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European co-ordinated action on improving justification of computed tomography

Results and Recommendations from a First-Time Multi-National Study on CT Justification in the EU

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List of Abbreviations

AG Advisory Group

AR Appropriateness Rate

BELMIP Belgian Medical Imaging Platform

BSSD Basic Safety Standards Directive (Council Directive 2013/59/Euratom)

CDS Clinical Decision Support

CT Computed Tomography

CTA Computed Tomography Angiography

EC European Commission

EFRS European Federation of Radiographer Societies

EHIF Estonian Health Insurance Fund

EO Expert opinion

EOPYY National Organization for the Provision of Health Services (Greece)

ESR European Society of Radiology

EU European Union

EURAMED European Alliance for Medical Radiation Protection Research

FANC Belgian Federal Agency for Nuclear Control

GP General Practitioner

HB Estonian Health Board

HERCA Heads of the European Radiological protection Competent Authorities

INAMI-RIZIV National Institute of Health and Disability Insurance

INV Interventional (radiology)

MD Medical Doctor

MoH Ministry of Health

MRI Magnetic Resonance Imaging

NCA National Competent Authority

NEAC National Institute of Health Insurance Fund Management (Hungary)

NRS National Radiology Society

NUC Nuclear medicine

PET Positron Emission Tomography

QA Quality assurance

RP Radiation Protection

SG Steering Group

US Ultrasound

WP Work Package

WGMA Working Group on Medical Applications

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PART 1

Abstract

EU-JUST-CT is a European co-ordinated action on improving justification of computed tomography. It has specific objectives – to collect up-to-date information about justification of CT examinations in Europe; to develop a common methodology for auditing justification of CT examinations; to carry out co-ordinated pilot audits of justification of CT examinations in seven EU member states; to discuss the status of justification of CT examinations with the member states and identify opportunities for further action in a European stakeholder workshop.

A methodology for auditing the appropriateness of CT examinations was developed and used simultaneously in seven European countries with the ESR iGuide as a standard. A sample of around 1000 referrals was collected and audited by four auditors for each country. The appropriateness rates of the scored referrals in the seven countries varied between 57.9% and 85.9%, showing a large disparity between countries.

Differences in appropriateness rates were found according to body region, inpatient/outpatient, public or private institution and whether the referrer was a general practitioner or a medical specialist.

Awareness of legal aspects of radiation protection and justification still needs to be increased among member states. Further action to improve the justification of CT examinations in European countries should take place.

Résumé

EU-JUST-CT est une action européenne coordonnée visant à améliorer la justification de la tomodensitométrie. Elle a pour objectifs spécifiques de collecter des informations actualisées sur la justification des examens de tomodensitométrie en Europe, de développer une méthodologie commune pour l'audit de la justification des examens de tomodensitométrie, de réaliser des audits pilotes coordonnés de la justification des examens de tomodensitométrie dans sept États membres de l'UE, de discuter de l'état de la justification des examens de tomodensitométrie avec les États membres et d'identifier les possibilités d'action future dans le cadre d'un atelier européen des parties intéressées.

Une méthodologie d'audit de la pertinence des examens de tomodensitométrie a été développée et utilisée simultanément dans sept pays européens avec l'ESR iGuide comme norme. Un échantillon d'environ 1000 demandes des examens de tomodensitométrie a été collecté et évalué par quatre auditeurs pour chaque pays. Les taux de pertinence des demandes évaluées dans les sept pays variaient de 57,9% à 85,9 %, montrant une grande disparité entre les pays.

Des différences dans les taux de pertinence ont été constatées en fonction de la région du corps, des patients hospitalisés ou non, de l'établissement public ou privé et du fait que le médecin référent était un médecin généraliste ou un médecin spécialiste.

La sensibilisation aux aspects juridiques de la radioprotection et de la justification doit encore être renforcée dans les États membres. D'autres mesures devraient être prises pour améliorer la justification des examens par tomodensitométrie dans les pays européens.

Acknowledgements

The EU-JUST-CT consortium wishes to acknowledge the collaboration of the National Competent Authorities and radiological societies of the participating countries for their instrumental help in implementing the pilot audits. We would also like to thank all participating hospitals for having provided the referrals to be audited, the project's Advisory Group and Steering Group for their review and comment on all stages of the project, as well as the team of statisticians for their data analysis.

