1st European Inspection Workshop

HERCA MedInspector 2015

Working group template on optimization





Optimisation: General issues

- > To what extent is optimization part of the inspection process?
 - What is in focus of the inspection (compliance with requirements, guidance, information, identification of good practice, other?)
 - Elements of the inspections (interviews, observations, review of documentation, measurements, other)?
 - Process of optimization explicitly covered in QA-system?
- ➤ Is a proper risk assessment performed (patient and staff)?
- Does the inspection cover both patient and staff?
- Are patient and occupational RP covered by the same authority
 - If not, is there any cooperation and how?

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Optimization: Inspector training

- What is the competence (training and skills) of the inspectors in order to be able to inspect the process of optimization?
 - Professional background?
 - Clinical experience?
 - Training of inspectors, formal training program, others?
- Is the competence of the inspectors adequate in order to provide clinical assessment of optimization of practical aspects?

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Optimisation: Examination protocols

- > Do you inspect the availability of examination protocols?
- Are paediatric protocols developed and used? Do you evaluate them?
 - Use of grid, AEC, others?
- Are these protocols used as provided by the manufacturer or further optimised?
- Are procedures in place for updating these protocols when necessary?
- Are the optimization of procedures performed by a multi-disciplinary team?
 - Dose optimization of the staff considered?

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Optimisation: DRLs

- Are national DRLs established for common diagnostic examinations and interventional procedures?
 - If yes, based on national surveys, level of revision?
 - If not, use of European DRLs, others?
- Are local standard doses established and compared to national DRLs?
 - Local procedures on establishment and revision?
 - Local review and corrective actions if deviations from national DRLs?
 - Used actively as a tool for optimization (not only as regulatory tool)?
 - Used as a tool for education and training of staff
- Are the associated professionals (radiological practitioners, radiographers) aware of the concept of DRLs and how to implement them in clinical practice?

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Optimisation: Dose limiting tools/technique

- Are dose limiting tools of X-ray equipment available and in use (CT, interventional, other)?
- Are dose limiting techniques (compression, projection, shielding, etc.) in use?
- Are the associated professionals using these systems aware of and trained in the use of these dose limiting tools?





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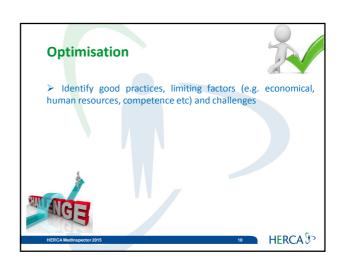
Optimisation: Training of staff Is the education and training of the staff assessed during inspections? Education and training records reviewed? General training in RP and safe use of radiation? Equipment specific training including RP issues? Who is providing the training (medical physicist, vendor, others?) Is the level of knowledge in RP and use of equipment assessed/checked during the inspection (by interviews)

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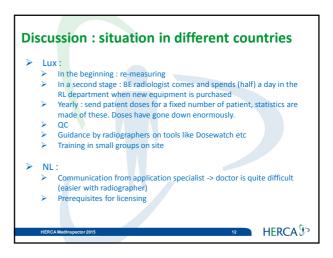
Optimisation: Equipment and QC Are equipment CE-marked and suitable for intended use? Provided with necessary protective devices (interventional radiology) Are user manuals available in proper language? Are patient doses part of the radiological report? If yes, manually or automatic reported? Are frequently QC performed and deviations followed up? Availability of acceptability criteria (like RP 162), local/national? Are the results of the QC tests checked and evaluated during inspections? Are QC tests performed based on national protocols? Are the calibration of QC equipment evaluated?

Involvement of a medical physicist evaluated?





