

WP 1, Final Report

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Working Package: 1

WP 1 – Final report

Optimisation of Patient Exposures in CT-Procedures

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CT-Procedures

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Executive summary

As a first step, the working group developed a matrix structure with seven pillars and eight crosscutting issues relevant to the optimisation of patient exposure in CT procedures:

Pillars	Cross-cutting Issues
CT medical exposures	CT paediatrics
CT risk / benefit estimation	CT oncology
CT dose reduction techniques: equipment	CT cardiology
CT dose reduction techniques: protocols	CT function: contrast enhanced dynamic investigation
CT dose efficiency parameters	CT colonography
CT dose reporting	CT screening
CT diagnostic reference levels	Networking
	Training and Education

Based on this matrix structure, the working group defined the following working packages (WP) and the responsibilities:

	Working Package (WP)	Responsible
1	CT medical exposures	J. Griebel (Lead), E. Nekolla
2	CT risk / benefit estimation	J. Griebel (Lead), E. Nekolla
3	CT dose reduction techniques: equipment	M. Prokop
4	CT dose reduction techniques: protocols	M. Prokop
5	CT dose efficiency parameters	H. D. Nagel
6	CT dose reporting	M. Ginjaume
7	CT diagnostic reference levels	V. Tsapaki
8	Training & education	D. Pekarovic (Lead),
		V. Tsapaki, M. Prokop

WP 1 was included to underline the impact of CT on medical exposures and the resulting need for reduction of CT patient doses. Consequently, WP 2 provided a review on CT risk - benefit for both healthcare and individual health assessment (opportunistic screening). An appropriate risk - benefit assessment is a prerequisite for any justification of CT procedures. Concerning healthcare, it is concluded that a reliable benefit-risk analysis of radiological imaging procedures has to be broken down to diagnosis-related groups of patients. Concerning individual health assessment, it is underlined that – when some CT procedures, such as CT colonography, are considered as an acceptable option for cancer screening – these CT procedures have to be embedded in a well-established screening algorithm with adequate quality assurance. In addition, in WP 2, the strong interrelation between justification and optimisation for the reduction of CT patient doses is addressed because actions initiated by international radiation protection organizations and national regulators often suggest separate approaches for the principles of optimization and justification.

WPs 3 to 7 directly address the issue of optimisation of CT patient exposure. This is in particular valid for WPs 3 and 4, highlighting the impact of equipment and protocols on CT dose reduction.

In **WP 3** it is concluded, that manufacturers should consider to provide a dose indicator on the scanner console that relates the prescribed dose to a reference level (e.g., average DRL across EU countries). A warning should be given if reference levels are exceeded. Adequate documentation of patient-specific parameters (weight and height) as well as exposure is necessary for monitoring exposure practices. Manufacturers should consider providing an automatic mode for generating a database for each individual scanner that records relevant patient and exposure parameters. Further automation to individually adapt kV settings and contrast material dose should be encouraged.

WP 4 introduces the "core team": Each CT facility should identify a core team including a radiographer, a radiologist and a medical physicist and being responsible for optimisation of CT protocols. This core team is also responsible for ensuring training of CT radiographers and supervision of utilization of scanning protocols. Although - in some European countries - there is a shortage of medical physicists trained and educated in radiological imaging, WG 1 wants to underline that medical physicists have to play a pivotal role in this process. Adequate training of the radiological "core team" for appropriate protocol setup and adjustment is mandatory. Manufacturers as well as professional societies need to be involved. Moreover, WP 4 concluded, that manufacturers should be requested to provide at least one standard set of protocols for new scanners, which is optimized towards diagnostically required dose levels. The dose for these protocols should be well below predefined levels that, for example, could be connected to the average DRLs across EU countries. Techniques for adapting standard protocols to individual patient size should be simplified. Regulatory boards and manufacturers should provide a common nomenclature for adaptive dose modulation techniques in order to be able to more easily compare settings. Further automation to individually adapt kV settings and contrast material dose should be encouraged.

WP 5 addresses a promising approach that may have a significant impact on CT patient dose reduction and, as a consequence, on upcoming regulations on CT. The introduction of a standardized benchmarking of CT systems characterizing the dose efficiency in relation to image quality (dose efficiency parameter) in relevant clinical scenarios, would facilitate decision making when purchasing a new scanner, allow for a fair competition between manufacturers, and enable to set the appropriate dose level in protocol optimization. The implementation of this standardized dose efficiency parameter and its declaration in the technical data-sheet for each CT system on the market requires the involvement of various stakeholders: (1) CT manufacturers and medical physicists (to develop and verify the test methods), (2) standard committees (to set up a standard), (3) regulatory bodies (to set up requirements) and (4) radiation protection authorities (to provide funds for the required activities).

