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(EUCLID)

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List of Abbreviations

ACR	American College of Radiology
CBCT	Cone Beam Computed Tomography
CT	Computed Tomography
DLPs	Dose Length Products
DRLs	Diagnostic Reference Levels
EANM	European Association of Nuclear Medicine
EC	European Commission
EU	European Union
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
I-EP	Interventional Electrophysiological Procedures
IR	Interventional Radiology
LDRLs	Local Diagnostic Reference Levels
MSD	Maximum Skin Dose
NCAs	National Competent Authorities
NDRLs	National Diagnostic References Levels
NM	Nuclear Medicine
PAHO	Pan American Health Organisation
P_{KA}	Air kerma-area product [$Gy \cdot cm^2$], also known as KAP (Kerma Area Product)
SB	Scientific Board
WHO	World Health Organisation
WP	Work Package

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1. Introduction

The EUCLID project was launched in August 2017 with the goal of advancing the optimisation of radiation protection of patients in Europe.

A specific objective of the project was to

organise a workshop to disseminate and discuss the results of this project with Member States and the relevant national, European, and international stakeholders and to identify the need for further national and local actions on establishing, updating and using DRLs.

The workshop was held at the European Convention Centre Luxembourg on Monday 9th and Tuesday 10th December 2019. Attendance was free of charge and based on an invitation-only basis at the request of the European Commission and due to restrictions based on the venue size.

The Project leaders, in consultation with the European Commission invited representatives from National Competent Authorities from all European Union member states, plus Switzerland and Norway. Additionally, experts from various national and international radiation protection bodies and health organisations were invited. Furthermore, experts from various (sub)specialty societies, representatives of relevant projects, and other selected experts and stakeholders, as well as representatives from hospitals participating in the EUCLID study, members of the Scientific Board, and members of the External Advisory Panel were invited to attend.

Attendance was affected by transport strikes in France; however, the workshop was well attended: the first day of the workshop was attended by 59 participants, with a further 10 participants joining via teleconference. The second day of the workshop was attended by 60 participants, with a further 6 joining via teleconference.

In the following, more detailed information on the workshop session summaries and conclusions will be provided. The complete workshop programme, list of attendees, and slides presented during all sessions are included as Appendices.

2. Session Summaries

Session 1: Opening and Scene Setting

Aims of session

The main aim of session 1 was to set the scene for the workshop i.e. to provide information about DRLs in the radiological protection system, explain how DRLs can improve quality of care and promote safety in medical imaging, and explain the advantages of establishing DRLs for the most important clinical indications. Moreover, an overview of EUCLID project was provided.

Key points

- Member States must establish, regularly review, and use DRLs.
- Establishment of clinical DRLs is important because different image quality is needed for different clinical indications of the same anatomical area.



- The EUCLID project has established DRLs for 10 Computed Tomography (CT) indications and 4 fluoroscopically guided / Interventional Radiology (IR) procedures by collecting data from 14 European member states.

Summary of presentations

1st speaker (Michael Hubel) provided information about the new European Basic Safety Standards Directive (Council Directive 2013/59/Euratom) and articles on DRLs. There are important new obligations for Member States: they have to not only establish, but also regularly review and use DRLs to optimise patient radiation protection. The speaker presented the results of the paediatric DRL (PiDRL) project. Results were not very encouraging since less than half of EU Member States had paediatric DRLs and only about one fifth were based on EU members' own dose surveys. He also presented the situation with adult DRLs according to the DoseDataMed survey published in 2015. Most Member States had some DRLs for adult patients, but the values diverge considerably between Member States and sometimes do not seem to correspond to the reported national mean effective doses. The latest EU guidance was published 20 years ago and there is a need for an update. The ICRP recommends taking into account the clinical indication, specific imaging protocol etc. but most existing DRLs in the EU are simply based on the anatomic region. National DRLs based on clinical indications are rare. The EC decided to launch the EUCLID project to explore the feasibility of establishing DRLs based on clinical indications through a survey of selected hospitals in 14 Member States. The EUCLID workshop provides an opportunity to discuss with Member States their progress in establishing and using DRLs and the needs for further national and European advances in this field.

2nd speaker (Colin Martin) explained that several different components are needed in hospital systems: professional skills and collaboration, methodology and technology and organisational processes. He presented a methodology to achieve optimisation involving analysis and evaluation of radiological images, patient dose audit and evaluation of X-ray equipment performance testing and calibration and he explained the place of DRLs in optimisation strategy.

3rd speaker (Jenia Vassileva) presented the international BSS and specific aspects of dose optimisation. She presented the definition of DRLs and mentioned that numerical values of DRLs are not provided in the international BSS. Comparisons of local data with the national DRL value should trigger the first step in the optimisation process. Once the investigation has revealed the reasons for any higher values of DRL quantities, remedial action needs to occur. The speaker also focused on the main difficulties associated with DRLs and dose optimisation and possible solutions (increasing the number and recognition of medical physicists, improving training in radiation protection, funding etc.).

4th speaker (Maria Perez) presented DRLs as tools for improving the quality of health care. Achieving universal health coverage is a priority for health authorities. Advancing universal health coverage encompasses safety and quality. Implementing DRLs contributes to improving quality of health care. She stressed that optimisation and use of DRLs is one of the priorities of the Bonn Call for Action. Practitioners should understand their role in the optimisation and use of Clinical Diagnostic Reference Levels (DRLs based on clinical indication). Once a procedure has been justified, it must be performed in such a way as to optimise patient protection. DRLs should be defined separately for different clinical indications if these require different image quality.



5th speaker (Guy Frija) explained why DRLs based on clinical indication rather than anatomical DRLs are needed. Different image quality is needed for different clinical indications of the same anatomical area. The number of phases depends on the clinical indication. Moreover, the scanning length depends on the clinical indication. The speaker provided many examples to demonstrate the importance of DRLs based on clinical indication. He also briefly presented the aims and main activities of the EuroSafe Imaging campaign.

6th speaker (John Damilakis) provided an overview of the EUCLID project. The project is divided into 5 work packages (WPs). WP1 is responsible for the management and general coordination of the project, as well as for dissemination of activities. The main aim of WP2 was to create a list of CT and IR clinical indications for which DRLs should be established. The objective of WP3 was to develop and implement an EU-wide study (survey) to collect data from hospitals across Europe following a methodology predefined by the project team in accordance with the most up-to-date international recommendations. The main responsibility of WP4 was to define a data analysis methodology, collate and analyse results and establish clinical DRLs. WP5 was responsible for the organisation of the EUCLID workshop in Luxembourg.

Summary of discussion

This was a 'setting the scene' session and due to lack of time there was no discussion.

Actions to take / Conclusions from session

The approach to DRLs must be geared to the level of expertise and the facilities available in a country. DRLs based on clinical indication can improve quality of care and promote safety in medical imaging. However, practitioners should understand their role in dose optimisation and use of DRLs based on clinical indication. The latest EU guidance on the establishment and use of DRLs was published 20 years ago and there is a need for an update.



Session 2: The EUCLID Project: Methodology and Main Results

Aims of session

The aim of this session was to remind attendees of the EUCLID project's methodology and present the project's main results.

Key points

- Large differences between hospitals were found due to the number of phases for CT.
- No relation was found between exposure and equipment age.
-

Summary of presentations

1st speaker (G. Frija) explained how the list of clinical indications was established and the challenges that were faced: the frequency, dose relevance, and naming/ambiguity. Involved in this process were the National Competent Authorities, Scientific Board, and external expert bodies (European Society of Cardiology and European Association of Nuclear Medicine). Two surveys were conducted: one in 2018, and a follow-up in 2019. A literature review was also conducted. By September 2019, questionnaires had been sent to 31 countries. All except one replied. 24 responded that they did have some form of DRLs. However, only 5 reported that they had DRLs based on clinical indication. These often-used similar indications, but the number of phases and the protocols used were not commonly mentioned.

For each clinical indication chosen for the EUCLID project, in order to obtain an overview of what protocols are used in practice, it was left to the participating centres to decide which phases they would include. A similar approach was used in the UK.

Large variations were reported in DLP values (e.g. 100% for kidney stones). This suggested that, in some clinical context, either terminology is not used precisely enough, or protocols have some differences, or maybe both.

2nd speaker (J. Damilakis): Provided an overview of the data collection stage of the project (WP3), the objective of which was to develop and implement a survey to collect data from European hospitals following a methodology predefined by the project team in accordance with the most up-to-date international recommendations. The issues of: i) what data would need to be included to successfully establish DRLs based on clinical indication; and, ii) how privacy could be protected, were also considered during this process. Data verification was conducted by the Scientific Board (SB), which was comprised of representatives from national regulatory authorities and national professional/scientific societies from each of the 14 countries with participating centres.

