

## **HERCA EUROPEAN ACTION WEEK – RESULTS OF A COORDINATED INSPECTION INITIATIVE ASSESSING JUSTIFICATION IN RADIOLOGY**

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### **Abstract**

Justification is a fundamental principle in radiation protection and has to be carried out before any individual exposure, according to the European Basic Safety Standards Directive. However, there are strong indications that up to 20-30% of medical imaging exposures are unjustified in many economically developed countries. Heads of the European Radiological Protection Competent Authorities (HERCA) has recognized that the regulatory bodies have an important role in promoting and ensuring that the principle of justification is properly implemented at medical imaging facilities. HERCA performed a coordinated European Action Week on inspection of justification in radiology in November 2016. The aim was to identify the main challenges in the justification process. 17 European countries participated in the Action Week, and 148 inspections were carried out. All inspections were performed according to a common inspection template. Main weaknesses identified were: 1) lack of written procedures describing the justification process, 2) lack of availability, awareness and use of referral guidelines, 3) lack of national or local procedures for performing clinical audits and 4) incomplete referrals from referring practitioners. HERCA has identified a need to increase the awareness of justification among health professionals and facility management in follow-up actions in 2017 and 2018.

### **1. INTRODUCTION**

Justification is one of the fundamental principles in the international radiation protection framework established by the International Commission on Radiological Protection [1]. The intention behind the act of justification is to ensure that the benefit of the exposure outweighs the associated potential radiation detriment. To ensure the appropriate use of medical imaging, justification has to be carried out at an individual level before the exposure takes place. The necessity for individual justification is reinforced in the new European Basic Safety Standards Directive and the International Basic Safety Standards [2, 3]. However, there are strong indications that up to 20-30% of medical imaging exposures are unjustified in many economically developed countries [4]. Therefore, the International Atomic Energy Agency (IAEA) have introduced the “Triple A” initiative, promoting Awareness about radiation risks; Appropriateness to ensure that those referred for radiological examinations really need them; and Audit to check the effectiveness of the referral and related processes [5]. The need to enhance the implementation of the principle of justification is also addressed in the joint position statement “Bonn Call for Action” by the IAEA and World Health Organization (WHO) and in the council conclusions on justification by the European Commission [6, 7].

Heads of the European Radiological protection Competent Authorities (HERCA) has recognized that the regulatory bodies have an important role in promoting and ensuring that the principle of justification is properly implemented at medical imaging facilities. Consequently, HERCA has published a position paper on justification of individual medical exposures for diagnosis to provide clarity on the regulatory framework for justification [8]. HERCA highlighted that justification is not just one action, but a process that includes a number of events from initial presentation of the patient to the radiology department to the final authorization for an exposure to take place. During the European Inspection Workshop organized by HERCA in 2015, it was revealed that very few radiation protection authorities actually inspected the justification process in depth [9]. HERCA identified an urgent need to improve the implementation of justification in medical exposure situations and decided to support this through a coordinated European Action Week on the inspection of justification, focussing on radiology departments. [10].

### **2. METHODS**

A European Action Week, with the scope of performing coordinated inspections of justification in radiological medical imaging facilities across Europe, was undertaken by HERCA in November 2016 [11]. The aim was to assess whether justification takes place in the facilities and to identify the main challenges in the justification process. All HERCA countries were invited to take part in this Action Week and to perform inspections in a representative number and type of imaging facilities. All inspections were notified in advance and performed according to a common inspection template provided by HERCA Working Group on Medical Applications (WGMA). Requested documentation was, in most countries, submitted to the competent authorities prior to the inspections. The inspection template collected information about the regulatory framework and the competent authority and inspection teams of the participating countries in addition to the results from each inspected medical imaging facility. Questions addressed during the inspections were aimed to identify if and how justification was implemented in the daily workflow. Availability of written procedures for the justification process, assignment of tasks and responsibilities, daily processes for assessment of justification and appropriateness of referrals, general practice to handle incomplete or unjustified referrals, availability and use of referral guidelines together with performance of clinical audits were among the examined topics. The overall quality of 10 referrals (5 for CT and 5 for conventional X-ray) per inspected facility was also reviewed to check if there was sufficient information for the radiological practitioner to assess if the referred examination was justified and appropriate.

### 3. RESULTS

In total, 17 countries participated in the Action Week and 148 inspections were carried out. The participating countries and number of inspections performed per country are shown in FIG. 1. The mean number of inspections per country was 9 (range: 1-19). 44% of the inspected facilities were public and 56% were private. The inspections were carried out by one, two or three competent authorities in 76%, 18% and 6% of participating countries, respectively. Radiation protection competent authorities were mainly the responsible authority for medical exposures. The inspection teams generally consisted of medical physicists and radiographers and/or engineers, but in some countries physicians or radiologists were also part of the inspection teams. Key personnel to be interviewed were typically the facility management, radiological practitioners and radiographers. Additional staff such as medical physicists, radiation protection officers and responsible persons for the quality assurance system, were also interviewed in some countries.