WP 6 on CT dose reporting notes, that the *European Guidelines on Quality Criteria for Computed Tomography* were published in 2000. Later, the EC funded, as part of its 6th Framework Programme, the project *CT Safety & Efficacy. A Broad Perspective*, which provided in 2004 useful recommendations and guidelines for optimization in emerging techniques such as multi-slice CT. However, since then, the EC has not published any other official document for quality criteria in CT. This highlights the need of harmonisation and of new guidelines. In this connection, a greater role of radiologists and other practically involved heath care professionals is warranted. The concept of organ dose instead of effective dose should be introduced more into clinical practice. However, it is

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^{*} The order of the professions does not reflect any difference in their importance.

too early to come with concrete suggestions. The same holds true for the introduction of new measurement techniques for measuring dose in CT systems with a wide x-ray beam and detector. An international consensus should be reached before introducing such new techniques into EU recommendations. There is a need for introducing a program within the EU for calibration of instruments to ensure traceability in quality assurance programmes for CT.

In **WP 7** on CT diagnostic reference levels, it is outlined that DRLs published so far show large variations which – with regard to CTDI – may be mainly due to variations in the technical protocols used and differences in the CT scanner. Therefore, more standardized protocols could harmonize CTDI-DRL values. Variations in DLP-DRL values are mainly due to variations in the clinical set up (e.g. definition of abdomen CT). These large variations, especially for DLPs, show that appropriate optimisation offers great potential to reduce patient CT dose. Joint attempts for harmonization and optimization could be addressed to the ESR, EFOMP and the EFSR. European DRLs do not include MSCT and the dose quantity CTDI_{vol}. In several countries, CT DRLs are missing.

WP 8 on training and education is considered as an important cross-cutting issue which emphasizes the multidisciplinary challenge of optimization. It particular reflects the points of view of radiographers, medical physicists and radiologists, and thus, of EFRS, EFOMP and ESR. Each CT facility should identify a core team (see WP 4) responsible for optimisation of CT protocols. This core team is also responsible for ensuring training of radiographers and supervision of utilization of scanning protocols. Training of at least one member of the core team should be based on the Core Curriculum for Medical Physicist in Radiology developed by EFOMP. There is need for dedicated courses that focus on optimizing CT protocols in general and are geared to the whole core team. ESR, EFRS and subspecialty societies can play a major role in establishing these training programs. There is a need for a formal accreditation procedure of CT training and education programs established by ESR. Training courses after the acquisition of new equipment are needed, taking into particular account the specific features of the new equipment.

Recommendation to the EC

WG 1 considers the Working Packages WP 1 to 8 as equally important. Derived from these Working Packages, the following actions are considered to be pivotal. However, they do not represent any kind of ranking.

- 1) Launch of EU research to adequately validate the results of studies on CT medical exposures by a thorough analysis weighing the clinical benefit from the increasing use of CT against the associated radiation risks and by taking into account detailed information on age of the patients and clinical indication of the performed CT exams.
- 2) Concerted action to extend the ALARA approach by taking into account not only the principle of optimization but also the principle of justification.
- 3) Concerted action to develop and implement harmonized referral guidelines on a European level.
- 4) Concerted action to clarify the interaction between referral and justification and the roles of the responsible professionals, i.e. the medical practitioner (referral process) and the radiological practitioner (justification process).

- 5) Launch of EU research to assess benefit-risk ratios for diagnosis-related groups of patients in CT healthcare, especially for those being highly exposed as well as for those being particularly radio-sensitive, e.g. pregnant women, children and young adults.
- 6) Concerted action to develop standardised and optimised protocols and algorithms in individual health assessment concerning the definition of risk profiles, technical performance of CT, reading and diagnostic workup of suspicious findings, training and education as well as documentation and evaluation.
- 7) Manufacturers should be requested to provide
 - an automatic mode for generating a database for each individual scanner that records relevant patient-specific (weight and height) and exposure parameters;
 - a reliable and easy-to-use dose reporting software
 - o to display the actual medical exposure of each individual patient, and thus,
 - to relate the prescribed dose to a reference level (e.g., average DRL across EU countries), and to warn the operator if reference levels are exceeded;
 - to keep patients well informed and to enable the health professionals to critically analyze the protocols of individuals and also of groups of patients (patient dose records).
 - simplified techniques for adapting standard protocols to individual patient size with standardized terminology for adaptive dose modulation techniques across manufacturers in order to more easily compare settings;
 - automation techniques to individually adapt kV settings and contrast material dose;
 - at least one standard set of protocols for new scanners, which is optimized towards diagnostically required dose levels. The dose for these protocols should be below predefined levels - for example, the average DRLs across EU countries.
- 8) Concerted action to implement a standardized benchmarking for CT systems characterizing the dose efficiency related to image quality of CT systems (dose efficiency parameter) and to declare this standardized dose efficiency parameter in the technical data-sheet for each CT system on the market.
- 9) Concerted action to harmonize nomenclature of dose-specific parameters, in particular concerning C_{KL} and P_{KL} on the one hand and CTDI and DLP on the other hand. Hereby, a greater role of radiologists and other practically involved heath care professionals has to be warranted.
- 10) Concerted actions to consider the question whether
 - the concept of organ dose, as compared to the effective dose, and
 - new measurement techniques for measuring dose in CT systems with a wide x-ray beam and detector

