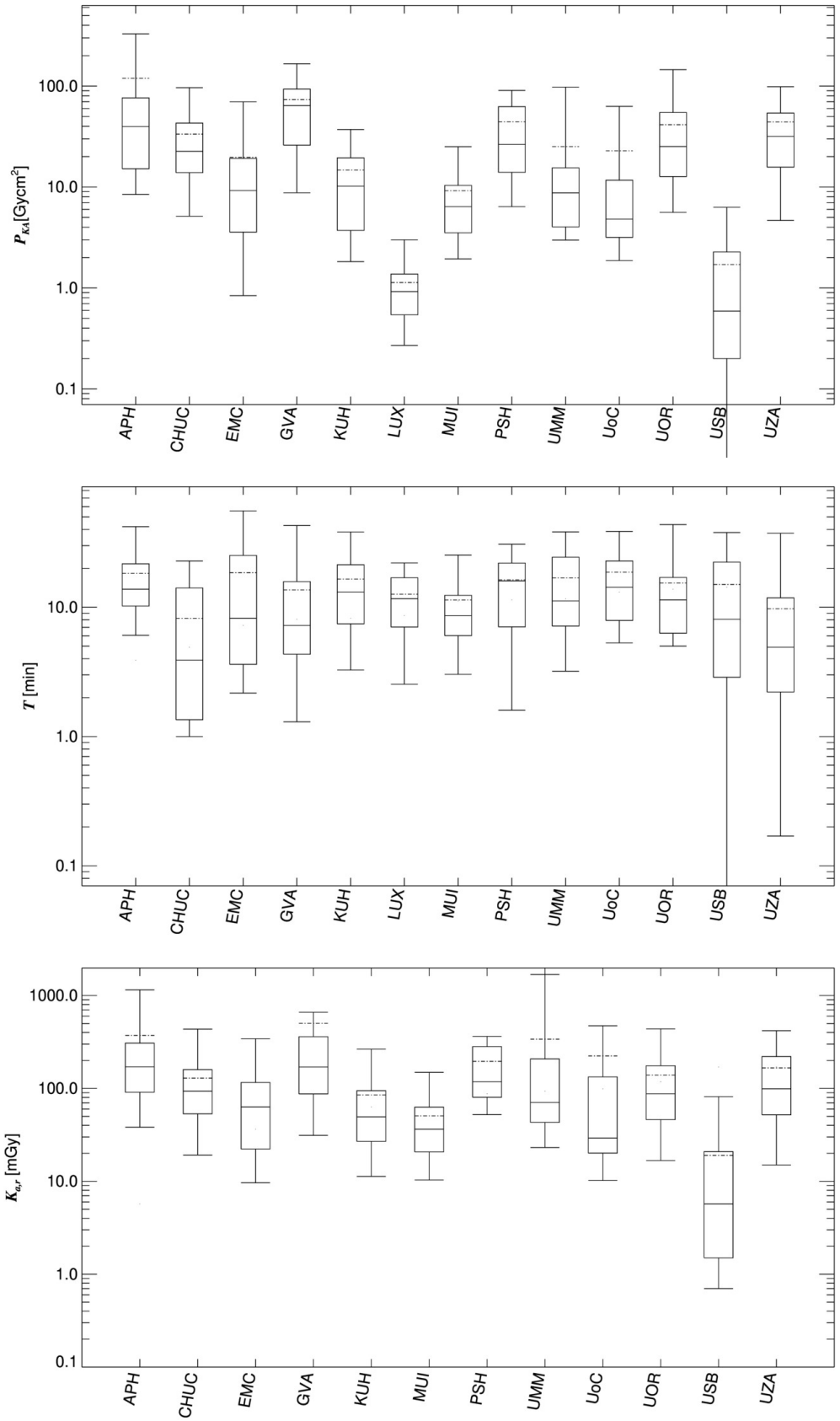