The hospitals involved in the network were briefly introduced. This was followed by a discussion on the information (quality control, dosimetry, image quality, body size, equipment) needed from each.

For IR: complexity and experience of the operator were considered. Surrogates of exposure reported by IR systems were briefly explained.

In terms of image quality, there should always be a system in place to judge whether image quality is adequate for the diagnosis according to the indication of the examination.



Questions were included on the survey, for both CT and IR, asking about image quality. The inclusion of DICOM reports was also encouraged. For fluoroscopy guided procedures, not only were questions about the experience of the clinician included, but also questions about the complexity of the procedure.

The data collection platform was introduced and briefly explained. This was established by EIBIR using the redcap software system. The key feature was security. All data managers from participating centres were trained on using the system. Most centres ended up providing more data that was originally agreed.

3rd speaker (V. Tsapaki): Provided an overview of the data analysis stage of the project (WP4) and gave a presentation of the main results. International Commission on Radiological Protection (ICRP) methodology was strictly adhered to, thus, CDTIvol (per phase) and total DLP (per study) were used as measures of CT DRLs. However, the DLP per phase and scan length were also considered for CT.

For IR, DRLs were defined in terms of: Air kerma-area product (P_{KA}); (Cumulative air kerma at the patient entrance reference point; T (Fluoroscopy time); and, NI (Total number of images). The consortium also considered the possibility of defining IR DRLs in terms of complexity of clinical case. In order to evaluate complexity of case the paper of Ruiz-Cruces et al was followed (i.e. grading difficulty as low, medium, or high). Ultimately, only 6% of data collected was deemed to be 'complex'. Again, ICRP methodology was followed, taking the rounded 75% percentile values to define the DRLs.

The key results in CT and IR were presented. Large differences were found between data sets from different centres. This may be because, in multi-phase procedures, different centres employed different sequences. Terminology also differed between centres. Some potential reasons for this were discussed. Features that manufacturers provide are not well utilised for optimisation.

It was ultimately decided not to define DRLs in terms of number of images.

ACR (American College of Radiology) CT DRL values were found to be higher than the ones reported in the EUCLID project.

Summary of discussion

Diagnostic quality should not be sacrificed just to 'hit numbers' selected to minimise dose or noise levels. A 'standard patient' remains an extremely valuable approach.

The distribution of values is also important to consider. The value distribution may be far more informative in terms of identifying errors.

It was suggested that the ICRP and IAEA should call on industry to use the same dosimetric units. HERCA recommendations should also be more broadly known – a new standard has been drafted and will be adopted for P_{KA} meters soon.

Actions to take / Conclusions from session

The EUCLID list of DRLs was well received. However, the EUCLID results need to be more comprehensively analysed. How to explain DRL variations across centres remains an issue.



Session 3: Considerations in Conducting Surveys to Establish DRLs

Aims of session

The main aim of session 3 was to discuss technical aspects of surveys designed to establish DRLs such as sample size, image quality assessment, data cleaning, the role of dose management systems and complexity indices in IR.

Key points

- Dose management systems can facilitate data collection and help in establishing, updating, and using DRLs.
- During dose data collection for DRL establishment, there should be a system in place to evaluate image quality.
- Data cleaning is an important process of detecting and correcting inaccurate records.
- For some IR procedures, the impact of the procedural complexity on patient doses is important and should be taken into consideration when establishing DRLs.

Summary of presentations

1st speaker (David Celier) presented 2 types of samples that should be considered i.e. the sample of hospitals and the sample of patients. If the number of institutions is too low, the 3rd quartile of the typical doses may be non-representative of the real practice in the country or the region. When the number of patients is too low, the median value (typical dose) may be non-representative of the real practice of the institution. Although a large sample size will reduce the statistical uncertainties it is difficult to include a very large number of institutions asking them to collect many examinations. The speaker presented the number of patients per sample for each modality recommended by the EC (RP 185, RP 109), IAEA and ICRP. Dose management systems will help within the next few years to make the sample sizes (institutions and patients) larger and decrease statistical uncertainties.

2nd speaker (Federica Zanca) presented the role of dose management systems in conducting DRL surveys. She explained how these systems can: facilitate data collection; help in establishing, updating, and using DRLs; check patient positioning; and, provide dose information for the patients' report etc. An important advantage is that they can identify population groups which undergo high number of imaging exams. If hospitals have dose data management systems, they could automatically send the data to national registries for national patient dose studies. This is a convenient way to establish and update national DRLs.

3rd speaker (Angelica Svalkvist) presented methods to assess clinical image quality. Assessment of clinical image quality is important to ensure sufficient diagnostic information and reduce the amount of examinations that provide inadequate information. Dr. Svalkvist presented the advantages and disadvantages of; a) detection studies; and, b) visual grading studies, in assessing image quality. Detection studies require both normal and abnormal cases and are an easy way to compare image quality for two modalities or protocols. Visual grading studies are based on evaluation of visibility of anatomical structures. The use of dedicated software, such as ViewDEX, enables easy and effective review of image quality.



4th speaker (Alexander Schegerer) focused on data cleaning. EUCLID data was carefully reviewed to avoid incorrect records. Software looked for patients' weight and body mass indices beyond the indicated range, dose records significantly exceeding or falling below the corresponding national DRLs (if available), sizes of the CT dosimetry phantom that do not match the corresponding examination and CT scan lengths that are not compatible to answer the corresponding clinical question. If scan lengths of single phases deviated more than 30% from standard scan lengths of the corresponding examinations, hospitals were contacted. Furthermore, data was manually reviewed to check, for example, if phase names refer to a potentially wrong examination, modern technical features are used in old devices etc. In cases of discrepancies, institutions were contacted, and data was discarded if discrepancies were not clarified. About half of EUCLID institutions had to be contacted to provide clarifications.

5th speaker (Werner Jaschke) first explained the parameters affecting radiation dose in fluoroscopically-guided procedures. Then he focused on the main aim of his presentation i.e. complexity indices in interventional radiology. He presented complexity indices established by Ruiz-Cruces et al, (European Radiology, 2016, 26:4268-4276). This publication was used by EUCLID project to define the complexity of the 4 fluoroscopically-guided procedures for which DRLs were established. Prof. Jaschke mentioned that, in most studies, less than 10% are complex procedures. If DRLs are calculated for different complexity levels, 2 levels (standard and complex) are probably enough.

Summary of discussion

Discussion was focused mainly on dose management systems and their role in the establishment and use of DRLs. Export functions exist in many of these systems and, therefore, local data can be transferred to a national registry for the establishment of national DRLs or to a regional registry for the establishment of regional DRLs. There was also some discussion about sample size and whether scientific studies are needed to define the optimum number of patients or institutions. Ideally, hundreds of patients per clinical indication and all CT scanners or fluoroscopy systems available in a country should be included in a survey. In practice, this is not possible. Research studies are needed to determine the optimum sample sizes for establishing clinical DRLs.

Actions to take / Conclusions from session

Dose management systems can play an important role in the establishment and use of DRLs. During data collection for the establishment of DRLs, image quality should be assessed according to the indication of the examination. Data cleaning is an important process of detecting and correcting inaccurate records. During a data cleaning period, about half of EUCLID institutions had to be contacted to provide clarifications. National competent authorities responsible for establishing DRLs should clean and verify data before data analysis. Some fluoroscopically-guided examinations are complex procedures. For these procedures, the impact of complexity on patient doses is important and should be taken into consideration when establishing DRLs. If DRLs are calculated for different complexity levels, 2 levels (standard and complex) may be enough.



Session 4: Using DRLs to Optimise Patient Radiation Protection

Aims of session

The main aim of session 4 was to set out the current status of DRLs in Europe: how they are used on a local, national, and regional level, and the role of DRLs in the protection of children, before laying the foundation for a broader discussion on how DRLs can be used for the optimisation of patients' radiation protection.

Key points

- Within Europe there is significant heterogeneity as most European national competent authorities still consider DRLs for anatomical location rather than for clinical indication, despite longstanding advice from the ICRP, which is backed up by recent publications on DRLs for specific indications. This was evident in the EUCLID project's literature review.
- The EuroSafe Imaging campaign has played a significant role in raising awareness of DRLs.
- The experience from the UK: Patient dose audits are a vital tool in the optimisation process; however, they are not the only thing to consider – image quality must also be considered. DRLs should not be used merely as a compliance tool – the data should be utilised to make improvements. DRLs can help identify simple changes to clinical practice that may enable optimisation of exposures and provide assurance that any interventions are working.
- In the case of paediatric imaging, there is little data and few countries have updated paediatric DRLs.