Executive Summary

Appropriate justification and optimisation of all medical imaging procedures involving patient ionising exposure are essential elements of good and safe clinical practice. Adherence to the principles of ALARA (as low as reasonably achievable) and, particularly in radiotherapy, ALARP (as low as reasonably practicable) are essential for good practice.

Diagnostic radiological imaging is the most widespread form of medical application of ionising radiation with an excess of 500 million procedures carried out in the EU annually. The significant rise in the use of computed tomography (CT) over recent decades is a particular subject of concern due to its increased availability, over-utilisation and suboptimal justification and optimisation practices. It has led to a significant increase in the patient radiation doses in advanced economies and is now responsible for more than half of the medical radiation exposure of the EU citizens [1]. The Basic Safety Standards Directive (BSSD) 2013/59/Euratom [2] requires medical exposures to be 'justified', to ensure that their health benefit outweighs the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques. The Directive further requires individual radiological procedures to be justified in advance taking into account the specific objectives of the procedure and the patient's characteristics and prescribes a justification process under the clinical responsibility of a practitioner and involving the referring physician. The Directive also requests Member States to introduce referral guidelines for medical imaging, which should be made available to the referrers.

The European Commission carries out compliance checks of national legislation and supports Member States' implementation of the legal requirements through scientific seminars, studies and guidance [3].

Several studies have shown a significant rate of unjustified CT exams, in the range of 20-40% overall and reaching more than 70% for some procedures [4,5]. Effective strategies for significant improvement of the CT justification have also been demonstrated [6]. Recognising the significance of the above issues, in December 2015 the European Council issued Conclusions on "Justification of medical imaging involving exposure to ionising radiation" [7]. The Council Conclusions call upon Member States to undertake actions to improve the situation, including strengthening the application of clinical audits in relation to justification and the implementation of referral guidelines for medical imaging.

The EU-JUST-CT Project on audit of justification of CT examinations is embedded in a broader European Commission initiative: Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA)¹ initiated by European Commission DG Energy, a key pillar of the Europe's Beating Cancer Plan.

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¹https://energy.ec.europa.eu/topics/nuclear-energy/radiological-and-nuclear-technology-health/samira-action-plan_en

Objectives of the EU-JUST-CT Project

The 'European co-ordinated action on improving justification of computed tomography' (acronym: EU-JUST-CT) is a European Commission funded Tender project that ran from April 2021 until March 2024 and pursued the following specific objectives:

- a) Collect up-to-date information about justification of CT examinations in Europe through literature review and a pan-European survey.
- b) Develop a common methodology for auditing justification of CT examinations applicable across EU member states.
- c) Carry out co-ordinated pilot audits of justification of CT examinations in seven EU member states, either in the entire country or in specific regions.
- d) Discuss the status of justification of CT examinations with the Member States and identify opportunities for further action in a European stakeholder workshop.

Overview of the EU-JUST-CT Work Programme, Structure and Methodology

The EU-JUST-CT Project was carried out by a group of experts under the co-ordination of the European Society of Radiology (ESR). The project core team consisted of radiologists, a radiographer, national radiation protection authority and health authority representatives, statisticians, an ESR iGuide expert, as well as experienced project managers.

The project core team was supported by an Advisory Group and a Steering Group. The Advisory Group consisted of seven radiologists, with direct recent experience in auditing justification of CT examinations, who provided guidance and advice to the pool of auditors and the countries or regions participating in the co-ordinated audits. The Steering Group consisted of independent experts and included representatives of international and European organisations, competent authorities and experts with direct recent experience in auditing justification of CT examinations. The Steering Group and Advisory Group worked closely on all stages of the project, reviewing deliverables and providing feedback on all aspects of the work.

The project was divided into several components, including a literature review and a European survey on the status of CT justification in EU member states, the development of the audit methodology, the selection of the member states interested in participating in the pilot audits, the recruitment of the pool of auditors, the collection of the referrals in participating member states, the implementation of the pilot audits and analysis of the audit reports, as well as the development of a guidance document on CT justification for radiology departments. In addition, a European workshop was held in the last phase of the project to discuss the results and the need for further action in this area.

