European Medical ALARA Network

WP3, Final Report

WP leader
Renato Padovani

Version/Document date: July 5, 2012

Working Package: 3

WP 3 – Final report

Optimization of radiation protection for x-ray procedures outside the radiology department

Project	European Medical ALARA network (EMAN)
	Contract No. TREN/09/NUCL/SI2.542127
Document	Final report for Work package 3: Executive smmary
WP start date	November 2009
WP end date	June 2012
Coordinator	Swedish Radiation Safety Authority, SSM
WP manager	Renato Padovani (EFOMP)
Authors	Eila Lantto (ESR), John Damilakis (ESR), Anders Widmark (EFSR), Stelios Christofides (EFOMP), Caroline Schieber (CEPN), Laure-Anne Boffa (CEPN)
Attention of	Georgi Simeonov European Commission, Directorate-General for Energy

Content

Executive summary

Radiation protection of patients and staff for practices performed outside radiological departments are of particular interest due to:

- the limited information on type and frequency of procedures performed mainly with mobile radiography and fluoroscopy equipment,
- the increased frequency of procedures, some of them complex, in surgical theatres,
- the limited information on patient and staff exposure involved,
- the fact that procedures are performed by non-radiologists and nurses with poor or without training on radiation protection and procedure optimisation.

The practices where patient and staff exposures require optimisation have been identified in the following clinical areas: vascular surgery, gastroenterology, urology, orthopaedics, neurosurgery, anaesthesiology, gynaecology and X-rays at bedside.

The EMAN WG 3 is composed by radiologists, medical physicists, radiographers and radiation protection experts representing major European professional and scientific groups in this field, the European Society of Radiology (ESR), the European Federation of Organisations for Medical Physics (EFOMP), the European Federation of Radiographer Societies (EFSR) and the CEPN, a French radiation protection body. A representative of the European Society of Gastrointestinal Endoscopy (ESGE) has joined the group from the 3rd meeting to develop a networking experience with a stakeholder performing an important fraction of radiological practices outside radiology department.

The WG 3 had 5 face-to-face meetings and several distant contacts. In the first phase of the project the WG collected and analysed the existing information on the practices, trying to identify lack of information and optimisation and developing a synthesis document where elements of recommendations have been included.

Synthesis document

The Chapter 1 provides an overview on the impact on population exposure of radiology, nuclear medicine and dental practices, as derived by the DoseDatamed survey in 2004-2007. It is reported that for practices performed outside radiological departments there are limited information on frequency and patient and staff doses.

In chapters 2 and 3 a description of the most frequent radiological procedures and literature, data on frequencies on patient and staff doses are reported. The evidence is that only for few procedures, literature patient data are relative numerous and demonstrating the existence of large variation of patient doses. Staff dose data are always limited and reported with different quantities, making comparison difficult. Because literature is not reporting frequencies, some preliminary evaluations have been derived from data collected in WG member's hospitals.
When a limited set of patient dose data is available, a pragmatic methodology to assess Diagnostic Reference Levels (DRL), has been proposed as the 3rd quartile of the distribution of the mean values from a sample of installation for fluoroscopy time and KAP.
Chapter 4 describes the mobile radiography and fluoroscopy equipment technology and the relevant international standards, like CE mark of medical devices, IEC and CENELEC. The quality assurance programme, required by the MED EU Directive, includes the quality control programme of the radiological equipment. In documents of AAPM (US) and IPEM (UK), the Quality control of x-ray units is adequately covered.

Staff protection devices and discussion on the effectiveness of the shielding are included in chapter 5. Because there is a non harmonised adoption of protective devices, the development of a guideline specific for the different specialties is necessary. Chapter 6 on staff exposure monitoring discusses the methods for the evaluation of personal dosimetry data, including the investigation of high dose

levels. The survey conducted in 7 European countries on personal monitoring practice is reported as an example of the differences in the national monitoring practices. A review of the EC RP Report 160 on technical recommendation of staff monitoring is provided as guidance.

Chapter 7 introduces direct, indirect and calculation methods for patient dosimetry. As an example of the differences in the patient dosimetry practice, a detailed description of the approached adopted in 5 European countries is reported.

Education and training in radiation protection of the personnel is discussed in chapter 8 starting from the results of a survey conducted in 23 European countries demonstrating a non harmonised approach to education and training. In particular the need of a more effective harmonisation and implementation of the national regulations, the introduction of a credentialing system for RP, the reinforcement of the importance of the Continuous Professional Development system are underlined.