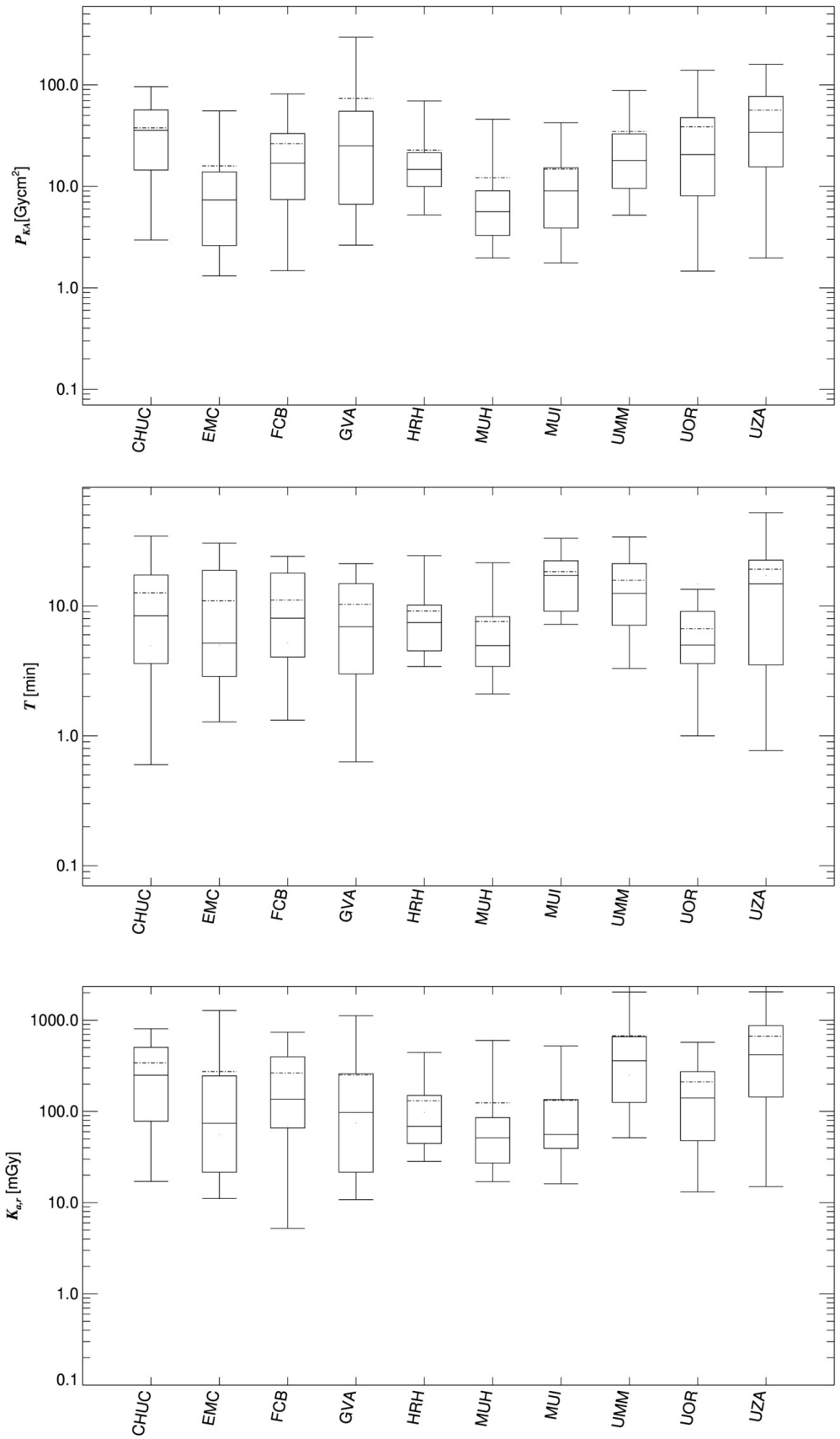