<u>Survey among national competent authorities and national radiology societies on status of CT justification</u>

The EU-JUST-CT survey carried out at the beginning of the project aimed at identifying up-to-date information about justification of CT examinations in Europe and to collate data on previous audits on CT justification across European member states. This was done by surveying both the relevant radiation protection national competent authorities (NCAs) and the national radiological societies (NRS) across Europe. Responses were received from 30 countries. The survey presents valuable information on current CT justification practices across Europe, with perspectives from both NCA and NRS. Areas for improvements highlighted by the survey findings include ensuring earlier involvement of the medical practitioner in the process of justification of CT examinations. Less than half

of the respondents reported that CT referrals are always justified by a medical practitioner in advance of the examination taking place. Almost all countries reported referral guidelines as being available, however there is a significant lack of familiarity and use of these. Imaging referral guidelines should be made available as part of clinical decision support systems so that referrers will be required to consult referral guidelines before submitting a referral. According to the survey, CT for health screening purposes is not widely used at present in Europe either within or outside of approved screening programmes. The survey clearly showed that more regular audits of CT justification are encouraged throughout all EU Member States to ensure appropriate and efficient use of CT examinations. The results of the survey were published in a peer-reviewed article in Insights into Imaging [9].

Pilot audits and methodology

Seven EU Member States volunteered to participate in the pilot audits carried out as part of the project (Belgium, Denmark, Estonia, Finland, Greece, Hungary, Slovenia). The participating countries or regions had not carried out external/centralised audits of justification of CT examinations in the previous five years. Strong involvement of the national/regional competent authorities and radiology societies has been sought in order to ensure representative results and coverage of adult and paediatric populations, public and private institutions, and CT referrals from general practitioners, emergency rooms and clinical specialists.

National competent authorities played an important role in the identification of the imaging centres to be invited and in informing them of the project and encouraging them to participate, outlining the national laws and regulations related to justification and audit.

A pilot liaison group consisting of one NCA representative and one national radiology society representative per country was set up to facilitate the implementation of the audits. A pool of auditors was set up with the support from the national radiology societies of the participating countries, including four auditors per country, and the NCAs identified a total of 125 participating imaging centres.

The EU-JUST-CT audit methodology was based on the methodology of the audit process in Northern Ireland [10] and Luxembourg [4] and was adapted taking into account the findings from the literature review and survey on the status of implementation of CT justification carried out at the beginning of the project.

As a first step the methodology foresaw a survey completed by the participating centres in order to evaluate the implementation of the process of justification in the centres through written procedures. The second step was to evaluate the appropriateness of the CT examinations already performed on a specific date/dates. The percentage of appropriate CT examinations performed in each centre was considered an indicator of the implementation of justification.

The referrals of already performed CT examinations (both adult and paediatric) were sampled for a specific date/dates in early 2022 in public and private facilities and collected by the NCAs. Weekends and public holidays were excluded as dates for sampling.

After referrals had been collected, they were anonymised by the NCAs and then sent to the auditors. According to the methodology, the auditors would not be assigned referrals from their own region/centre. Prior to sending the referrals, all auditors were offered to participate in an online training session on the ESR iGuide, the ESR's imaging referral guidelines in clinical decision support format² used as a standard for the audits and provided in electronic form to be completed by each auditor.

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² https://myesr.org/esriguide

By January 2023 all audits had been completed in all countries and analysis of the data was able to begin.

The audit methodology used in the project is publicly available³ in order to encourage and facilitate audits of CT justification in other Member States and regions.

Data analysis

The data provided by the auditors was analysed by two radiologists with expertise in auditing CT justification with the support of a team of statisticians. The analysis determined the appropriateness rates in the country/region, in the adult and paediatric population, in the public and private sectors, according to anatomical region, in-patient vs outpatient and, where available, according to the specialty of the referrer. Analysis also evaluated what would have been a more appropriate examination in the case of inappropriate CT imaging and whether the imaging department has MRI available or not.