should have a stronger impact on the clinical practice. An international consensus should be reached before introducing such novel approaches into EU recommendations.

- 11) Launch of an EU research program
 - for the calibration of dose-specific instruments to ensure traceability in quality assurance programmes for CT.

12) Launch of EU research programs

- to revise CT-DRLs in adults, in particular with respect to MSCT, DLP and CTDI_{vol};
- to evaluate CT-DRLs in cardiac or perfusion CT;
- to evaluate CT-DRLs in children and young adults.

13) Concerted actions

- to implement CT-DRLs in more European countries;
- to implement revised and extended CT-DRLs in adults EU-wide;
- to implement paediatric CT-DRLs EU-wide.

14) Concerted actions to ensure EU-wide

- the identification of a radiological "core team" (including a radiographer, a radiologist and a medical physicist*) for each CT facility, being responsible for
 - o the optimization of CT scanning protocols;
 - o the supervision of utilization of scanning protocols;
 - the training of CT staff, and
- an adequate training and education of the radiological "core team", that should focus on:
 - o the optimization of CT protocols in general and
 - the appropriate protocol setup and adjustment with respect to the specific CT systems running in the CT facility.

Hereby, training of at least one member of the "core team" should be based on the Core Curriculum for Medical Physicist in Radiology developed by EFOMP. Although in some European countries there is a shortage of medical physicists trained and educated in radiological imaging, medical physicists have to play a pivotal role in this process.

15) Concerted actions to ensure

- a formal accreditation procedure of CT training and education programs established by ESR;
- the development of training and education recommendations for radiographers established by EFRS;
- the provision of dedicated training courses after the acquisition of new CT equipment.

Conclusions from the workshop

The contents of the three WG sessions were prepared at the last WG meeting on 4 May 2012. WG 1 decided to focus on the following topics in the WG sessions:

[•] the order of the professions does not reflect any difference in their importance

WG session CT	Topics
Session 3 – Problems and solutions: Technical issues: How to reduce dose in practice?	 Knowledge dissemination Standard protocols provided by the manufacturers Dose efficiency parameter Dose recording and reporting
Session 5 – Making solutions happen: Regulatory issues: How to ensure optimum use of technology?	 Requirements for new equipment Dose reporting and monitoring including DRLs Core teams Incentives for using low-dose protocols
Session 7 – Future activities for EMAN	 Multi-stakeholder efforts for training and education Web-based knowledge dissemination / forum EMAN contribution to congresses / meetings EMAN as a sustainable network

For every topic, an introduction was given by the Co-chair to provide background information to the audience. Then key questions were posed to the audience, and a voting system was used to explore various alternatives for answers. Finally, the results were discussed with the audience and potential suggestions for action were explored. The summaries below focus on those actions where broad consensus was reached.

Problems and solutions (Technical issues: How to reduce dose in practice?)Chair: Peter Vock, ESR; Co-Chair: Virginia Tsapaki, EFOMP; Rapporteur: Elke Nekolla, BfS

Knowledge dissemination:

Lots of technology for dose reduction is already commercially available, but knowledge about how to use it is often lacking. Required levels of expertise differ between professions. A core team should therefore be established consisting of a medical physicist, a radiologist, and a radiographer. This core team should be trained by a regional, national, or European "super core team".

Standard protocols provided by the manufacturers:

Standard protocols are of crucial importance. Most sites use standard protocols that they modify only sporadically. They are often based on luminary sites, and usually not adapted to local conditions. A platform should be created to share best practices and advice on how to adapt them. A system for testing new standard protocols as well as a system for feedback to manufacturers through hospitals should be created. Manufacturers should provide dedicated sets of protocols for different quality levels.