Figure 14: Data results for CI IR 4 (Biliary drainage - Localisation of biliary obstruction and percutaneous treatment of biliary obstruction)



According to the EUCLID project methodology, DRLs are 75% of the median values of each centre involved in this project. These are shown for all IR clinical indications in Table 36.

Clinical indication	P_{KA} (Gy.cm^2)	T (min)	$K_{a,r}$ (mGy)
Arterial occlusive disease of iliac arteries	57	10	251
TACE	241	18	1867
Arterial occlusive disease of femoropopliteal arteries	26	12	99
Biliary drainage	22	10	194

Table 36: DRL values for the four IR clinical indications

Data analysis showed that:

- TACE (CI IR 2) DRL value is the highest of all four IR DRLs.
- Biliary drainage (CI IR 4) DRL is the lowest of all four IR DRLs.
- Results show that P_{KA} is not correlated to fluoroscopy time.
- There are large differences in P_{KA} between hospitals. This is shown both in individual analysis and in comparing all countries and hospitals together.
- The low number of patients in each complexity level and in each operator experience level for individual hospitals did not allow us to draw firm conclusions per hospital. In general, grading complexity levels of procedures appeared to have too many uncertainties per hospital.

Further statistical analysis was performed in order to investigate whether radiation dose in terms of P_{KA} correlated to any of the technical parameters collected during the collection period. Correlation of P_{KA} was investigated for:

A Year of the installation: < 2011, 2011-2014, > 2014
B Availability and use of automatic exposure control function
C Manufacturer
D Operator skills of the user
E Complexity of case

The Mann-Whitney or the Kruskal-Wallis tests were used for statistical analysis and results were considered statistically significant when significance level was less than 0.05. According to our data, for arterial occlusive disease of the iliac arteries (CI IR 1), arterial occlusive disease of femoropopliteal arteries (CI IR 3), and biliary drainage (CI IR 4), newer X-ray machines seem to impart less radiation to the patient than older ones. The same is not found for CI IR 2. For CI 1-4, PKA increased between simple and high-complex procedures by 40%, 276%, 26%, and 232%, respectively. But this increase was significant for CI 2 and CI 4, only. Similarly, between medium- and high-complex procedures, PKA significantly increased for CI 2 and CI 4 by 50% and 118%, respectively. Further statistically significant correlations were not found. EUCLID procedures were mainly of low or middle complexity and, therefore, these findings should be considered preliminary.

It is difficult to compare our results with national DRLs reported for other countries due to the following reasons: (i) the values were reported for IR procedures and not for clinical indications; (ii) inconsistencies in the reported description of IR procedures; and (iii) missing information on clinical task, anatomical location, and technical procedure. With these limitations in mind, results of EUCLID are lower than those reported in studies within the last five years. The reason for the difference could be the time gap between the surveys and the evolution of technique within that period, in particular for the case of Ruiz-Cruces et al. (2016) [10] who collected data between 2010 and 2013. Another reason could be that participating hospitals were volunteers and belong to the "EuroSafe Imaging Stars" initiative. This might have led to select hospitals engaged in an optimisation program and to lower doses.

Clinical indication	Quantity	EUCLID 2020	Etard et al. 2017 [11]	Ruiz-Cruces et al. 2016 [10]	Schegerer et al. 2019 [9]	Schmitz et al. 2019 [46]
Arterial occlusive disease of iliac arteries	P_{KA} (Gycm^2)	57		170	87	
	T (min)	10		21	17	
	$K_{a,r}$ (mGy)	251				
TACE	P_{KA} (Gycm^2)	241	250	303	224	
	T (min)	18	28	26	25	
	$K_{a,r}$ (mGy)	1867	990			
Arterial occlusive disease of femoropoplite al arteries	P_{KA} (Gycm^2)	26		119	35	
	T (min)	12		30	18	
	$K_{a,r}$ (mGy)	99				
Biliary drainage	P_{KA} (Gycm^2)	22	35	30		24
	T (min)	10	16	17		13
	$K_{a,r}$ (mGy)	194	260	7		

Table 37: Comparison of IR DRLs with international literature

8. Conclusions and Recommendations

Conclusions

The main goal of the EUCLID project was to establish DRLs based on clinical indication through a European survey. A list of ten clinical indications for CT and four clinical indications for fluoroscopically-guided procedures for which DRLs are considered to be needed at European level was established in several consultation loops with the EAP and SB. An EU-wide study was performed to collect data from hospitals in order to establish DRLs based on clinical indication across Europe. To optimise the geographical coverage of the project, nineteen hospitals from fourteen countries were included in the network. The study presents "EUCLID DRLs based on clinical indication" for these CT clinical indications and IR indications. These values could be considered as the preliminary choice for the national CT and IR DRLs until national DRLs are established by an authoritative body.

The ICRP methodology was followed in order to define DRLs based on clinical indication. For CT, $CTDI_{vol,p}$, DLP per phase, scan length and total DLP were used as measures of DRLs. For IR, DRLs were defined in terms of kerma area product, cumulative air kerma at the patient entrance reference point and fluoroscopy time. The possibility of defining IR DRLs in terms of complexity of clinical case was also considered. Unfortunately, only a small percentage of examinations was deemed to be 'complex', so it was not possible to define DRLs based on clinical indication in terms of complexity.