Summary of presentations

1st speaker (Graciano Paulo): Outlined the limitations of an anatomical approach to DRLs. Prof. Paulo then proceeded to explain the methodology used for the EUCLID project's literature review and its outcomes:

The national competent authorities of 31 European countries were contacted in September 2017 and asked to provide available national data on CT, interventional radiology and radiography. They were invited to provide an update shortly before the workshop. Additionally, a comprehensive literature review was undertaken in order to identify which clinical indications were specifically studied; in particular, additional information on year of publication, CTDi and DLP values for CT, and P_{KA} for IR was sought. The literature review was also updated before the workshop. 27 National Competent Authorities responded to the request for updates on their DRLs. 23 countries reported having national DRLs in CT (Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Slovenia, Slovakia, Spain, Sweden, Switzerland, and the United Kingdom). A further 2 countries (Cyprus and Portugal) declared they do not have DRLs. 2 more (Italy and Romania) indicated they are in the process of calculating DRLs.

For CT, 56 papers, articles, or reports were considered in the literature review. Of the 17 which included clinical DRLs, only ten had regulatory value and are therefore officially recognised as such by the health authorities. Some problems with terminology were revealed (e.g. 'abscess' and 'acute abdomen' likely refer to the same thing).



For IR, around 20 papers/studies were considered for the data collection of existing or new proposed DRLs related to clinical indications. Due to a 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 were found in the literature.

2nd speaker (Sue Edyvean): DRLs are benchmarks that function as simple descriptors for complex distributions. Many factors influence dose and image quality. Skepticism was expressed towards relying on a single parameter as a good descriptor. The third quartile might not necessarily be appropriate for well optimised systems: by definition – a quarter of systems will be above the DRL, even if well optimised.

The importance of image quality for establishing DRLs and for dose audits was emphasized – frequently unnecessarily high-quality images are produced, resulting in too high doses. UK law requires hospitals to implement DRLs with reference to European levels.

The UK has achieved a 10-30% reduction of DRLs. The importance of variations at a subnational level (e.g. local patient average size, variations in equipment, in types/size of hospital – university, district, private etc.) was highlighted as these all affect medians. The importance of the audit cycle, the importance of the image optimisation team, and the importance of quality control and of audit were also highlighted.

3rd speaker (Claudio Granata): Although the establishment of DRLs for children is beyond the scope of the EUCLID project, a list of DRLs based on clinical indication for the children was proposed. Some countries have already established some DRLs for children, but data is scarce.

It remains difficult to set up DRLs in a paediatric setting due to different age and weight needing to be considered.

Candidates for areas in which DRLs for children might be considered for CT studies include the head (trauma, ventricular size (shunt), inner ear for deafness, sinusitis), chest (infection, oncologic staging, cardiovascular CT angiography), abdomen and pelvis (infection, oncologic staging, urinary stones), and trunk (whole-body CT for trauma). Although the number of IR procedures performed on children has greatly increased in the last 20 years, in IR there are currently no DRLs for children.

Clinical DRLs for interventional procedures should be primarily be defined for procedures which are clinically well established, contribute significantly to patient care, or involve a relatively high radiation exposure for the patient and operator. Candidates include, cardiac procedures (patent ductus arteriosus occlusion, atrial septal defect occlusion, pulmonary valve dilatation, diagnostic cardiac catheterization); and non-cardiac procedures (central venous catheter placement).

Clinical DRLs have the potential to play a pivotal role in further improving radiation protection of children undergoing CT studies and IR procedures.

Summary of discussion

The subsequent discussion revealed the growing interest in DRLs in Europe. The importance of quality control and audit were recognised. It was suggested that the



European commission should consider a tender for establishing DRLs for paediatric imaging.

The need for limitations on the number of DRLs was discussed.

The fact that there are no DRLs based on clinical indication for radiography was raised.

Actions to take / Conclusions from session

This session revealed the importance of developing guidance for an accepted Europe-wide list of DRLs based on clinical indication. Furthermore, the development of paediatric DRLs based on clinical indication should be the subject of a European Commission tender.

Work remains to be done in order to better understand the reasons of variations in DRLs. There is a need for dose management systems to be developed.

A review of the methodology for national DRLs and local data collection ought to be considered.

In Interventional Radiology, an improvement in the use of terminology is required: the definition of complexity for IR and the definition of clinical indication for IR are not currently precise enough.

A request was made to the European Commission for a tender for paediatric DRLs based on clinical indications.



Session 5: Establishing DRLs for Interventional Procedures

Aims of session

The main aim of session 5 was to report on and discuss how to establish DRL in Interventional Radiology (IR) and Cardiology as well as in non-invasive cardiac imaging. Cardiac procedures and imaging studies may contribute a relevant dose to patients.

Key points

- Retrieving appropriate CT data sets including necessary additional information like weight, height, reconstruction algorithm etc. is challenging.
- Grading of image quality is not standardised.
- Like in IR, nomenclature of different interventional electrophysiological procedures (I-EP) is ambiguous.
- Like in IR, dose data of I-EP differs considerably between procedures and institutions.
- Currently, DRLs for nuclear cardiology and I-EP are lacking.
- Radiation exposure of invasive and non-invasive coronary angiography decreased substantially over the last years.

Summary of presentations

1st speaker (Michael Verius) described problems and challenges in collecting dose data for the EUCLID project. Inconsistent branding of CT-protocols turned out to be a major challenge. For example, CT protocols of the brain, clinical indication: stroke, differ between institutions and countries. In IR, some institutions reported a sum of exposures and fluoroscopy frames. Grading of image quality is another problem, since assessment of image quality is based on subjective criteria and not on measurements.

2nd speaker (Joris Ector) provided insights in ongoing activities to establish DRLs in I-EP. He pointed out that there is a large variety of EP-procedures. The scatter of dose data between procedures and institutions is large which can be partially explained by technical and operator dependent factors. He recommends establishing European DRLs for I-EP derived from a prospective international multi-centre study. In a first step, data should be collected for AF ablation and cardiac resynchronisation therapy (CRT) device implantation.

3rd speaker (Jeremie Dabin) presented data from the ongoing VERIDIC Project (Validation and estimation of radiation skin dose in interventional cardiology). Veridic is part of the CONCERT project (European Joint Programme for the Integration of Radiation Projection Research). The VERIDIC project tries to overcome problems with maximum skin dose (MSD) measurements and 2D presentation of skin dose distribution. So far, the study evaluated MSD in 875 procedures in total: percutaneous coronary intervention (**PCI**); PCI for Chronic total occlusions (**CTO**); transcatheter aortic valve implantation (**TAVI**). About 50% of procedures reported dose with RDSRs (Radiation Dose Structured Report). MSD was calculated using –validated –online and/or offline systems (default mode mostly!). Data will be grouped according to complexity and patient equivalent thickness. The Final results will be available soon.

4th speaker (Alessia Gimelli) discussed the problems associated with establishing DRLs for nuclear cardiology and cardiac imaging. No DRLs exist for nuclear cardiology, but standards of practice are clearly defined and used by most institutions. DRLs for invasive and non-invasive coronary angiography (CA) are implemented in some countries. In



addition, there are several multi-centre reports on radiation exposure during invasive and non-invasive CA. The inter-site variability for CTCA is 37-fold as reported from a dose survey performed in 2017. Overall, dose for CA decreased significantly over the last 10 years. Registries 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.



Session 6: The Value of Repositories for the Establishment and Use of DRLs

Aims of session

The main aim of session 6 was to learn about the value of repositories and dose management system for the establishment and use of DRLs and its impact in clinical practice.

The three invited speakers have different affiliations and backgrounds, which enriched the session, since (1) gave an overview of a private institution (Groupe 3R – Réseau Radiologique Romand, Switzerland); (2) gave an overview of a national radiation protection authority (Swedish Radiation Safety Authority) and (3) gave an overview of a national professional society (American College of Radiology).

Summary of presentations

1st speaker (Hugues Brat), from the Groupe 3R – Réseau Radiologique Romand, a Swiss private radiology group, shared their experience in using a dose management system, to which the group has connected 10 CT scanners from 2 different vendors.

They first started to collect data to observe how the 40 radiographers and 26 Radiologists were performing the CT scanner protocols, having identified large dose variations, protocol parameters inhomogeneity, number of series variability and lack of staff training uniformity. To tackle the problems identified, they setup a “dose excellence programme” that went from justification of high doses delivered, to a harmonisation and optimisation phase, in order to achieve the ALARA (As Low As Reasonably Achievable) principle.