Dose efficiency parameter:

There should be a set of standardized dose efficiency parameters providing the relation between the image quality and the dose required to attain it, in order to compare different scanners, to facilitate decision making about new equipment, and to give an indication of relative dose requirements (target level). Since not all quality aspects can be incorporated, this is a scientific challenge. The system should be based on an objective method, checked against subjective methods, easy to use, not too complex, but fair for all scanners.

Dose reporting and recording:

Newest scanners have good reporting tools. Commercial software is able to import DICOM structured reports into databases. Dose recording should be made mandatory including patient size information (height, weight). There should be a common database format for local dose monitoring, cross-country comparison, and for yearly updates of DRLs. There should be a standard set of protocol names depending on clinical question and scan region.

Making solutions happen and action plan (Regulatory issues: How to ensure optimum use of technology?)

Chair: M. Prokop, ESR; Co-Chairs: H.D. Nagel, SASCRAD/D. Pekarovic, EFRS; Rapp.: E. Nekolla, BfS

Requirements for new equipment:

There are lots of new features, i.e. important prerequisites for dose reduction available, but not all are standard (depending on manufacturer, purchased option). Moreover, not all features are sufficiently fool-proof. Users should be informed about scanner specific limitations of dose reduction by dedicated training on site. New scanners should issue a warning when scanning range is outside the radiogram, the geometric efficiency is less than 70% or the DLP is exceeded. Reporting of CTDI_{vol} and DLP should be made mandatory.

Dose reporting and monitoring including DRLs (See also Session 3, Topic 4):

Reporting tools are available from manufacturers / 3rd parties. However, size information is often lacking. An unsolved issue is the conversion of DLP to E for non-standard size patients. Since no standard dose database structure is available yet, a common format should be suggested by scientific societies. Continuous update of DRLs will gradually force lower doses. Research on conversion of DLP to E should be supported.

Core team

Optimization is a multidisciplinary challenge. A core team, consisting of radiologist, radiographer, and medical physicist is therefore desirable, where the members should be assigned clear responsibilities, i.e. trained according to their specific roles and requirements. It should be made mandatory, however, allowance should be given for restricted personnel resources (start with minimum recommendations). The core team should take over competencies and duties for optimization and training on site. It should be empowered to supervise/change protocols. It should be trained by experienced RP experts and manufacturers.

Incentives for using lower-dose protocols:

Current requirements (DRLs) can be met easily. Performing a low dose exam is associated with the risk to miss a diagnosis. Competition favours good image quality, but not low dose. There is no regulatory incentive yet to do better than necessary. Manufacturers should provide a set of low-dose protocols in order to make dose reduction easier. It might also be helpful to create an EU-EMAN platform to exchange low-dose protocols. It is important to establish individual responsibility of the performer (link dose info to individual radiographer/radiologist). A "collective responsibility" (standardized procedures) is counter-productive with regard to RP.

Future activities for EMAN

Chair: Mathias Prokop, ESR; Co-Chair: Mercè Ginjaume, EURADOS; Rapporteur: E. Nekolla, BfS

Multi-stakeholder efforts for training and education

Rapid changes of technology require vendor-specific training. This training should mainly be offered for members of the core teams. COCIR proposed to provide an extensive training to ensure appropriate, safe and effective use of imaging equipment, to provide specific training curricula on existing and new techniques, and to deploy features in daily practice. There should be specialized training for radiologists / radiographers / physicists separately and a coordinated module for joint issues. Input from industry is essential. EMAN could be a vehicle for joint efforts with vendors and specialist societies (e.g. EMAN workshops at ESR or other specialist societies).

Web based knowledge dissemination / forum:

There is no single web source on medical radiation dose. However, world-wide dissemination requires effective peer-reviewing and continuous updates to stay valuable. EMAN synthesis reports are valuable, but "hidden" in EMAN website and could be a source for such a website. A Wikipedia approach (with fast peer review) could be of high value ("Dosepedia"). To start, it could be filled with information from the EMAN synthesis reports. New contributors should be invited. The website should contain general information about RP (including regulations, DRLs), best practices, tested protocol suggestions, and a discussion forum. The website could be hosted by EMAN directly or under the umbrella of ESR. Requirements are: webmaster, editorial board, reviewers, and (minimum) funding. Author names should be provided to make it quotable.

EMAN contribution to congresses / meetings

EMAN documents include valuable information and lots of work and therefore might be published (e.g. one chapter at a time in *Insights into Imaging*). EMAN has knowledge about who knows what, and might therefore provide content and suggest speakers for other societies. EMAN can be used as an information distributor. However, there is need of stronger coordination, of an administration, and more stakeholders willing to contribute.