Analysis of the CT data showed that there are large differences in patient dosimetric values and in CT techniques between hospitals, mainly due to a variable number of phases and/or different scan lengths. There is a need to develop knowledge, skills and competences of health professionals involved in the use of CT equipment to improve the use of dose reduction tools available in CT equipment. More efforts are needed towards training operators on dose optimisation on the same CT scanner used clinically.

EUCLID survey findings show that the installed base of CT and IR equipment in Europe is old. More than 30% of the CT scanners of the hospitals participating in the EUCLID project were ten years or older (installation year ≤ 2011, 32.8%). Moreover, a considerable percentage of IR equipment (23%) had an image intensifier instead of a digital detector.

The EUCLID project also provides an overview of existing DRLs for plain radiography at national level as per the information provided by the NCAs. The number of these DRLs per country varies greatly, from two to twenty-seven. Moreover, European DRL values were calculated for plain radiography. These values could be considered only as the preliminary choice for the national DRLs until appropriate national patient dose surveys have been carried out and national DRLs based on these surveys have been established by an authoritative body.

An important goal of the EUCLID project was the collection of information on the status of national DRLs and of DRLs based on clinical indication in Europe from NCAs, from literature, and from a workshop. Almost all countries have put in place a regulatory system for DRLs, in line with the current EU BSSD, and most countries have reported the implementation of relatively up-to-date, mainly anatomical, DRLs, with a periodic revision system. However, six countries out of the thirty-one surveyed did not report having any national DRLs in CT. Although some countries have national DRLs for all modalities, the relative paucity in IR and in the paediatric sector, as has been already highlighted in the PiDRL study [2], should be noted. It is encouraging that, during the workshop, several EU member states declared that the establishment of paediatric DRLs is included in their future plans.

In general, the DRL values reported by the participating countries were very heterogeneous for CT and IR and, to a lesser extent, for radiography. It has been shown that several factors and especially differences in acquisition protocols may contribute to the heterogeneity of results. A refinement of terminology, with the precise description of the clinical indication, should be encouraged in order to minimise any variation related to the meaning of the clinical indication.

In IR, the definition and use of complexity of the procedure looked to be challenging, and there is a need to cover a wider spectrum of clinical indications. For radiography, the impact of digital devices is not reflected in the data analysed because the EUCLID report was only based on the literature review and on previous studies such as Dose Datamed [3]. As regards paediatric imaging, there is little data and only a few countries have updated their paediatric DRLs.

In nuclear medicine the use of DRLs is limited. The establishment of European DRLs for specific applications of CT in multi-modality systems is challenging mainly for the following reasons: there are different clinical aims of CT scans; there is no standardisation in use of CT in nuclear medicine; and, there is a large variety in CT instrumentation.

Nuclear medicine DRLs are expressed in administered activities (MBq) rather than as absorbed doses. For adults there is still a wide variety of DRLs within the EU. There are clinical cases in which standard administered activities must be modified if one needs to decrease injected activity or decrease the acquisition time. There are also often issues of radiopharmaceutical shortage that result in changes of administered activities and causes problems if comparison with national DRLs is made. The everyday clinical practice in nuclear medicine shows that, even in countries in which national DRLs exist today, they are not applied in clinical practice and physicians frequently do not fully understand them and cannot use them in everyday clinical practice.

Dose management systems can facilitate data collection and help in establishing, updating, and using DRLs and, hopefully, will become widely available in all countries. In practice, if hospitals have dose data management systems, they could automatically send the data to national registries for national patient dose studies. This would be a convenient and easy way to establish and update national DRLs. European recommendations in this regard would facilitate the implementation of dose management systems. Their dissemination would dramatically impact the current data collection methodology for the establishment of national DRLs and the clinical practice through the development of local DRLs and may open the way for development of a European dose repository.

Recommendations for future work

CT DRLs are not reported in a similar way, as some are considering the exposure of the whole procedure whereas others are considering one phase only. Determination of CT DRLs taking into account all phases is recommended since they reflect the exposure conditions of the whole procedure. To avoid mistakes, common language should be used i.e. a set of radiology terms for DRLs establishment, use, communication and comparison of results should be determined. European guidance on a common lexicon should be set up to avoid the current difficulties caused by inconsistent use of terminology between and within institutions.