The harmonisation phase consisted of protocol harmonisation among the different centres, designing a clinical indication-based protocol map with 2 categories of patients for each clinical indication protocol, according to Body Mass Index. The RadLex playbook served for mapping and image quality was correlated to phantom analysis. The value of the harmonisation phase was very important since it allowed the: a) elimination of redundant protocols; b) benchmarking of comparable data; c) the standardisation of diagnostic image quality; and, d) reduction of dose globally.

For the optimisation phase they have set local DRLs (LDRLs) per clinical indication and compared with the new national ones (NDRLs) from Switzerland. The value of the optimisation phase allowed: a) an additional dose reduction of 26%; b) the establishment of clinical Indication and BMI based protocols, with significantly lower dose levels than existing DRLs; c) an understanding that because of faster processing and revision of LDRLs brings more agility to the process when compared to national DRLs.

The presentation ended by highlighting the importance of continuous education to guarantee the “right dose for the right diagnosis”, especially when new health professionals are integrated in the team or new CT scanners are installed.

2nd speaker (Anja Almén), from the Swedish Radiation Safety Authority (SSM) presented the Swedish experience on using DoseReg tool for benchmarking. Since 1999, to gather data from the Swedish sites in order to fulfil the legal requirements in establishing DRLs, SSM used basic excel files, with all the known limitations, but however served to publish several reports on NDRLs. In 2018, SSM decided to implement a web-based dose



registration solution, with the support of the Australian Radiation Protection and Nuclear Safety Agency, that allowed: a) to collect data for setting National Diagnostic Reference Levels (NDRLs); b) to give real-time feed-back to hospitals; c) to give the opportunity to hospitals to compare protocols.

This action was made for CT, Mammography, Conventional x-ray, Interventional radiology, Dental CBCT, Nuclear medicine.

The data is organized by modality; type of investigation; paediatric or adult; clinical indication. Patient specific data is also included such as: kVp, CTDIvol, DLP, SSDE, age, sex, length, and weight.

Several challenging issues were shared, such as: a) nomenclature of examinations; b) data management capacity and skills; c) operation and maintenance of the system; d) adaptation to clinical changes.

3rd speaker (Priscilla Butler), from the American College of Radiology (ACR) shared the lessons learned from the ACR Dose Index Registry (DIR), a tool for quality improvement that: a) enables facilities to review dose indices and optimise protocols; b) collects and compares dose index information across facilities; c) supports research focused on quality improvement; d) develops size-specific DRLs.

Focused primarily on CT since 2011, ACR DIR has or is preparing pilots for Fluoroscopy, plain radiography, PET-CT.

The ACR DIR provides to the centres involved (3121 facilities that have to pay an annual fee to register) a quarterly feedback report and real-time, web-based interactive reports which in addition, provide feedback on performance, which allows the facilities to correct and update their data.

In 2017, a paper was published with the USA DRLs and Achievable Doses for 10 Adult CT exams (Kanal KM, Butler PF, Sengupta D, et al., *Radiology* 2017; <http://pubs.rsna.org/doi/pdf/10.1148/radiol.2017161911>)

Discussion

During the discussion of this session, inputs from the representative of the Affidea group were provided, namely the fact that they have 75 CT scanners from more than 40 centres linked to the same dose management system, which allows them to harmonise the procedures in the different centres. One of the main reasons given for the implementation of such a system was the increased awareness for patient safety.

Most of the participants agreed that the future will be based on dose management systems but that new guidelines at European level are needed, especially for paediatric clinical indications and definition of patient size. It was considered of extreme importance to harmonise the dose units used, namely in plain radiography and fluoroscopy guided procedures. HERCA representative informed that there is already a commitment with COCIR for this objective.



It was considered positive to develop a European Dose Registry in a near future, that would facilitate the harmonisation at EU level.

Actions to take / Conclusions from session

Dose repositories/dose management systems are very useful and hopefully will become widely available in all countries. Dose repositories/dose management systems are also tools to support the process of the optimisation of the imaging procedures through the establishment of LDRLs. Finally, dose repositories/dose management systems are tools to easily establish LDRLs and potentially NDRLs as an important tool for benchmarking.



Session 7: Establishing National Clinical DRLs in Europe

Aims of session

The main aim of session 7 was to present the efforts of seven European countries in collecting dose data and defining national clinical DRLs.

Key points

- Many states have already defined DRLs based on clinical indication.
- National DRLs are regularly updated.
- Member states appreciate the high impact of (C)DRLs on the optimisation of X-ray applications and on establishing a nationwide radiation protection culture.
- In Switzerland and Ireland, the average effective dose per caput remain constant or even decreased because of strict optimisation of X-ray procedures.
- Member States face similar problems (representativeness, variability in morphology and in radiological practice) when collecting dose data for defining (clinical) DRLs.
- Switzerland and Finland plan to establish a national dose registry.
- In France and UK, there is a strong collaboration among authorities, the medical physics community and medical radiological societies to define DRLs based on clinical indication.

Summary of presentations

1st speaker (Alexander Schegerer), who formerly worked for the German federal office for radiation protection (BfS), presented the outcome of the recent update of the German reference levels for diagnostic and interventional X-ray procedures. For procedures with already existing DRLs before the update, the DRLs were lowered by ca. 20%, on average. In fluoroscopy, interventional radiology (IR), and computed tomography (CT), several DRLs were defined for clinical indications in addition to conventional DRLs which are specified for anatomical regions. In CT, DRLs were defined for scan series, only. Therefore, for multi-phase CT examinations, DRLs must be added by the user to get a reference level for the entire examination. Instead of defining DRLs for many different clinical indications, two separate DRLs were defined for the anatomical regions chest, spine, abdomen, and pelvis, respectively: one DRL at high dose for low-contrast indications (to obtain low-noise images) and one DRL for high-contrast indications with lower requirements on image quality. One DRL was defined for the technical, dose-saving feature "ECG-triggering" used in CT coronary angiography while coronary CT angiography with retrospective ECG comparison is not recommended since this method is associated with a significant increase in patient dose. In IR, DRLs for three different levels of complexity of endovascular aneurysm repair were primarily defined. However, as these DRLs could not be clearly differed by the users, the DRLs were finally replaced by one single value.

As **2nd speaker** (Thibault Vanaudenhove) presented, the Belgian federal agency for nuclear control is responsible for the update of the national DRLs in Belgium. Since 2006 up to now, there were 9 nationwide surveys in CT, 4 nationwide surveys in conventional radiography, IR and mammography, and 3 surveys in nuclear medicine to collect dose data for standard examinations as well as information on device brand, year of installation, detector and image reconstruction as well as processing software. The average doses for different standard examinations steadily decreased over years, by 80% at maximum. Finally, Vanaudenhove discussed the impact of the number of devices and the number of data per device on the findings, i.e. on statistical quantities such as the percentiles and,



thus, on DRLs. He recommended a harmonisation of the methods of defining DRLs among national authorities.

3rd speaker (Atte Lajunen) presented the legal framework and the history of the implementation of DRLs in Finland. He briefly discussed different challenges (e.g., manual vs. automatic data collection, data collection in paediatric radiology) in collecting dose parameters. To obtain a statistically adequate number of dose data in paediatric radiology, STUK gained good experiences in defining national DRL curves, where dose is plotted versus patient's weight instead of defining DRLs for separated weight (or age) classes. To compare individual exposure practice with DRLs, institutions check if approximately 20 dose data points which are randomly selected from the weight range of 0 kg and 80 kg are below the DRL curve of the corresponding examination. In order not to exclude overweight and underweight *adult* patients for data collection (and to obtain a higher number of dose data points, therefore), STUK plans to define DRL curves for adults, too. STUK will support the use of automatic dose collection systems and implement a national PACS where dose data will be stored in near future.

4th speaker (Serge Dreuil) talked about the French expertise in implementing DRLs. DRLs were established in 2004 for the first time and updated in 2011 and 2019. DRLs for interventional radiography were established in 2019 for the first time. To ensure ongoing adjustment of DRLs to the current state of the art and changes in examination practices, a cyclical process including medical institutions, the IRSN, which collects dose data and further information from medical institutions, and the French authority (ASN), which finally define DRLs, is implemented in France. Serge Dreuil underlined that there is a need for defining clinical DRLs in interventional radiology, computed tomography, nuclear medicine, and conventional radiology. Clinical DRLs were established in interventional radiology, nuclear medicine, and CT. The challenges in defining clinical DRLs are to define non-ambiguous clinical indications and to obtain a large number of patients to cope with variability in morphology and radiological practice. A close collaboration between authorities, medical radiological societies and the medical physics community is an essential requirement for implementing national DRLs based on clinical indication.

