1st European Inspection Workshop

HERCA MedInspector 2015

Working group justification – group 4

FANC federal agency for nuclear control

HERCA Heads of the European Radiological protection Competent Authorities

Justification: General aspects

- To what extent is justification 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, other)?
  - Process of justification explicitly covered in QA-system?
  - Do you perform inspections only with the radiological practitioners practice or also the practice of the referral physicians practices (like inspections of GPs outside the hospitals, etc.)?
- Is patient medical confidentiality an issue to access necessary information to inspect justification (like referrals)
- How can different Health Care Systems affect justification?
  - Reimbursement, responsibilities, other aspects?

Justification: Inspector training

- What is the competence (training and skills) of the inspectors in order to be able to inspect the process of justification?
  - Professional background?
  - Clinical experience?
  - Training of inspectors, formal training program, others?

Justification: Level 3

- Are referrals present for each exposure?
  - Is necessary information available for the evaluation of justification? If not, is the referral physician contacted?
  - Is appropriateness of the referrals evaluated? If yes, are modality changed or referrals refused (foster challenge of referrals)?
  - Is feedback to referral physician provided (educational)?
  - Is justification of individual heath assessment inspected and national guidelines available?
- Are referral guidelines available?
  - Are they local/regional/national/other?
  - Are referral guidelines used in the justification process?
  - Are Computerised Decision Support (CDS) systems in use?

Justification: Level 2

- Is level 2 justification inspected?
  - Local procedure for introduction of new methods/techniques/equipment?
  - Documentation available for generic justification of new methods
- National system for level 2 justification?
- Is justification of screening programs inspected?
  - Approved by Health Authority?
  - Is criteria for the screening program defined by the health authority followed?

Justification: Responsibilities

- Are responsibilities and roles explicitly assigned and agreed upon for the related professionals (referrers, practitioners)?
- Who has the responsibility of justification (in practice)?
- Can the radiological practitioner delegate practical aspects of the medical radiological procedures to others (e.g. radiographers?)
- If CDS systems is in use, does their use alter the responsibilities assigned to the associated professionals?

Justification: Patient issues

- Is the patient informed on the radiological risks and benefits of the exposure and gives his/her consent (informed consent)?
  - For all or just high-dose examinations?
- Is pregnancy identified before each exposure?

Justification: Clinical audit

- Are clinical audits performed?
- Is the procedure followed by clinical audits evaluated during the inspections?

Justification

- Identify good practices, limiting factors (e.g. economical, human resources, competence etc) and challenges

Working group justification group 4

FR : Carole Rousse
LU : Alexandra Schreiner
NL : Sjirk BOON
IRL : Tanya KENNY
LT : Irena RACIENE
HR : Zeljka TOPOLAVA
UK : Sarah PETERS and Steve EBDON-JACKSON
NO : Reidun SILKOSET
BE : An FREMOUT

Discussion : situation in different countries

What are we allowed to inspect with respect to justification ? What do the regulations say ? Who is allowed to look at what ? If we don't inspect justification, why ?

- Lithuania : justification not checked during inspection because of lack of time. However a survey has been carried out, by means of a questionnaire about x-ray exams on referral (a registered form exists) : ~38% of the examinations is unjustified
  Clinical audit should be organised regularly

Discussion : situation in different countries

- FR : no legal barriers. Radiologist makes the decision. During inspection : 3 patient files, check : name of the patient, clinical question, act. If inspector is not a physician : anonymised (ex. : "the 2nd patient of the day")
  it is not checked whether it is coherent with the referral guidelines
- Kroatia : the law stipulates that the inspector can obtain anything he wants. License for practices with ionising radiation has to be renewed -> justification could be challenged
- Norway : interviews with all staff at the RL department, questions like : "is clinical information always available ? If no, what do you do ? If you don't contact the referrer, why ?..." if wrong patient : not justified

Discussion : situation in different countries

- Ireland : there is a cultural issue about justification, clinicians don't expect to be challenged about justification. Encourage to hospitals to challenge on justification, with the help of a radiologist that takes the lead
- UK : act is very clear but the regulations aren't -> inspector should be aware of his powers. Sample of 20 records : can we identify the referrer, clinical question, standard procedure for pregnancy, why is this exam still on your list of protocols while it isn't justified anymore. A study was carried out in Northern Ireland, based on examination of a set of 24h CT scans taken : ~5% not justified (most frequent reasons : should have been MRI or ultrasound, but MRI long waiting list). Referral guidelines = golden standard