During the analysis, referrals were categorised according to the appropriateness score of the originally matched ESR iGuide exam. Referrals given a score of 7-9 were considered fully appropriate. Referrals given a score of 4-6 were considered moderately/partially appropriate. Referrals given a score of 1-3 were considered inappropriate, and those given no score (due to lack of data) were considered not justified due to no or insufficient clinical data. Where auditors scored a referral differently, analysis was conducted as to whether their scores placed the referral in the same category (in which case the auditors were considered to be in agreement), adjacent categories (in which case the auditors were considered to be in partial disagreement), or opposite categories (i.e. one auditor scored the referral as justified and the other scored it as not justified). In the latter case, the auditors were considered to be in significant disagreement. In cases of significant or partial disagreement between the two auditors over a referral, the two expert radiologists overseeing analysis acted as arbitrators. In cases where only one auditor audited a given referral, one of them acted as the second auditor.

The NCAs were provided the detailed analysis of their audit data as well as the results of the survey among the participating imaging centres.

Guidance document to assist radiology departments in improving justification

A key element of the project has been the development of a guidance document for radiologists including concrete advice, examples of good practices and guidelines on how to implement the process of justification of individual imaging procedures using CT for adult and paediatric patients in a hospital or private practice. Elements of the guidance document include: requirements of the BSSD for justification, related definitions as well as a description of the justification process, description of the stakeholders involved and description of their responsibilities, education and training as well as practical examples and tools to facilitate the justification process and an overview of related challenges.

The guidance document is publicly available and was informed by information provided from inspections undertaken by regulatory bodies (on a national and international basis through HERCA), audits undertaken by approved bodies and professional societies as well as experience of practising radiologists and radiographers involved with the project. Findings and conclusions from the literature review, survey and the pilot audits, alongside input from key stakeholders, provided essential input to the guidance document.

European workshop

The EU-JUST-CT workshop took place in Luxembourg in September 2023 and offered an opportunity to representatives of national radiology societies, national radiation protection authorities, national health authorities, health professionals and patient representatives

³ http://www.eurosafeimaging.org/eu-just-ct/wp-4

⁴ http://www.eurosafeimaging.org/eu-just-ct/wp-6

from EU member states to learn about the state of play of justification of CT examinations in the EU.

The workshop generated considerable interest (103 attendees), strengthening the hope that the results will encourage other Member States to carry out audits on their CT justification using the methodology developed and employed within the EU-JUST-CT project, which is freely available on the EU-JUST-CT website. This would be of particular importance as the level of compliance with the BSSD still shows room for improvement and awareness of legal aspects of radiation protection and justification needs to be increased among Member States.

In terms of moving forward, the lively discussions and interest among the audience in performing national audits applying the EU-JUST-CT methodology nurture the hope that the results of the EU-JUST-CT project will incentivise national authorities to enhance efforts towards justification, e.g., by the increased use of guidelines, ideally in the form of a CDS system, by training medical professionals on justification and by awareness raising and other activities by NCAs and relevant stakeholders.

Key Findings, Conclusions and Recommendations of the EU-JUST-CT Project

Findings

- Awareness of legal aspects of radiation protection and justification still needs to be increased among Member States.
- The EU-JUST-CT project has contributed to reaching this goal by having carried out pilot audits of justification of CT examinations in seven countries simultaneously, with the ESR iGuide as reference standard.
- The appropriateness rates of the scored referrals in the seven pilot countries/regions varied between 57.9% and 85.9%, showing a large disparity between countries and the need for further action to improve justification of CT examinations.
- The proportion of examinations whose appropriateness could not be assessed because of no or insufficient clinical data also varied considerably between countries (from 0.3% to 27%).
- Very few countries have performed audits of justification of radiological procedures.
- Very low numbers of paediatric CT examinations were observed in all countries, showing a low use of CT for this age group.
- Appropriateness rates were lower for general practitioners compared to (other) specialist doctors.
- Differences in appropriateness rates between body regions were observed and in six countries spine had quite low appropriateness rates, followed by extremities and pelvis. The results are comparable to the audit study in Luxembourg.
- Differences in appropriateness rates were observed between public and private institutions with better appropriateness rates in public institutions.

- MRI was the most appropriate examination in many cases where the CT examination was inappropriate.
- The appropriateness rate for CT was better for inpatient/emergency patients than for outpatients.