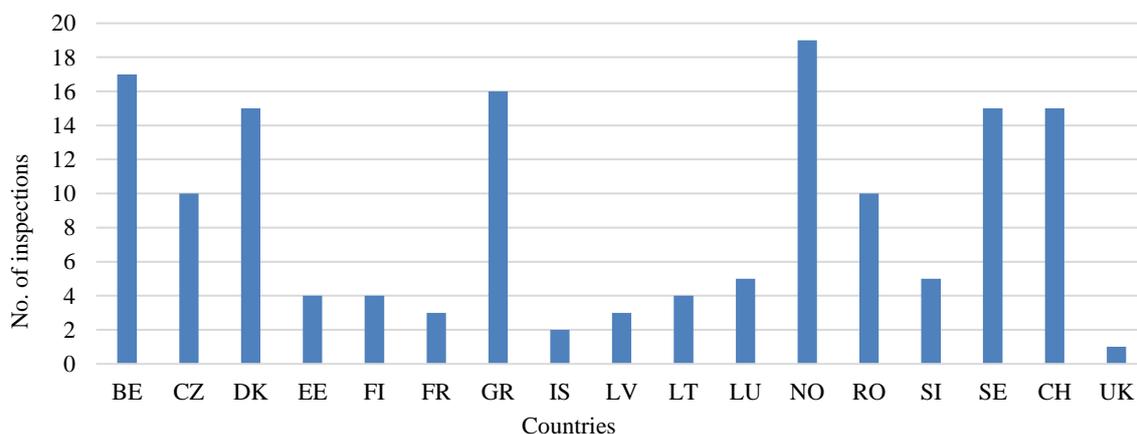


FIG. 1. Overview of participating countries and number of inspections performed per country. BE: Belgium, CH: Switzerland, CZ: Czech Republic, DK: Denmark, EE: Estonia, FI: Finland, FR: France, GR: Greece, IS: Iceland, LT: Lithuania, LU: Luxembourg, LV: Latvia, NO: Norway, RO: Romania, SI: Slovenia, SE: Sweden, UK: United Kingdom.

Results regarding the availability, knowledge and content of procedures for the justification process are shown in FIG. 2.A. Written procedures were only available at 55% of the inspected facilities. Even though written procedures were not available in almost half of inspected facilities, many had established processes for justification. About 10% of facilities had no procedures or routines for justification at all. Where procedures and processes were available, the staff involved implemented these in daily practice. They were frequently revised and updated in about 70% of facilities. Most topics identified by HERCA as important to ensure proper justification process were covered by 60% to 80% of facilities, while information to patients about risk and benefit,

a requirement of the latest Euratom Basic Safety Standards Directive, was only addressed by 34% of facilities. Allocation of tasks and assignment of responsibilities were clearly defined and documented for referring physicians, radiological practitioner, radiographers and the receptionist in 52%, 65%, 71% and 62% of facilities, respectively. Allocated tasks and responsibilities were known by the staff in 76% of facilities where these were defined, while delegation of tasks was only documented in 52% of facilities.

Results relating to the availability and use of referral guidelines and performance of clinical audits are summarized in FIG. 2.B. Referral guidelines for medical imaging were available in 70% of inspected facilities. The sources of referral guidelines were national (58%), regional (15%) and/or local (28%). These guidelines were made available to the referrers in almost all facilities, but assumed to be implemented in daily use by only 31% of the referrers and 48% of the radiological practitioners. Only 20% of the inspected facilities had local procedures for clinical audits and clinical audits were seldom performed. Less than half of the facilities performed any other type of audit or review (internal or external) covering the justification process.