EMAN as a sustainable network:

The added value of EMAN is that it provides a multidisciplinary platform. Sustainable funding is crucial, i.e. EMAN could become a sustainable network by EU funding plus contribution of partner societies plus sponsorship by manufacturers. EMAN could become a separate scientific society (including new members). However, it is more realistic that it is integrated into EAN or ESR as a subgroup (at least as a first step). The future success of EMAN will depend on strong leadership and the enthusiasm and commitment of its members.

Key suggestions of WG 1 derived from all three WG sessions:

- Standard protocols by manufacturers
 - at various image quality levels, well below current DRLs
- Common database format for dose data
 - with standardized protocol names to collect and compare dose
- Core team
 - to focus training and provide clear responsibilities
- Web-based forum and knowledge repository
 - to disseminate knowledge
 - to share best practices and provide feedback

Administrative summary

In WG 1, representatives of the relevant scientific societies with regard to CT optimization were included (ESR, EURADOS, EFOMP, EFRS) as well as experts in the field of CT technology and in the field of assessment of medical exposures and associated radiation risk:

Members of Working Group 1:

Griebel Jürgen	Lead, BfS, Federal Office of Radiation Protection	Germany
Mathias Prokop	ESR, European Society of Radiology	Netherlands
Dean Pekarovic	EFRS, European Federation of Radiographer Societies	Slovenia
Virginia Tsapaki	EFOMP, European Federation of organisations for Medical	Greece
	Physics	
Merce Ginjaume	EURADOS, European Radiation Dosimetry Group	Spain
Elke Nekolla	Expert, BfS, Federal Office of Radiation Protection	Germany
Hans Dieter Nagel	Expert, SASCRAD	Germany
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Six WG meetings took place:

- 1st meeting: Kick-Off meeting in Munich on 17 May 2010
- 2nd meeting: Nijmegen on 4-5 October 2010
- 3rd meeting: Barcelona on 1-2 February 2011
- 4th meeting: Munich on 4-5 July 2011
- 5th meeting: Vienna on 16 January 2012
- 6th meeting: Munich on 4 May 2012

The meetings were documented with minutes which were sent to the coordinator of the EMAN project (SSM). In its six meetings, WG 1 focussed on the optimisation of patient exposure in CT procedures. Originally, the mandate also included occupational exposures. But it was decided by the Steering Committee not to work on this issue, since CT fluoroscopy – the only application of CT relevant to occupational exposures – will be dealt within the framework of WG 2.

As already mentioned in the Executive Summary, the working group developed a matrix structure with seven pillars and eight cross-cutting issues (1st meeting). Based on this matrix structure, the working group defined working packages and corresponding responsibilities (see above). The Synthesis document was created mainly between the 1st and 2nd meeting, and submitted after final discussion shortly after the 2nd meeting. At the 3rd meeting, the content and contributions of each WP to the Progress Report were discussed and fixed. The last meetings focused mainly on structure, content and WG 1 contributions to the EMAN workshop, and on the Future Network. A special focus of WG 1 was stakeholder involvement to provide mutual information: WHO joined the 3rd meeting, and two joint meetings took place with COCIR (4th and 5th meeting). The potential scope of cooperation with COCIR at the EMAN workshop was discussed.

Networking challenges

One of the striking features of the Working Groups and in particular of Working Group 1 "Optimisation of Patient Exposures in CT-Procedure" is its multi-disciplinary and multi-cultural composition. A further important feature is stakeholder involvement. Working Group 1 considers these features as pivotal for its successful work within the last three years. Medical radiation protection – even if it is restricted to the optimisation of CT procedures – is a very complex issue. The identification of problems as well as the development of possible solutions and recommendations

require the contribution of a wide range of stakeholders: medical physicists, radiographers and medical doctors. A sound discussion further requires the involvement of manufacturers as well as authorities and international organisations. The experience in Working Group 1 is that the resulting discussions were quite often very intense but always inspiring and fruitful – due to the multidisciplinary but also multi-cultural composition of the group. As a consequence, especially during the team-building phase, face-to-face meetings were essential. For the organisation of meetings as well as the preparation of documents, the use of electronic tools is very helpful, such as Doodle and emailing. In Working Group 1 the use of e-meetings such as Skype or videoconferences was not possible due to the lack of adequate equipment. However, given a clearly defined agenda and well-prepared position papers, e-meetings might be helpful and efficient, in particular for discussing agreements or making decisions within the group.

Attachments

- Minutes from each of the six working group meetings
- Synthesis document
- Interim report