Conclusions

- The results obtained point to the conclusion that overall, a correlation exists between justification efforts in specific countries and the audit results. Considerable justification efforts have so far been performed in Belgium, Denmark and Finland.
- The availability and use of imaging referral guidelines is crucial in the process of justification of CT examinations as it helps ensure that the patient gets the appropriate examination.
- Education and training on justification and clinical audit are essential to improve the implementation of the process of justification.
- Inspection of justification and clinical audit of justification should take place.
- Clinical imaging guidelines and CDS systems can provide essential tools and their generation, availability and use should be considered a priority by hospital and healthcare providing organisations.
- Auditors need to be willing and able to dedicate sufficient time and energy to perform high-quality audits and the expected effort and methodology to be used need to be thoroughly explained at the beginning of the process. Auditors' effort needs to be compensated.

Recommendations

- The quality of referrals collected from the participating imaging centres was very diverse, hence ensuring a high quality of the referrals is a clear recommendation to Member States.
- Appropriate justification of individual CT procedures remains a key aspect of patient safety, patient outcome, and the effective and efficient use of radiological imaging resources.
- Dialogue with referring clinicians is essential if conflicts between referrers and radiological imaging departments are to be avoided.
- Radiologists should be involved either directly or in setting up and approving policies, processes and procedures where other medical specialists and healthcare professionals provide justification.
- In all cases, the roles and responsibilities of all those involved in the justification process should be clear and identifiable.
- Improving individual justification requires a multi-factorial approach, involving education and training, as well as workflow engineering and clinical audit.
- Direct access to patient records and previous imaging is paramount for proper justification to take place.
- Availability of MRI can play an important role where the appropriateness of CT examinations is concerned.
- Assessment of appropriate individual justification can be provided by clinical audit.

- Inspection is an important process, but its scope and aim as well as its frequency may limit its impact on a daily basis.
- The workshop demonstrated considerable interest in the topic from all relevant stakeholders.
- The study group welcomes the European Commission's intention to continue supporting audits and work on justification within the framework of the SAMIRA Action Plan and fully supports the EC's efforts towards better implementation and increased commitment among Member States.
- Member States are encouraged to avail themselves of the methodology and experience of the EU-JUST-CT Project and are encouraged to carry out similar audit campaigns.

The project team remains available for questions and guidance.

Synthèse

La justification appropriée et l'optimisation de toutes les procédures d'imagerie médicale impliquant une exposition ionisante du patient sont des éléments essentiels d'une bonne pratique clinique sûre. Le respect des principes ALARA (as low as reasonably achievable) et, en particulier en radiothérapie, ALARP (as low as reasonably practicable) est essentiel pour une bonne pratique.

L'imagerie radiologique diagnostique est la forme la plus répandue d'application médicale des rayonnements ionisants, avec plus de 500 millions de procédures effectuées chaque année dans l'UE. L'augmentation significative de l'utilisation de la tomodensitométrie (TDM) lors des dernières décennies est un sujet de préoccupation particulier en raison de sa disponibilité accrue, de sa surutilisation et de pratiques de justification et d'optimisation sous-optimales. Elle a entraîné une augmentation significative des doses de rayonnement reçues par les patients dans les économies avancées et est désormais responsable de plus de la moitié de l'exposition aux rayonnements médicaux des citoyens de l'UE [1]. La directive sur les normes de base (BSSD) 2013/59/Euratom [2] exige que les expositions médicales soient "justifiées", afin de s'assurer que leur bénéfice pour la santé l'emporte sur le préjudice individuel que l'exposition pourrait causer, en tenant compte de l'efficacité, des avantages et des risques des techniques alternatives disponibles. La directive exige en outre que les procédures radiologiques individuelles soient justifiées à l'avance en tenant compte des objectifs spécifiques de la procédure et des caractéristiques du patient, et prescrit un processus de justification sous la responsabilité clinique d'un praticien et impliquant le médecin référent. La directive demande également aux États membres d'introduire des recommandations de bonne pratique médicale pour orienter les patients en imagerie médicale, qui devraient être mises à la disposition des médecins traitants.

La Commission européenne vérifie la conformité des législations nationales et aide les États membres à mettre en œuvre les exigences légales par le biais de séminaires scientifiques, d'études et d'orientations [3].