Chapter 9 on clinical audit, reports the fact that only Finland has performed a clinical audit on the radiological practices outside radiology. In this survey the auditors gave a number of recommendations about fluoroscopy outside radiological departments, mainly about training and education of the staff, the use of shielding devices, and examination guidelines. Chapter 10 reports the main outcomes from the inspection on these practices in Norway. Interviews revealed serious lack of skills in radiation protection, for example: staff were unable to identify the X-ray tube from the image intensifier of the C-arm, had inadequate knowledge of the operating console, of the three cardinal principles for staff protection (time, distance and shielding) and, total lack of knowledge about patient doses and risks. Finally, chapter 11 collects a list of lessons learned and examples of bad practices, material that can be conveniently used in training courses.

Recommendations

The synthesis document is providing an overview of the present status of the optimisation level of the radiological practices performed outside the radiology department and provides the basis for the development of a European guideline.

The identified lack of optimisation allows identifying actions useful to improve optimisation levels, summarised in the following recommendations:

1. The lack of information on the practice requires European scientific societies to promote national data collections. EC should also strengthen Member States to implement the practice of patient dose monitoring, as requested by MED for these “special practices”.
2. A methodology to assess DRLs, when a limited set of data is available, is proposed. The 3rd quartile of the distribution of the mean values for fluoroscopy time and KAP from a sample of installation can pragmatically provide preliminary reference levels. EC and European scientific societies have to develop European surveys aiming to assess and adopt DRLs.
3. Staff exposure monitoring requires harmonisation because countries have different recommendations or some don’t have at all. EMAN should support HERCA to develop a European recommendation. The recommendation should promote also the use of additional active dosimeters for educational purposes, the identification of high dose procedures requiring hand and eye lens dosimetry and the adoption of ambient dosimetry, as part of the radiological equipment.
4. HERCA should also work on the harmonisation of national staff dosimetry databases where the inclusion of specialist radiological workload will allow extracting dose information for specific group of specialists.
5. Inadequate mobile fluoroscopy equipments are frequently used to perform complex and long procedures in surgical theatres. International standards should require equipment functions to reduce patient and staff doses, including provisions for staff shielding. COCIR should promote this action. Hospitals are invited to provide adequate shielding to high workload mobile fluoroscopy units and to acquire new equipments with KAP display, as required by MED.

6. Hospitals should be encouraged to setup patient dose information systems to automatically collect patient doses for a better monitoring of the practices adopting existing international standards, e.g. IHE REM profile (Radiation Exposure Monitoring Integration Profile, Integrating the Healthcare Enterprise). COCIR should promote the development of such information systems.
7. Education and training of professionals involved are seen as a priority. Most of practitioners have little or no education in radiation protection and optimisation methods. Specific methodologies are required to reach the large number of practitioners (medical specialists, nurses, radiographers and medical physicists). MEDRAPET recommendations will properly address on the training methodology and contents (KSC methodology), while knowledge can be conveniently provided via the development of distance learning tools, while hospitals should provide the skill via practical exercises. EMAN should promote these actions and offer educational sessions at the European congresses of the different specialities.
8. Clinical audit, as requested by MED, has been performed only in one European country. Starting from this experience EMAN can develop proper methodology and setup multidisciplinary teams.
9. Inspection activity is again rarely performed. EMAN can recommend to HERCA the development of guidelines and support inspectors training.
10. Stakeholder's involvement. The experience and the agreement reached with the European Society of Gastrointestinal Endoscopy (ESGE) can be taken by EMAN as a model to propose to other professional specialities to enlarge the network
11. Optimisation of the practices. It is recommended to hospitals to setup a multidisciplinary "core team" to support optimisation. EMAN has also developed a list of contents for a guideline for optimisation. The guideline content is addressed to EC that should consider the opportunity to develop a Radiation protection Guideline for the optimisation of radiological practices performed outside radiology departments.

Recommendation to the EC

The following recommendations are addressed to the European Commission as an outcome of the WG to improve optimisation in the radiological practice performed outside radiology departments:

1. EC should also strengthen the patient dose monitoring at the hospital level as requested by MED for these "special practices".
2. EMAN has proposed a methodology to assess DRLs when a limited set of data is available. In the context of the necessary revision of the *EC Guidance on Diagnostic Reference Levels for Medical Exposure (RP 109)* it is recommended to assess and include specific DRLs for the most frequent procedures performed outside radiology departments.
3. EC should recommend to Member States to apply harmonised staff exposure monitoring guidelines. The guideline should be conveniently developed by HERCA and EMAN.
4. EC should recommend to Member States to apply art. 8.6 of the MED Directive where *new radiological equipment shall have a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure.*
5. EC should promote clinical audit and inspection activities. EMAN can support such actions developing specific methodology to apply in pilot project via multidisciplinary teams.
6. Because of the lack of optimisation in these practices, EC should consider the opportunity to develop a Radiation protection *Guideline for the optimisation of radiological practices performed outside radiology departments*. A draft structure is proposed by EMAN.