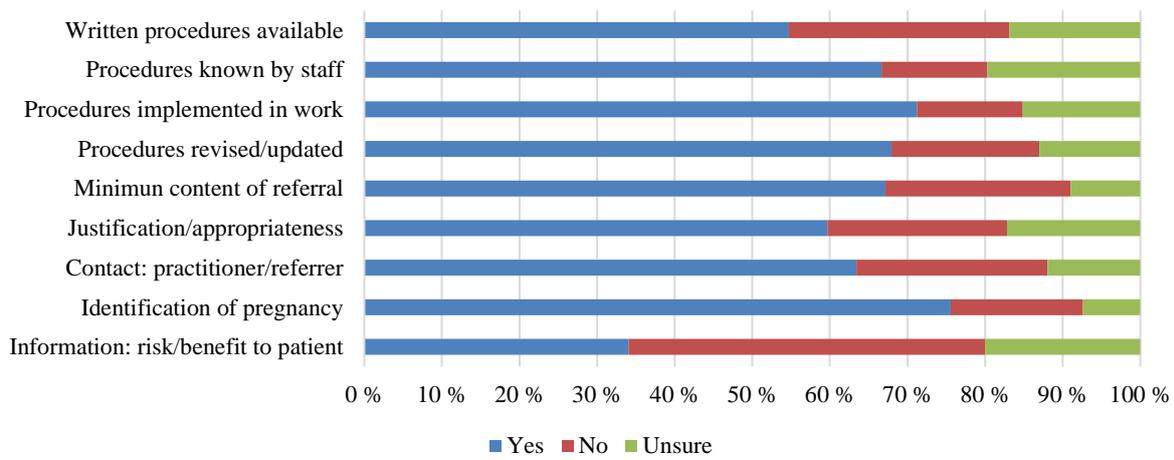


FIG. 2.A: Summary of the results regarding the availability of procedures for justification and their coverage of important topics to ensure for a proper justification process.

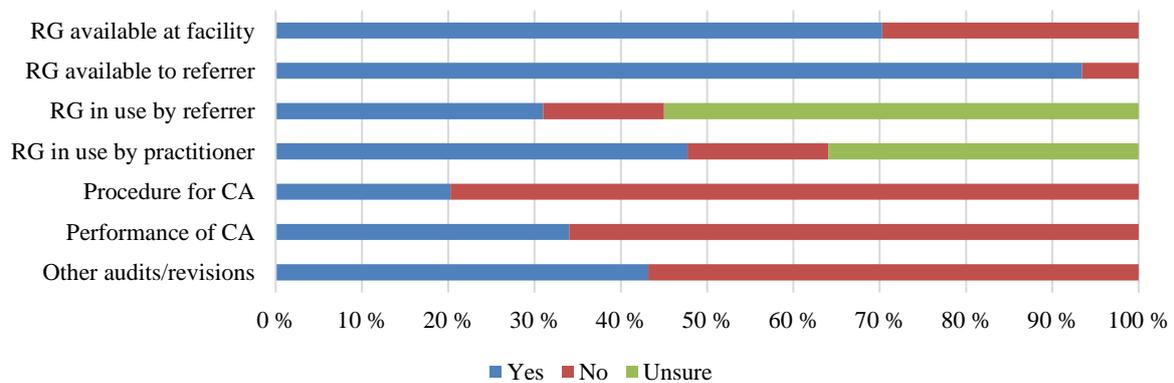


FIG.2.B Summary of the results regarding referral guidelines (RG) and clinical audits (CA).

Many of the inspected facilities had established good practice for evaluation of the referrals before the examinations were performed, as shown in FIG. 3.A. However, as many as 26% of facilities did not perform a satisfactory evaluation of the referral before the examinations were performed and even more did not reject unjustified examinations (31%) or fully prove that the examinations were authorized by the radiological practitioner (35%). The presence and overall quality of the referrals are summarized in FIG. 3.B. Referrals were available for almost all examinations (99%). Information about the patient, referrer, date and signature of the referral was satisfactory in over 90% of referrals. Clinical information was sufficient and contained the clinical question to be answered in 86% and 81% of referrals, respectively. Information about previous examinations and identification of pregnancy was only included in 54% and 63% of referrals, respectively. Education and training, covering the justification process, was documented in only 60% of the inspected facilities.

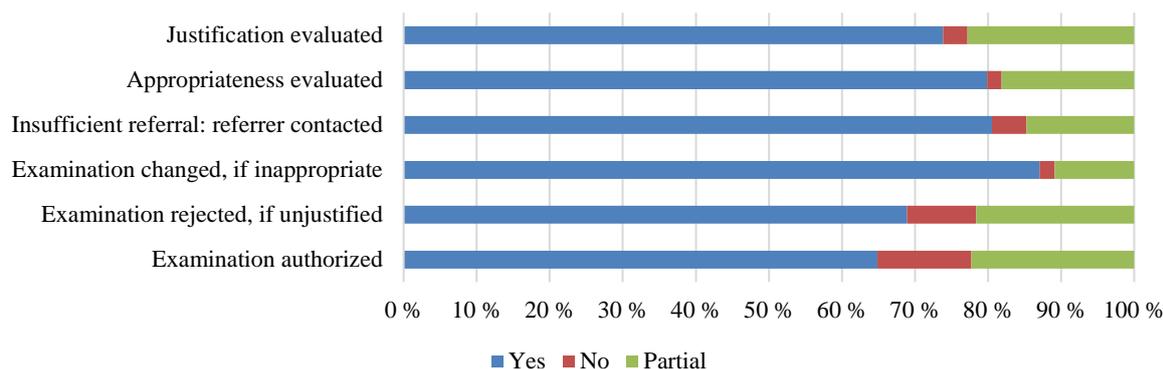


FIG.3.A: Summary of the results regarding the daily practice on evaluation of referrals prior to the performance of the examination.