Plusieurs études ont montré un taux important d'examens tomodensitométriques injustifiés, de l'ordre de 20 à 40 % dans l'ensemble et atteignant plus de 70 % pour certaines procédures [4,5]. Des stratégies efficaces pour améliorer de manière significative la justification des examens de TDM ont également été démontrées [6]. Reconnaissant l'importance des questions susmentionnées, le Conseil européen a publié en décembre 2015 des conclusions sur la "Justification de l'imagerie médicale impliquant une exposition à des rayonnements ionisants" (Justification of medical imaging involving exposure to ionising radiation) [7]. Les conclusions du Conseil invitent les États membres

à prendre des mesures pour améliorer la situation, notamment en renforçant l'application des audits cliniques en matière de justification et la mise en œuvre des recommandations de bonnes pratiques pour orienter les patients vers l'imagerie médicale.

Le projet EU-JUST-CT sur l'audit de la justification des examens de TDM s'inscrit dans une initiative plus large de la Commission européenne : Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA)¹ lancé par la DG Énergie de la Commission européenne, un pilier essentiel du plan "Vaincre le cancer en Europe".

Objectifs du projet EU-JUST-CT

- « L'action européenne coordonnée sur l'amélioration de la justification de la tomodensitométrie » (acronyme : EU-JUST-CT) est un projet d'appel d'offres financé par la Commission européenne qui s'est déroulé d'avril 2021 à mars 2024 et qui poursuivait les objectifs spécifiques suivants :
 - a) Recueillir des informations actualisées sur la justification des examens de tomodensitométrie en Europe par le biais d'une analyse de la littérature et d'une enquête paneuropéenne.
 - b) Élaborer une méthodologie commune pour l'audit de la justification des examens de TDM, applicable dans tous les États membres de l'UE.
 - c) Réaliser des audits pilotes coordonnés sur la justification des examens de TDM dans sept États membres de l'UE, soit dans l'ensemble du pays, soit dans des régions spécifiques.
 - d) Discuter avec les États membres de l'état de la justification des examens de TDM et identifier les possibilités d'action future dans le cadre d'un atelier européen des parties prenantes.

Aperçu du programme de travail, de la structure et de la méthodologie du projet EU-JUST-CT

Le projet EU-JUST-CT a été mené par un groupe d'experts sous la coordination de la Société européenne de radiologie (ESR). L'équipe centrale du projet était composée de radiologues, d'un manipulateur d'électroradiologie médicale, de représentants des autorités nationales de radioprotection et des autorités sanitaires, de statisticiens, d'un expert iGuide de l'ESR, ainsi que de gestionnaires de projet expérimentés.

L'équipe centrale du projet a été soutenue par un groupe consultatif et un groupe de pilotage. Le groupe consultatif était composé de sept radiologues ayant une expérience directe et récente de l'audit de la justification des examens de TDM, qui ont fourni des orientations et des conseils au groupe d'auditeurs et aux pays ou régions participant aux audits coordonnés. Le groupe directeur était composé d'experts indépendants et comprenait des représentants d'organisations internationales et européennes, d'autorités compétentes et d'experts ayant une expérience directe et récente de l'audit de la justification des examens de TDM. Le groupe de pilotage et le groupe consultatif ont travaillé en étroite collaboration à tous les stades du projet, en examinant les travaux livrés et en fournissant un retour d'information sur tous les aspects du travail.

Le projet a été divisé en plusieurs composantes, notamment une analyse documentaire et une enquête européenne sur la situation de la justification des examens de TDM dans les États membres de l'UE, le développement de la méthodologie d'audit, la sélection des États membres souhaitant participer aux audits pilotes, le recrutement du groupe d'auditeurs, la collecte des demandes dans les États membres participants, la mise en

œuvre des audits pilotes et l'analyse des rapports d'audit, ainsi que l'élaboration d'un document d'orientation sur la justification des examens de TDM pour les services de radiologie. En outre, un atelier européen a été organisé durant la dernière phase du projet afin de discuter des résultats et de la nécessité de poursuivre l'action dans ce domaine.