5th speaker (Lee O'Hora) presented the legal framework in radiation protection in Ireland and the role of his institution in promoting better exposure practice across all institutions. There were surveys on patient doses in CT in 2009 and 2017, in dental radiology and nuclear medicine, both in 2010. Clinical tasks were differentiated. First DRLs were defined in 2013 and updated in 2017. Although the number of CT examinations increased by 90% between 2010 and 2017, the collective effective dose remains constant. This finding is explained by the increase use of modern, dose-saving technical features. Like other European countries, there is the challenge to collect an adequate number of dose data in Ireland, for CT coronary angiography, body trauma imaging, and particularly in paediatric examinations. In 2019, new national DRLs were defined and a guidance on the establishment and use of DRLs were published. HIQA plans several future surveys in fluoroscopy and interventional radiology, followed by surveys in nuclear medicine, PET, dental tomography and CT. HIQA will also support the determination of local (facility) DRLs at institutions.

6th speaker (Barbara Ott) pointed out that average effective dose per caput decreased in Switzerland in 2018 for the first time resulting from strict optimisation of medical X-ray procedures. In fact, the DRLs in CT, for instance, could be decreased by 30%, on average,



in 2018. Several Swiss DRLs in CT were defined for clinical indications which involve a dose reduction of up to 88% compared to the corresponding conventional anatomical DRLs. In a follow-up project, the quality of images that are obtained at different CT scanners is assessed considering a specified clinical task. In this task-based approach, radiologists must detect pathological structures at different dose levels. FOPH will define national DRL for dental cone-beam CT for five most relevant indications and for CBCT examinations in orthopaedics, neurosurgery and traumatology in the near future. FOPH will establish a national CT dose registry with a link to image quality.

7th speaker (Sue Edyvean) gave a historical overview of different dose surveys and the establishment of DRLs in the UK, beginning in the early 90's. Additionally, the precursor of PHE assessed dose and image quality for different clinical protocols by using objective quality parameters. First DRLs were based on clinical indications. Furthermore, for different clinical indications, PHE provide key words for RIS or dose management search and typical corresponding scan lengths. Currently, there are several national dose audits underway in specialist areas (e.g., in coronary angiography, nuclear medicine, radiotherapy, CBCT) which was initiated by medical physicist. National DRL were updated in 2019.



Session 8: Establishing DRLs in Nuclear Medicine and Multi-Modality Systems

Aims of session

The main aim of session 8 was to present all relevant information on DRLs in Nuclear Medicine and on the use of CT in multimodality systems such as SPECT-CT or PET-CT, etc.

Key points

- The use of DRLs in NM was discussed.
- The challenges and benefits of using DRLs in NM were discussed.
- Future actions were recommended.

Summary of presentations

1st speaker (Michael Lassmann) represented the European Association of Nuclear Medicine (EANM). The title of his presentation was "The present system of DRLs in Nuclear Medicine Diagnostics". The main outcomes from his talk were the following:

In diagnostic 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 European Union.

For estimation of effective dose, even the latest reports still use the ICRP 60 weighting factors.

In paediatric nuclear medicine data on the proper use of radiopharmaceuticals and standardised protocols with respect to the proper use of gamma cameras, PET and CTs are needed.

With the harmonisation of the 2008 paediatric EANM dosage card and the National Authority consensus guidelines a better standardisation of Nuclear Medicine procedures has been achieved by some adaptations of both recommendations.

2nd speaker (Roland Hustinx), also represented EANM. The title of his presentation was "Establishing DRLs in Nuclear Medicine: Opportunities and challenges". The main outcomes from his talk were the following:

- DRLs are in direct relationship with the administered activities.
- DRLs depend on size, equipment, and examination.
- They must be different in cases one needs to decrease the injected activity or decrease the acquisition time or combine both (optimal, versus normal, versus degraded conditions).
- There are often issues of radiopharmaceutical shortage which causes decreased level of administered activity.
- For cardiac studies, PET studies, or other studies, etc., there are many variables such as protocol, type of machine, type of radiopharmaceutical, etc.

3rd speaker (Klaus Bacher) represented the MEDIRAD European project who is also the EURAMED President. The title of his presentation was "Establishment of European DRLs for specific applications of CT in multi-modality systems: Experience from the MEDIRAD project". He briefly presented the MEDIRAD project. This is a H2020 EU project, that started on 1 June 2017, has 33 partners and its main objective is the following: "MEDIRAD aims to enhance the scientific bases and clinical practice of radiation protection in the



medical field and thereby addresses the need to better understand and evaluate the health effects of low dose ionizing radiation exposure from diagnostic and therapeutic imaging and from off target effects in radiotherapy.” According to Prof Bacher, establishing CT DRLs for dedicated CT applications in nuclear medicine is challenging for the following reasons: different clinical aims of CT scan; no standardisation in use of CT in nuclear medicine; large variety in CT instrumentation; and, it is sometimes difficult to define anatomical region of scan.

Summary of discussion

The audience agreed that there are many variables and challenges in NM procedures in the attempt of establishing DRLs. Examples are variability in 1) administered activity, 2) physical and chemical properties of the radiopharmaceutical, 3) spatial variability of the biodistribution, 4) biological uptake and excretion, 5) image quality.

It appears that DRLs exist today in NM, but they are not applied in clinical practice. Physicians do not fully understand them and cannot use them in the everyday clinical practice.

More efforts should be made to harmonise diagnostic procedures (and injected activities) in Nuclear Medicine.

There is high variability in awareness of the NM physicians concerning radiotracer activities and thus DRLs.

Actions to take / Conclusions from session

The definition of DRLs must be reconsidered. More efforts are needed to raise awareness on the use and benefits of DRLs in NM especially in clinical practice.



Session 9: Roundtable

Aim of session

The main aim of session 9 was to provide an overview and discussion of national perspectives in 18 EU Member States with respect to their regulatory achievement related to the development and implementation of DRLs.

Summary of the session goals

18 EU or EEA countries were invited to present and discuss their national situation with respect to:

- The current regulatory national framework concerning the establishment and implementation of DRLs.
- The set of DRL values which have been adopted or are currently being considered at national level.
- Future plans for the development of national policy concerning DRLs.

Summary of presentations

15 national presentations were made at the workshop. Hungary, Italy, and Spain were excused, however Hungary and Italy provided information in writing.

The national situations are synthetized in the following table:

Country	Ministry Health	Nuc & RP authority	DRL legal framework	CT DRL	IR DRL	Xray DRL	Nuclear medicine	DRL revision	New DRL envis	CDRL envis
Austria	x		x	7	8 (2+6car)	8	28	5/7 years	CT paediat	YES
Bulgaria		x	x	12	2	17	5	2021		possible
Czech Rep		x	x	6	2 (card)	21	83	2023	YES	YES
Denmark	x		x	7		5	20	Ongoing	IR, Xray	YES
Estonia	x		x			5		2022	CT/IR	
Greece		x	x	7	4(car)	12	12	Ongoing	Yes IR	
Hungary	medical colleges		PENDING (voluntary scheme)	0	0	0	0			
Latvia	x		x	3		16	59	Ongoing		YES CT
Lithuania	x		x	11	3(card)	27	72	Ongoing	Yes IR	
Luxembourg	x		x	9	7(3 car)	10	38	2020/2025	Yes	YES
The Netherlands	x		x	4		7				
Norway	x		x	11	5(4car)	7		5 years Automated Dose collection	Yes Children	



								system planned		
Poland	x		x	9	7(2card)	24	32	Ongoing		
Romania	x		x	7	2(card)	18	5	2022	Yes	
Slovenia	x		x	6	6(2card)	17	26	Automated dose collection system planned	Yes	Yes
Spain										
Sweden		x	x	6	1 (card)	7	12	Automated dose collection system planned		Yes
Italy	x		(planned)	4		20	50	2020		YES

Table 1: Status of DRLs in Member states

Summary of discussions

The relevant legal framework implementing the EU BSS directive requirements about DRLs is in place in all but one country, where it is still in draft form. In 12 countries, the competent authority is the health ministry, and in 4 it is the radiation protection/nuclear safety authority.

DRL development varies significantly from one country to another, reflecting mainly national history on professional guidance on radiological exposure for recurrent protocols. National DRLs are mainly derived from information periodically sampled from selected health institutions, with technical and scientific support from professional expert committees and /or institutes.

Several countries have reported ongoing national projects aiming to develop a systematic and automated patient dose reporting system, that will facilitate the future development, maintenance and use of DRLs.