Radiation dose should be considered together with appropriate image quality. Assessment of clinical image quality is important to ensure sufficient diagnostic information and reduce the amount of examinations that provide inadequate information. The EUCLID project showed that image quality assessment for the determination of DRLs based on clinical indication is not a trivial or a simple task. Research studies and guidelines on image quality criteria are needed as this should be assessed relative to the indication of the examination.

The establishment of DRLs in IR presents a challenge because of various factors, including procedural complexity, influence patient dose. Further research work is necessary to understand the quantification of complexity of fluoroscopically-guided procedures and its usefulness in the establishment of DRLs.

Experience from EUCLID data collection shows that data cleaning and data verification are essential steps when establishing DRLs. Moreover, professional and ethical codes of conduct need to be considered (guarantee of anonymity, protection of personal data etc.). EUCLID developed a policy in order to clean and verify data and guarantee protection of personal data. However, European guidelines are needed on the above topics.

There are many differences from one country to another as regards the status of establishment of DRLs and their use, which highlights the opportunities which could result

from closer cooperation between countries, and between the different actors in the health systems, to overcome the barriers that currently exist. The approach to DRLs needs to be adjusted to the level of expertise and the infrastructure available in different countries. DRLs based on clinical indication can improve quality of care and promote safety in medical imaging. The latest EU guidance on the establishment and use of DRLs was published twenty years ago. Although European and international publications have been issued mainly on anatomical DRLs (Radiation Protection No 185 on PiDRL guidelines [2], Dose Datamed 2 project reports [3], and ICRP Publication 135 [4]) there is a need for an update of the EU guidance, including guidance for DRLs based on clinical indication and for an accepted Europe-wide list of indications.

Areas where collaboration at European level is considered important include: collaboration with vendors on standardisation of and automatic transmission of dose-related data; collaboration on defining ethics guidelines and identifying good practice; standardisation of protocols; establishment of national, regional and/or European dose repositories; stronger involvement and commitment of professional societies in the dialogue and collaboration; introduction of local DRLs based on clinical indication as a tool to further optimise radiological practice and the resulting collective patient dose; harmonisation of the terminology used to define the protocols specially in multiphase CT examinations; harmonisation of needed DRLs, as some countries have only a few whilst others have a large number.

The EUCLID workshop also clearly showed the need to move ahead towards the development of DRLs in the fields of cardiac procedures and nuclear medicine, where the lack of DRLs, as well as absence of the use of those that have been established, became evident. Healthcare professionals involved in these fields should be trained on how to use DRLs. Special attention should be given to interventional procedures as DRLs based on clinical indication should be defined for techniques that are clinically well-established, contribute significantly to patient care, or involve a relatively high radiation exposure for the patient and operator. Suggestions in cardiac procedures could be patent ductus arteriosus occlusion, atrial septal defect occlusion, pulmonary valve dilatation and diagnostic cardiac catheterisation, whereas for non-cardiac procedures a good candidate could be central venous catheter placement.

The development of paediatric DRLs based on clinical indication should be considered as a priority in future European Commission funded projects. In paediatric nuclear medicine, guidelines on the proper use of radiopharmaceuticals and standardised protocols with respect to the proper use of gamma cameras and hybrid systems are needed.

The EUCLID project showed that the establishment of DRLs based on clinical indication is an achievable task and broad European dissemination of the concept may be desirable given the impact of DRLs based on clinical indication on quality and safety. Results demonstrated the effectiveness and usefulness of a common methodology to determine values of DRLs based on clinical indication on a European scale, by collecting data from a set of hospitals and clinics representative of different practices across countries. It appears, however, that a prerequisite for such a development of acceptable European reference values would be to address the root causes of diverging practice in the different countries by stimulating cooperation between all stakeholders concerned, nationally as well as between countries. Special consideration should be given to the collaboration of industry with the end users as analysis showed that the technical features introduced for dose optimisation seem not used properly or not to be known. More efforts are needed towards training users on available tools for dose optimisation especially for CT. CT protocol design should not be done solely by manufacturers but tailored according to user needs.

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MJ-XA-21-001-EN-N

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of the European Union

ISBN 978-92-76-28565-6