Conclusions from the workshop

WP3 prepared the workgroup activity at the workshop discussing optimisation issues in the identified «special practice», reported in order of relevance: vascular surgery, gastroenterology, urology, orthopaedics, neurosurgery, anaesthesiology, general surgery, gynaecology, neonatology (bedside X-rays), dentistry (above all cone beam CT).

In the three workgroup sessions, the problems, action plan and future EMAN activities have been discussed and the following recommendations agreed as priorities for the improvement of optimisation. Recommendations are addressed to EMAN, for its future activity as a sustainable network, to EC, HERCA and European scientific societies representing medical specialists, radiographers and nurses involved in the radiological practices performed outside radiology departments.

1. Data collection on frequency of procedures and related patient and staff doses. Dose monitoring for special practices, as required by the Directive, is not common and should be realised through the European scientific societies and at the national level.
2. There is the need to asses DRLs for frequent and for high-dose procedures.
3. The EC has to develop a specific RP Guideline for the optimisation of special practices and EMAN should contribute.
4. Harmonisation of staff monitoring is necessary. A European recommendation, developed together by HERCA and EMAN should be promoted.
5. Mobile fluoroscopy equipment for complex and long procedures used in surgical theatres are frequently inadequate. COCIR should promote the development of revised standards for equipment and shielding, and patient dose monitoring devices.
6. Most practitioners have little or no education and training in RP. MEDRAPET recommendations should address learning objectives (KSC) and EMAN should promote and develop distance learning tools and courses. Hospitals should be encouraged to provide practical training. Hospitals can benefit in setting up a multidisciplinary core team.
7. Clinical audit. The methodology for special practices should be developed and EMAN can contribute.
8. HERCA should promote inspections and EMAN can contribute to guideline development.
9. Stakeholders involvement in EMAN is probably the most critical and difficult task. The experience with ESGE should be used as a model for future networking.

Administrative summary

The EMAN WG 3 is composed by radiologists, medical physicists, radiographers and radiation protection experts representing major European professional and scientific groups in this field, the European Society of Radiology (ESR), the European Federation of Organisations for Medical Physics (EFOMP), the European Federation of Radiographer Societies (EFSR) and the CEPN, a French radiation protection body.

Members of the WG 3:

NAME	e-mail address	Appointed by
Anders Widmark	anders.widmark@nrpa.no	ESFR
Caroline Schieber	schieber@cepn.asso.fr	CEPN
Celine Bataille	bataille@cepn.asso.fr	CEPN (until September 2010)
Laure-Anna Boffa	laure-anne.boffa@cepn.asso.fr	CEPN (since October 2010)
Eila Lantto	eila.lantto@phsotey.fi	ESR
John Damilakis	damilaki@med.uoc.gr	ESR
Stelios Christofides	cstelios@cytanet.com.cy	EFOMP
Renato Padovani	padovani.renato@aoud.sanita.fvg.it	EFOMP

Representatives of the European Society of Gastrointestinal Endoscopy (ESGE) has joined the group from the 3rd meeting.

The WG had 5 face-to-face meetings (5 minutes attached) and several distant contacts.

The WG has conducted on these radiological practices surveys on:

status and recommendations for staff dose monitoring in fluoroscopy guided procedures (7 countries);
education and training regulation and practice in 23 European countries;
clinical audit experiences;
inspection activities;
frequency, patient and staff doses in some hospitals of Cyprus, Finland, Italy, Norway to integrate literature data;

Networking challenges

The more than 2 years activity of this working group has demonstrated the possibility and the benefit to work in a multidisciplinary team in different ways, i.e. face-to-face meetings, document developments, Workshop group work, e-meetings, etc.

The WG 3 mandate was also to attract other stakeholders. Here the activity developed with the ESGE (European Society of Gastrointestinal Endoscopy) and the formal agreement reached is outlined:

- to establish a common working group
- to develop RP Guidelines
- to evaluate frequency and patient doses of Gastroenterology procedures in Europe
- to assess DRLs (Dose Reference Levels) for ERCP
- to collaborate in future survey development and data analysis
- to develop training material on RP for education actions of ESGE and to integrate RP sessions in ESGE Workshops
- to contribute to the EMAN Workshop and to have links in the respective websites.

This extensive and promising agreement should be taken as a model for the future enlargement of the EMAN network.

EMAN has also worked with MEDRAPET providing suggestions for the education and training of the professionals involved in these practices.

Attachments

- Synthesis document
- Structure of the proposed European Guideline on Optimisation of Radiation Protection in Radiological Practices Performed Outside the Radiological Department
- Minutes of the 5 working group meetings