Some countries have indicated that due to the limited numbers of health institutions practicing certain radiological protocols, particularly in nuclear medicine, the setting up of appropriate DRLs could benefit from information from other European countries with similar health system profiles. However, although all national DRL systems are derived from the EU BSS directive, there is limited reported cooperation in this field between competent national authorities.

One country indicated that the implementation of national DRLs was seen as an important instrument to curb the historical growth of patient collective dose observed in recent years due to major technological evolutions, such as the wider access to CT scanners.

About half of the countries reported an intention to move towards clinical DRLs in the near future, sometimes citing the EUCLID study as a useful source of information for policy planning.



Actions to take / Conclusions from session

Most EU & EEA countries, according to information provided in this as well as earlier workshop sessions, have a regulatory Framework in place for setting up national DRL's, and for monitoring their impact on radiological practice.

However, session 9 illustrated the existence of many differences from one country to another, and the opportunities which could result from a closer cooperation, on issues such as: relations to vendors about the standardisation of dose related data provided and potentially automatically transmitted by their respective devices; protocols and ethics good practice for an automated transmission of such data to national repositories; relations with medical professional organisations about the necessary complementarity of NDRL's and LDRL's reflecting the current practice in medical institutions, in the context of their overall quality management of patient care, and; future possible approach to the introduction of clinical DRL's, as a tool to further optimise radiological practice and the resulting collective patient dose. This will however require an effort to harmonise the vocabulary used to define the clinical protocols to which such future DRL's will apply.

The revised EU BSS directive strengthened the role of DRL's for managing national policies for the optimisation of radiological patient exposure. However, discussions showed that in order to reap the full benefit of such a system, it will be necessary to enhance cooperation at all levels between all actors involved, in order to encourage the development of an 'ecosystem', on the scale of Europe, which would facilitate and perpetuate the tasks of each actor towards the ongoing optimisation of patient care with respect to radiological protocols.



Session 10: Panel Discussion - Part 1

Aims of session

The main aim of part one of session 10 was to receive the views of the organisations taking part in this session on the use of DRLs: what are the important factors that must be taken into consideration when one attempts to define with local or national, regional DRLs. This was designed to set up an interactive discussion around the concept, challenges, novelties, future vision on DRLs, with the representatives of the relevant stakeholders.

Key points

- Several questions were raised with the intention of answering them during this and the next session.
- Examples of such questions are found below:
 - What are the pros and cons of clinical vs. anatomical DRLs?
 - What must be considered (sample size, image quality, data cleaning, GDPR) when establishing a survey to establish DRLs?
 - What are the difficulties in setting reference levels for interventional procedures?
 - What is the role of radiation protection authorities, professional societies, international organisations, health authorities in establishing and using DRLs?
 - What is the role of dose management systems and repositories?
 - What is the perspective of industry representatives?
 - What are the opportunities and challenges presented by European collaborations in dose surveys and DRLs?
 - How can the concept of DRLs be introduced into daily routines in our hospitals?

Summary of presentations

This was a panel discussion session. No presentations in this session.

The panel consisted of:

- Riccardo Corridori (European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry (COCIR))
- Serge Dreuil (Institute for Radiological Protection and Nuclear Safety, France)
- Atte Lajunen (Radiation and Nuclear Safety Authority, Finland)
- Georgi Simeonov (Policy Officer, Unit Radiation Protection and Nuclear Safety in DG ENER)
- María Perez (World Health Organisation)
- Thibault Vanaudenhove (Federal Agency for Nuclear Control, Belgium)
- Jenia Vassileva (International Atomic Energy Agency)
- Hanne Waltenburg (Heads of the European Radiological Protection Competent Authorities (HERCA))

Summary of discussions

Jenia Vassileva stated that it should be made clear that we should not speak of compliance with DRLs but rather use DRLs as a tool for optimisation as the IAEA BSS also state.

Maria Perez mentioned that DRLs should not be seen as only a number but a process. She reminded the workshop that according to the presentations at the EUCLID workshop, clinical DRLs are the only way forward due to equipment and protocol variability.



Jonn Damilakis reminded the workshop that, in Europe, DRLs are part of the legislation (according to the European Directive and to the national respective laws) and thus DRLs need to be established in each Member State.

Georgi Simeonov fully supported this and mentioned that in Europe we have a specific legal framework and we should work within this. Thus, DRLs must be established and action should be taken if these are systematically exceeded.

The representatives of both STUK and GAEC also mentioned that, according to the national and European regulations, DRLs must be established. Also exceeding national DRL values can be indicative of poor optimisation processes. The representative of GAEC further reminded that DRLs so far do not take image quality into account.

Regarding paediatric IR DRLs, many participants stated that data is difficult to collect. Maria Perez mentioned about a WHO study in collaboration with the Pan American Health Organisation (PAHO) and IAEA in Latin American countries in the attempt to collect data to establish DRLs in paediatric IR procedures. Werner Jaschke mentioned that the most frequent IR procedures are neurovascular procedures and Stathis Efstathopoulos (who represented CIRSE) mentioned that probably cardiac procedures should be also considered.

John Damilakis asked Mr Corridori, representative of COCIR, about the view of the organisation on the issue of DRLs. Mr Corridori mentioned that industry wishes to work with societies and EC on this issue. He mentioned that, listening to the presentations, he understood that some issues related to use of X-ray equipment and the role of dose management software must be taken into consideration by the industry.

Virginia Tsapaki mentioned that the EUCLID results revealed that the available features of the new X-ray machines are sometimes not well known to the users. The industry should find ways to inform the users more on the features available for optimisation. John Damilakis mentioned further that some of these features, for example CT tube current modulation or organ dose modulation are "black boxes", even for medical physicists. Industry must provide more information to the users in order to better address the issue of optimisation. Regarding the dose management software, Virginia Tsapaki mentioned that she fully supports these systems due to their importance in collecting data more effectively. She mentioned that the industry could consider providing this software as a standard feature of the X-ray machine and not as an optional extra. Before that though, more efforts should be made on connectivity issues.

It was agreed that:

- DLRs should be defined in Europe as they are part of the regulations in EC.
- DRLs should not be applied to individual patients, although there was disagreement on the use of LDRLs to individual patients.
- If image quality is to be taken into account, then guidance will be needed. Without guidance it will be difficult to take IQ into account.

[Actions to take / Conclusions from session](#)

Clinical DRLs are the only way forward. The clinical protocols for which these DRLs are defined should be clearly defined as terminology now is different between hospitals.



For NM specifically, other quantities than administered activities must be investigated for DRLs.

If image quality is to be taken into account, then guidance will be needed.

Paediatric DRLs should be considered at a European level than national level due to limited centres performing such procedures starting with neurological and cardiological procedures.

Exchanges with industry ought to be increased for DMS harmonisation.



Session 10: Panel Discussion - Part 2

Aims of session

The main aim of part two of session 10 was to have an interactive discussion around the concept, challenges, novelties, future vision on DRLs, with the representatives of the relevant stakeholders. This was based upon the views of the organisations taking part in this session on the use of DRLs as presented in the first part of the session: what are the important factors that must be taken into consideration when one attempts to define with local or national, regional DRLs.

Summary of presentations

This was a panel discussion session. No presentations in this session.

The panel consisted of:

- Riccardo Corridori (European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry (COCIR))
- Serge Dreuil (Institute for Radiological Protection and Nuclear Safety, France)
- Atte Lajunen (Radiation and Nuclear Safety Authority, Finland)
- Georgi Simeonov (Policy Officer, Unit Radiation Protection and Nuclear Safety in DG ENER)
- María Perez (World Health Organisation)
- Thibault Vanaudenhove (Federal Agency for Nuclear Control, Belgium)
- Jenia Vassileva (International Atomic Energy Agency)
- Hanne Waltenburg (Heads of the European Radiological Protection Competent Authorities (HERCA))

Summary of discussions

From the discussion several points were highlighted:

- Education and training on DRLs are crucial to have a common understanding on the use of the concept;
- Dose management systems will be the future and should be integrated into e-health platforms;
- LDRLs establishment should be developed and use would need some guidance;
- Clinical audit is an important concept to be used as a strategy to establish and review the implementation of DRLs;
- To guarantee the effective implementation and use of DRLs it's important that the national authorities have adequate resources (both human and financial);
- It's necessary to develop a better advocacy of radiation protection issues, changing them from important to urgent at the eyes of policy makers and health managers;
- National and local leadership as well as resources are needed for the implementation of surveys, making DRLs easy to use;
- The creation and development of a European Network for DRLs could be a solution, looking at the success and achievements obtained by other networks, such as European network for rare disease or EuroSafe Imaging stars and others;
- Best practice and guidelines shared within a common portal is another option to help the implementation of DRLs, through the development of synergy mechanism.