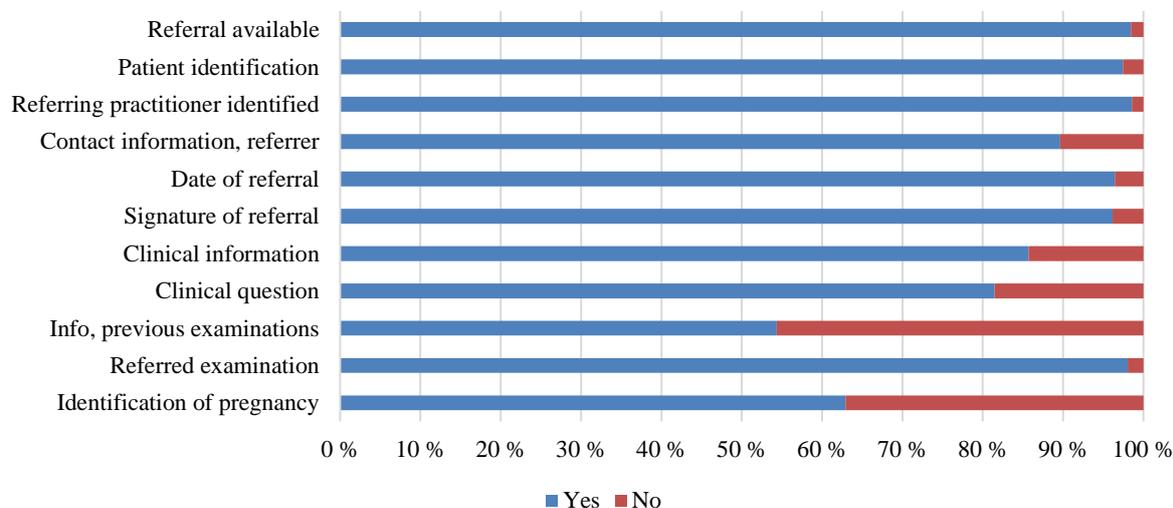


FIG. 3.B: Summary of the results regarding the presence and overall quality of the referrals. In total, 1367 referrals (for X-ray and CT) were evaluated.

#### 4. DISCUSSION AND CONCLUSIONS

The European Action Week was supported by all HERCA countries and 53% of countries participated. Half of the countries (53%) performed less than 10 inspections and the results may not be representative of the real situation in some of these countries. Results from the inspections were mainly based on interviews and reviews of documentation. Differences in the interpretation of some questions in the inspection template by different inspectors were observed, and areas for improvements identified. Even though this Action Week must be considered as a pilot study, the results obtained provide strong indications of the weak links in the justification process.

Implementation of the principle of justification varied among countries. Often, justification was only covered in general terms by the quality system and the justification process was not formally described and documented in procedures. However, established routines covered, to some extent, important steps in the justification process in most countries. Radiologists are mainly involved in the evaluation of referrals for CT, MR and “high-dose” or complex examinations, while radiographers are often allocated this task for many conventional X-ray examinations. In such cases it is usual to find examination appointments are arranged before referrals are evaluated. Radiographers almost always evaluate the referrals and check for pregnancy and other contraindications at the time of appointment, and immediately before the examination is performed. In this respect, radiographers carry out the key aspects of the justification process whether formally or informally, as a responsibility or as a delegated task. It is important that the different steps and associated tasks and responsibilities

are recognized by management, formalized in procedures and that involved staff receive proper training to take on the assigned tasks and responsibilities. Despite the presence of procedures and routines, steps in the justification process are sometimes not followed in daily practice. Lack of time, payment per procedure/examination, reimbursement systems and loyalty towards the referrers were given as reasons for this situation.

Reviews of the referrals indicated a need for improved quality, more structured referrals and harmonized guidance on minimum information to be included. Generally, the quality of referrals was worse among general practitioners, but large variations were observed among participating countries. Many inspection teams found it difficult to evaluate the quality of the referrals due to lack of expertise and the involvement of a radiologist in the team is highly recommended. Use of referral guidelines is modest and in many countries the only referral guidelines available are those covering standardized pathways for cancer and information about the radiation dose or risk is seldom included. The inspections revealed that the concept of clinical audit is not fully understood and rarely performed within medical imaging. Review of national regulatory frameworks among the participating countries also indicated that referral guidelines and clinical audits were not fully implemented at a national level.

Conclusions from the European Action Week: There is still a need to increase the awareness and to reiterate the importance of the justification process. Inspection is a good tool to address justification and HERCA will follow-up the identified weak links by providing targeted key messages to involved stakeholders on how they can take responsibility to act on the different aspects of the justification process.

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