Discussion : situation in different countries

- Lux : a lot of examinations but a sensitivity about justification -> focus on optimization.
  Recently : new minister of health, a clear mandate was given and an action plan was established, supported by the cancer prevention program. Financing by act stimulates overconsumption but can imply an economic gain for the government by limiting # examinations. Referral guidelines are established but they should be more actively promoted. First audit : does the prescription has everything filled in ? Second audit : auditors (doctors) from BE and FR to look more deeply. Excel file of UK is used.
- BE : collaboration with health authorities, and stakeholders (radiologists, MPE's, radiographers), global framework

Discussion : general conclusions

- we can learn from US as well as from other stakeholders like industry
  - US : responsibility for justification is with the referrer
  - Most European countries : referrer asks/proposes examination but the practitioner takes the final decision
- Most countries have the power to inspect the process, some of them go further.
- Asking for anonymised records always have the risk that you depend on what they give you.

Discussion : general conclusions

- If clinical audit is obliged, we can inspect this (is it done, are the criteria fulfilled)
- It helps if you have the confidence of the inspected
- It is important to know *who* is receiving the dose (population is aging, follow up after cancer diagnosis/treatment…)
- Swedisch study : guidelines were 8 years old
- Technical laws that are not (always) updated to the modern equipment

Clinical audit

- Use of audits : not to replace inspections but to help inspections
  Clinical audit is extended to the clinical outcome of the patient, clinical audit is not limited to dosimetry audit
- National authority has established criteria on how to perform audits -> during inspection it can be checked whether they apply these criteria, as regulator we should know that it is done
- Clinical audit in RL not yet implemented in all countries. In UK there is a long history of audit (internal audit with external direction), templates are available. Audit can provide advice.
- What is the responsibility of auditors (FR) ?

Patient information, informed conscent

- Doctors have a problem to inform the patient , it takes time, they don't have all the information or they don't know how to speak about risks
- Communication about risks is difficult
- General requirement in the regulation
- Lithuania : patient should always sign an informed conscent paper with risks (even for a chest x-ray). However it is not known what the doctor said verbally.
- Graded approach (UK, FR,…)
  - Leaflet/poster with all the risks can be sufficient for low doses
  - High doses (example : interventional) : active information on ALL the risks
  - Special attention to pregnancy - pediatric
- Often : conscent but no real awareness of radiation risks

Level 2 justification

- HERCA has started working around this
- Mostly looked at in authorisation process, feedback from inspection process can however be useful (for example for review of justification, identification of "new applications")
- Justification leads to payment of this technique ("benefit for the patient ?", pathway of the patient is taken into acount)

Inspector training

- What if the barrier for inspecting justification is the training of the inspector ?
  - Resources/ financing to employ people are limited -> train the people you have
  - Training is difficult : you cannot do this in 2 days
  - Training needed depends on what you inspect
  - Accompanying experts – how to cope with possible conflicts of interest ? keep roles separate (for example UK : in different regions), in Luxemburg : experts from BE, FR,…
  - Staffing in inspection departments : competence based, trying to have the right profiles. difficult to train a MPE to be clinical
  - Clinical experience helps to understand the clinical culture, someone who is part of their community adds credibility to the inspection team
  - Inspector mindset – soft skills (assertivity,…) are important

Inspector training

- Possibility to apply methods of other regulations on healthcare ? Often inspections are against standards, patient satisfaction, but not regulations -> enforcement is more difficult. In other countries, there are regulations, but there it can be a problem that other instances do not challenge on justification and it becomes more difficult for the radiation protection inspector to raise this.

Good practices

- Inspector needs the backup of a comprehensive framework, referral guidelines should be available,…several building blocks should be put in place so that inspection in the end can be carried out in a more relax way.
- Justification is not about stopping people to do things but about directing them to do the right examination. Inspection on justification should not be done from a negative perspective but from a positive perspective. Communication is key, respect professional experience, credibility, building the relationship.
- Inspection can be done in different stages but we can all inspect the process. Really challenging justification is harder

Good practices

- Industry can play a role : for example in continual education, in setting up the fields to be coherent with regulations,…
- Networks between the radiologists in the local hospital and the referrers to give feedback, newsletters. In return, it also allows to advertise new techniques in the hospital.
- Monitoring of the number of examinations, the number of concertations between radiologist and referrer,…

Good practices

- Audit methodology : it complements inspection and gives the possibility of large scale assessment of appropriate justification
- Level 2 justification is mainly done in the licensing process but inspection can feed this

Challenges

- No other examples where the personal judgement is challenged by someone other than their peers
- The regulator needs to be credible, firm but fair. This takes time
- Education of physicians, in particular for justification
- Focus profiles of staff : also change of culture needed *inside* the RP authority
- Payment per procedure stays a challenge
- Risk communication to patient – graded approach

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