Considering the Digital Agenda of the European Commission, funding to support innovation can be achieved for the scope of IT solutions for DRLs.



Session 11: Summary, Conclusions, Closing

1. The approach to DRLs needs to be adjusted to the level of expertise and the infrastructure available in European member states. Clinical DRLs can improve quality of care and promote safety in medical imaging. The latest EU guidance on establishment and use of DRLs was published 20 years ago and there is a need for update.
2. EUCLID has created a list of CT clinical indications that already has been used by colleagues in the USA. Switzerland has created a list of 5 clinical indications for Cone Beam Computed Tomography (CBCT) and this is very useful information complementary to EUCLID's list of CT indications.
3. 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, guidelines are needed on the above topics.
4. EUCLID data analysis showed that a) there are large differences in techniques and corresponding dosimetric data between hospitals for most clinical indications, b) for multiphase examinations the sequence of phases differ between hospitals and c) terminology differs between hospitals. Considerable differences in doses may be partly attributed to lack of optimisation. To avoid mistakes, common language should be used i.e. determine a set of radiology terms for DRLs establishment, use, communication and comparison of results, including LDRLs based on clinical indication.
5. EUCLID data analysis is still ongoing. Project findings have the potential to promote safety in medical X-ray imaging and improve dose optimisation of diagnostic and interventional examinations in Europe and beyond.
6. During data collection for the establishment of DRLs, image quality should be assessed according to the indication of the examination. Guidelines are needed to provide information on image quality criteria.
7. To facilitate the establishment of local and national DRLs and their updating, the use of dose management systems is strongly recommended.
8. All member states presented national anatomical DRLs for adult patients during the EUCLID workshop. Some states have established DRLs for few clinical indications. Establishment of clinical DRLs, establishment of paediatric DRLs and automatic data collection are included in the plans of many countries. A point that needs attention when comparing national DRLs is that some competent authorities report CT DRL values per acquisition and other total values for the whole examination.
9. DRLs establishment is challenging in interventional radiology because patient doses depend on many factors including the procedural complexity. More work is needed on quantification of complexity of fluoroscopically-guided procedures and its usefulness in the establishment of DRLs.



10. Limited number of member states have established paediatric DRLs for few examinations. 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) and was further highlighted during the EUCLID workshop. It is encouraging that, during the workshop, several member states mentioned that the establishment of paediatric DRLs is included in their future plans.

11. In nuclear medicine the use of DRLs is limited. According to a MEDIRAD survey, in 70% of SPECT/CT systems and in 30% of PET/CT systems installed in European countries there are no paediatric acquisition protocols. Although the frequency of paediatric SPECT/CT and PET/CT examinations is relatively low, this issue needs to be addressed urgently.



3. Impressions



Figure 1: The workshop venue in Luxembourg during a session



Figure 2: The presenters' bench during a session



4. Workshop Summary and Conclusion

The workshop was highly successful in achieving the stated goal of presenting and discussing the results of the EUCLID project with Member States and the relevant national, European and international stakeholders. The workshop provided a platform for the discussion of and exchange of experiences with DRLs. Competent authorities, as well as other relevant organisations, shared their knowledge and practical experiences of establishing DRLs. The workshop allowed for the presentation of the most recent progress on DRLs in Member States as well as of other relevant national or regional experiences, including an exchange of views on the transposition of the relevant BSS provisions. The needs for further national actions to establish, update and use DRLs in practice were identified and discussed through the workshop-related activities.

Some of the key conclusions of the workshop were:

In nuclear medicine the use of DRLs is limited. Data presented during the workshop showed that there are no paediatric acquisition protocols in 70% of SPECT/CT systems and in 30% of PET/CT systems installed in European countries (results of MEDIRAD project). Although the frequency of paediatric SPECT/CT and PET/CT examinations is relatively low, this issue needs to be addressed urgently.

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 European Union. 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.

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. Specific attention should be given to these two specialties in future. 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.

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 NDRL establishment and the clinical practice through the development of local DRLs and may open the way for development of a European dose repository. For example, the Digital Agenda of the European Commission might present opportunities for supporting innovation in IT solutions for supporting DRL systems, both as regards the conceptualisation and interoperability of related operational tools.

The EU's most recent guidance on the establishment and use of DRLs must be updated:

- 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. Professional and ethical codes of conduct need to be considered (guarantee of anonymity, protection of personal data etc.). Furthermore, 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 also benefit from the standardisation of techniques and sequences of multiphase examinations.
- Guidelines on image quality criteria are needed as this should be assessed relative to the indication of the examination.
- Guidance on whether CT DRL values should be reported per acquisition or for total values for the whole examination would be welcome as, currently, variations between national competent authorities prevents reliable comparison of NDRLs.
- New guidelines at European level are needed, especially for paediatric clinical indications and also definition of patient size. Harmonisation of the dose units used, namely in plain radiography and fluoroscopy guided procedures, is highly important.

The establishment of DRLs in interventional radiology presents a challenge because 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.

Many Member States are yet to establish paediatric DRLs despite the need identified in the 'European guidelines on DRLs for paediatric imaging' (Radiation Protection No 185). The workshop did, however, reveal that several Member States have made plans to establish paediatric DRLs in the future.



5. Appendices

Appendix 1: List of Attendees

This appendix has been removed prior to publication of the EUCLID workshop report on the EUCLID websites on the grounds of privacy protection.



Appendix 2: Workshop Programme

EUCLID | European Study on Clinical DRLs

EUCLID Workshop: Best Practices for the Establishment and Use of DRLs

9th – 10th December 2019, Room D, European Convention Centre
1 rue du fort Thüngen, Luxembourg, L-1499

Monday 9th December

09:00 - Session 1: Opening and Scene Setting

- 09:00** Welcome by the EC and the importance of the establishment and use of DRLs in Europe
Michael Hübel (Head of Unit Radiation Protection and Nuclear Safety in DG ENER, European Commission)
- 09:10** DRLs in the Radiological Protection System
Colin Martin (International Commission on Radiological Protection)
- 09:20** International recommendations for the establishment and use of DRLs
Jenia Vassileva (International Atomic Energy Agency)
- 09:30** DRLs as tools to improve quality of health care
Maria Perez (World Health Organisation)
- 09:40** Welcome by ESR: 'Promoting quality and safety in medical imaging: DRLs in EuroSafe Imaging'
Guy Frija (EUCLID Project co-manager, EuroSafe Imaging Chair)
- 09:50** Welcome by the EUCLID Project Manager and EUCLID project overview
John Damilakis (EUCLID Project manager, University of Crete/Greece)

10:00 - Session 2: The EUCLID Project: Methodology and Main Results

Moderator:

Georgi Simeonov (Policy Officer, Unit Radiation Protection and Nuclear Safety in DG ENER, European Commission)

- 10:00** Identification of clinical indications and summary of existing clinical DRLs in Europe and beyond
Guy Frija (EUCLID Project co-manager, EuroSafe Imaging Chair)
- 10:15** The EUCLID dose data collection and verification process
John Damilakis (EUCLID Project manager, University of Crete/Greece)



- 10:30** The EUCLID results
Virginia Tsapaki (EUCLID Project Team member, Konstantopoulio Hospital, Greece)
- 10:45** Discussion

11:00 - COFFEE BREAK (30 MIN)

11:30 - Session 3: Considerations in Conducting Surveys to Establish DRLs

Moderator:

John Damilakis (EUCLID Project manager, University of Crete/Greece)

- 11:30** Sample size an overview of current recommendations
David Celier (Institute for Radiological Protection and Nuclear Safety, France)
- 11:40** The role of dose data management systems
Federica Zanca (Palindromo Consulting, Belgium)
- 11:50** Assessing clinical image quality
Angelica Svalkvist (Sahlgrenska University Hospital, Sweden)
- 12:00** Data cleaning
Alexander Schegerer (EUCLID Project Team member, Federal Office for Radiation Protection, Germany)
- 12:10** Complexity indices in interventional radiology
Werner Jaschke (EUCLID Project Team member, Medical University Innsbruck, Austria)
- 12:20** Discussion

12:30 - LUNCH BREAK (60 MIN)

13:30 - Session 4: Using DRLs to Optimise Patient Radiation Protection

Moderator:

Hugues Brat (Groupe 3R – Réseau Radiologique Romand, Switzerland)

- 13:30** DRLs in Europe: the current situation
Graciano Paulo (EUCLID Project Team member, IPC Coimbra Health School, Portugal)
- 13:45** Methods of using local, national and regional DRLs
Sue Edyvean (Public Health England, UK)
- 14:00** The role and the need for clinical DRLs: what about children?
Claudio Granata (Ospedale Gaslini, Genova, Italy)
- 14:15** Discussion