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Discussion: situation in different countries

- - Medical doctors are left out in optimization process (radiographers + MPE), but they have to evaluate the image quality -> try to convince them that you don't need the best image quality, it should match the clinical question
 - Logbook signed by maintenance engineer
- Norway
- Look into the image parameters (magnification, collimation,...)
- Training of medical doctors in radiation protection in basic curriculum is limited, especially in justification
- Ireland
 - Not always a clinical specialist involved
- Lithuania:
 - possibility to consult a MPE in every procedure/stage
 - Reference levels for CT children + adults, MPE gives methodology and gives advice to optimize

Discussion: situation in different countries

- - Patient and occupational optimization is focus in inspection
 - Questionnaire is sent before the inspection, plenty of questions : which exams, number of exams, high dose exams,...
 - MPE and RPE are always interviewed during inspection
 - Recognize organisms for quality control and radiation protection. During inspection, the external report is available
 - **Training**
 - Protocol (national guides)
 - Assess knowledge with regard to optimization parameters
 - Focus on pregnant women + children

 - Incidents : sometimes because of maintenance problems -> clearance of the equipment after incidents or maintenance
- Kroatia
 - Some hospitals don't have MPE
- No checklist in inspection, some aspects of optimization are checked

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Discussion: general conclusions

- Can we look at the process? How can we challenge optimisation? We don't have the equivalent of referral criteria. We have to put the emphasis on "appropriate" image quality.
- DRL
 - What do we do with it, frequency of updating? National vs. local DRIS
 - No use if not used locally
 - "ambush" staff to know whether they really know and use their
 - Concept of DRL useful for interventional? Or evaluating the complexity of examinations? Better understanding of the tools?
 - Don't change definition of DRLs

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Discussion: general conclusions

- Benchmarking is a powerful tool
- Maintenance: communication between manufacturer/maintenance engineer and clinicians (verify parameters! Careful with default parameters)
- Knowledge and use of functionalities/awareness of tools that influence or monitor dose
 - for example 3 buttons with higher, lower dose and image quality, tools like dosewatch
 - can be audited because in DICOM: "why do you always that mode?"
 - statistics can be made on this and feedback can be given to doctors -> can give rise to training
 - Resistance because of work load or image quality: education "champians" teaching their colleagues

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Discussion: general conclusions

- Utility of "follow up training" by the manufacturers possibility to give credits of this kind of training (incentive)? Great value of on-site training! Manufacturers could also help by providing training material
- Training is not a guarantee for competence...
- Training: also soft skills!
- Written departmental procedures
 - + updates
 - Verify whether they do follow them ! (at least for standard patients)
- Usually there is no major problem for inspectors to attend a procedure (<-> France)

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Discussion: general conclusions

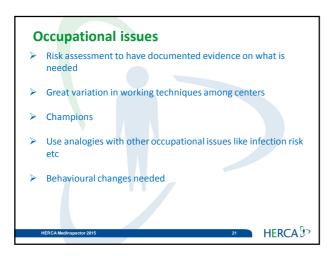
- Use of documentation cfr. Image gently
- Interventional
 - Dedicated pediatric hospitals usually do pay attention to optimization
 - Challenge (for example in UK): 24/7 interventional services
- Risk assessment = starting point.
 - Cfr. Other industries using ionising radiation : not always done in medical field
 - Operating procedures and optimization are following risk assessment
 - Cfr. case of CT fluoroscopy
 - Crucial for new techniques. It is more often done from occupational point of vue but it should been done from patient protection point of vue as well
- Radiologists should be involved, not only radiographers and

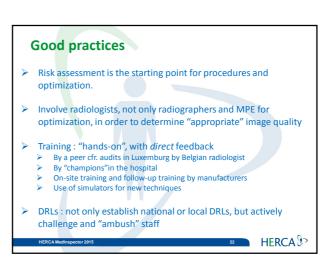
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Training of staff "the responsibility of the undertaking" How to assess ? Evidence of training records, sign off by trainer and by trainee Use of simulators before they use a new technique in clinic Appraisal of radiologist and renewal Visualisation of what you are doing = teaching tool

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Equipment and QC National protocols in national legislation RP162 ? most countries have their own acceptability criteria Regular review needed Protocols prepared by professional bodies, "adoption" by the authorities In-built QC tests: is not independent but it makes no sense to duplicate (all of) these test by MPE. However an independent test is still needed to detect human errors and to perform constancy testing Who should test what: has to be reviewed to not uselessly duplicate and to take into account technical evolutions





Good practices > Benchmarking increases awareness and motivation to optimize > Tools and functionalities for dose reduction/monitoring: communication with manufacturers, awareness of the capabilities, training > Look into the record of image parameters and question about the use of them, for example was the low dose setting used, etc. > Use the feedback from incidents in the optimization loop HERCA Medinapector 2015 A HERCA ♣