14:30 - Session 5: Establishing DRLs for Interventional Procedures

Moderator:

Werner Jaschke (EUCLID Project Team member, Medical University Innsbruck, Austria)

- 14:30** Experience gained from the EUCLID project
Michael Verius (Medical University Innsbruck, Austria)
- 14:42** Establishing the European DRLs for Interventional *Electrophysiology*
Joris Ector (European Society of Cardiology & European Heart Rhythm Association (EHRA))
- 14:54** Experience gained from the VERIDIC project
Jérémie Dabin (Belgian Nuclear Research Centre, Belgium)
- 15:06** Establishing European DRLs for nuclear cardiology and cardiac CT
Alessia Gimelli (European Society of Cardiology) (via Tcon)
- 15:18** Discussion

15:30 - COFFEE BREAK (30 MIN)

16:00 - Session 6: The Value of Repositories for the Establishment and Use of DRLs

Moderator:

Guy Frija (EUCLID Project co-manager, EuroSafe Imaging Chair)

- 16:00** An institutional experience in Switzerland
Hugues Brat (Groupe 3R – Réseau Radiologique Romand, Switzerland)
- 16:10** The Swedish experience: The DosReg tool for benchmarking
Anja Almén (Swedish Radiation Safety Authority)
- 16:20** The ACR CT dose index repository achievements: Lessons learnt
Priscilla Butler (American College of Radiology) (via Tcon)
- 16:40** Discussion

17:00 - END OF DAY 1



EUCLID | European Study on Clinical DRLs

EUCLID Workshop: Best Practices for the Establishment and Use of DRLs

9th – 10th December 2019, Room D, European Convention Centre
1 rue du fort Thüngen, Luxembourg, L-1499

Tuesday 10th December

9:00 - Session 7: Establishing National Clinical DRLs in Europe

Moderator:

Alexander Schegerer (EUCLID Project Team member, Federal Office for Radiation Protection, Germany)

Experiences in Establishing and implementing clinical DRLs

- 09:00** Introduction & The German experience
Alexander Schegerer (EUCLID Project Team member, Federal Office for Radiation Protection, Germany)
- 09:05** The Belgian experience
Thibault Vanaudenhove (Federal Agency for Nuclear Control, Belgium)
- 09:15** The Finnish experience
Atte Lajunen (Radiation and Nuclear Safety Authority, Finland)
- 09:25** The French experience
Serge Dreuil (Institute for Radiological Protection and Nuclear Safety, France)
- 09:35** The Irish experience
Lee O'Hora (Health Information and Quality Authority, Ireland)
- 09:45** The Swiss experience
Barbara Ott (Federal Office of Public Health, Switzerland)
- 09:55** The UK experience
Sue Edyvean (Public Health England, UK)
- 10:05** Discussion

10:30 - COFFEE BREAK (30 MIN)

11:00 - Session 8: Establishing DRLs in Nuclear Medicine and Multi-Modality Systems

Moderator:



Virginia Tsapaki (EUCLID Project Team member, Konstantopoulio Hospital, Greece)

11:00 The present system of DRLs in Nuclear Medicine Diagnostics

Michael Lassmann (European Association of Nuclear Medicine, Würzburg University, Germany)

11:15 Establishing DRLs in Nuclear Medicine: Opportunities and challenges

Roland Hustinx (European Association of Nuclear Medicine, Liège University Hospital, Belgium)

11:30 Establishment of European DRLs for specific applications of CT in multi-modality systems: Experience from the MEDIRAD project

Klaus Bacher (Representative of the MEDIRAD project & EURAMED President, Gent University, Belgium)

11:45 Discussion

12:00 - LUNCH BREAK (60 MIN)

13:00 - Session 9: Roundtable

Moderator:

Georgi Simeonov (Policy Officer, Unit Radiation Protection and Nuclear Safety in DG ENER)

All participating countries will give a 2-3-minute overview of the perspective in their country following a pre-defined template.

AUSTRIA – **David Wachabauer** (Austrian Public Health Institute, Austria)

BULGARIA – **Asen Dimov** (National Centre of Radiobiology and Radiation Protection (NCRRP), Bulgaria)

CZECH REPUBLIC – **Leoš Novák** (National Radiation Protection Institute, Czech Republic)

DENMARK – **Hanne Waltenburg** (Danish Health Authority, Denmark)

ESTONIA – **Kadri Kapp** (Health Board, Estonia)

GREECE – **Maria Kalathaki** (Greek Atomic Energy Commission (EEAE), Greece)

HUNGARY – **Richard Elek** (National Public Health Center (NPHC), Hungary) (via Tcon)

ITALY – **Paolo Rossi** (Ministry of Health, Italy)

LATVIA – **Emils Zalmanis** (Radiation Safety Centre of State Environmental Service of the Republic of Latvia, Latvia)

LITHUANIA – **Julius Žiliukas** (Radiation Protection Centre, Lithuania)

LUXEMBOURG – **Alexandra Karoussou-Schreiner** (Ministry of Health of Luxembourg, Luxembourg)

THE NETHERLANDS – **Harmen Bijwaard** (National Institute for Public Health and the Environment (RIVM), The Netherlands)

NORWAY – **Anders Widmark** (Norwegian Radiation and Nuclear Safety Authority (DSA), Norway)

POLAND – **Adam Tołkacz** (LUXMED)

ROMANIA – **Olga Girjoaba** (National Institute of Public Health, Romania)

SLOVENIA – **Damijan Skrk** (Slovenian Radiation Protection Administration, Slovenia)

SPAIN – **Yolanda Agra** (Ministry of Health, Consumption and Social Welfare, Spain)



SWEDEN – Torsten Cederlund (Swedish Radiation Safety Authority, Sweden)

14:00 - Session 10: Panel Discussion - Part 1

Moderators:

John Damilakis (EUCLID Project manager, University of Crete/Greece), **Guy Frija** (EUCLID Project co-manager, EuroSafe Imaging Chair)

Panelists:

Riccardo Corridori (European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry (COCIR)), **Serge Dreuil** (Institute for Radiological Protection and Nuclear Safety, France), **Atte Lajunen** (Radiation and Nuclear Safety Authority, Finland), **Georgi Simeonov** (Policy Officer, Unit Radiation Protection and Nuclear Safety in DG ENER), **María Perez** (World Health Organisation), **Thibault Vanaudenhove** (Federal Agency for Nuclear Control, Belgium), **Jenia Vassileva** (International Atomic Energy Agency), **Hanne Waltenburg** (Heads of the European Radiological Protection Competent Authorities HERCA)

15:00 - COFFEE BREAK (30 MIN)

15:30 - Session 10: Panel Discussion - Part 2

Moderators:

John Damilakis (EUCLID Project manager, University of Crete/Greece), **Guy Frija** (EUCLID Project co-manager, EuroSafe Imaging Chair)

Panelists:

Riccardo Corridori (European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry (COCIR)), **Serge Dreuil** (Institute for Radiological Protection and Nuclear Safety, France), **Atte Lajunen** (Radiation and Nuclear Safety Authority, Finland), **Georgi Simeonov** (Policy Officer, Unit Radiation Protection and Nuclear Safety in DG ENER), **María Perez** (World Health Organisation), **Thibault Vanaudenhove** (Federal Agency for Nuclear Control, Belgium), **Jenia Vassileva** (International Atomic Energy Agency), **Hanne Waltenburg** (Heads of the European Radiological Protection Competent Authorities HERCA)

16:45 - Session 11: Summary, Conclusions, Closing

16:45 Georgi Simeonov (Policy Officer, Unit Radiation Protection and Nuclear Safety in DG ENER)

16:50 Guy Frija (EUCLID Project co-manager, EuroSafe Imaging Chair)

16:55 John Damilakis (EUCLID Project manager, University of Crete/Greece)



17:00 - ADJOURN



Appendix 3: Workshop Presentations

All presentation slides can be found here:

<https://www.dropbox.com/sh/ci41133j0ajx3e0/AAVM7BsTCouyqCFdHcvfrl0a?dl=0>



Appendix 4: List of Rapporteurs to Sessions

Session	Assigned Rapporteur
1	Prof. John Damilakis
2	Prof. Guy Frija
3	Prof. John Damilakis
4	Prof. Guy Frija
5	Prof. Werner Jaschke
6	Prof. Graciano Paulo
7	Dr. Alexander Schegerer
8	Dr. Virginia Tsapaki
9	Dr. Jacques Repussard
10a	Dr. Virginia Tsapaki
10b	Prof. Graciano Paulo
11	Prof. John Damilakis