<u>Enquête auprès des autorités nationales compétentes et des sociétés nationales de radiologie sur le statut de la justification de la tomodensitométrie</u>

L'enquête EU-JUST-CT menée au début du projet visait à identifier des informations actualisées sur la justification des examens de TDM en Europe et à rassembler des données sur des audits antérieurs sur la justification des examens de tomodensitométrie dans les États membres européens. Pour ce faire, une enquête a été menée auprès des autorités nationales compétentes en matière de radioprotection (ANC) et des sociétés nationales de radiologie (SNR) dans toute l'Europe. Des réponses ont été recues de 30 pays. L'enquête fournit des informations précieuses sur les pratiques actuelles en matière de justification des examens de tomodensitométrie en Europe, avec les points de vue des ANC et des SRN. Les domaines d'amélioration mis en évidence par les résultats de l'enquête comprennent l'implication plus précoce du médecin réalisateur dans le processus de justification des examens de tomodensitométrie. Moins de la moitié des personnes interrogées ont déclaré que les demandes des examens de tomodensitométrie sont toujours justifiées par un médecin réalisateur avant que l'examen n'ait lieu. Presque tous les pays ont indiqué qu'ils disposaient de recommandations de bonne pratique médicale pour orienter les patients en imagerie médicale, mais ces recommandations ne sont pas suffisamment connues et utilisées. Les recommandations de bonne pratique en matière d'imagerie devraient être intégrées dans les systèmes d'aide à la décision clinique, pour que les personnes qui orientent les patients soient tenus de les consulter avant de les orienter. Selon l'enquête, la TDM à des fins de dépistage n'est pas largement utilisée en Europe, que ce soit dans ou en dehors des programmes de dépistage approuvés. L'enquête a explicitement montré que des audits plus réguliers de la iustification de la TDM sont encouragés dans tous les États membres de l'UE afin de garantir une utilisation appropriée et efficace des examens de TDM. Les résultats de l'enquête ont été publiés dans un article révisé par les pairs dans Insights into Imaging [9].

Audits pilotes et méthodologie

Sept États membres de l'UE se sont portés volontaires pour participer aux audits pilotes réalisés dans le cadre du projet (Belgique, Danemark, Estonie, Finlande, Grèce, Hongrie, Slovénie). Les pays ou régions participants n'avaient pas effectué d'audits externes/centralisés de la justification des examens de TDM lors des cinq années précédentes. Une forte implication des autorités compétentes nationales/régionales et des sociétés de radiologie a été recherchée afin de garantir des résultats représentatifs et la couverture des populations adultes et pédiatriques, des institutions publiques et privées, et des demandes des examens TDM des médecins généralistes, des salles d'urgence et des médecins spécialistes.

Les autorités nationales compétentes ont joué un rôle important dans l'identification des centres d'imagerie à inviter, en les informant du projet et en les encourageant à participer, en décrivant les lois et règlements nationaux relatifs à la justification et à l'audit.

Un groupe de liaison pilote composé d'un représentant de l'ANC et d'un représentant de la société nationale de radiologie par pays a été créé pour faciliter la mise en œuvre des audits. Un pool d'auditeurs a été constitué avec le soutien des sociétés nationales de radiologie des pays participants, à raison de quatre auditeurs par pays, et les ANC ont identifié un total de 125 centres d'imagerie participants.

La méthodologie de l'audit EU-JUST-CT est établie sur la méthodologie du processus d'audit en Irlande du Nord [10] et au Luxembourg [4] et a été adaptée en tenant compte

des résultats de la revue de la littérature et de l'enquête sur l'état de la mise en œuvre de la justification des examens TDM réalisée au début du projet.

Dans un premier temps, la méthodologie prévoyait une enquête complétée par les centres participants afin d'évaluer la mise en œuvre du processus de justification dans les centres par le biais de procédures écrites. La seconde étape consistait à évaluer la pertinence des examens de TDM déjà effectués à une ou plusieurs dates spécifiques. Le pourcentage d'examens de TDM appropriés réalisés dans chaque centre a été considéré comme un indicateur de la mise en œuvre de la justification.

Les demandes d'examens de TDM déjà effectués (adultes et enfants) ont été échantillonnées pour une ou plusieurs dates spécifiques au début de 2022 dans des établissements publics et privés collectées par les ANC. Les week-ends et les jours fériés ont été exclus des dates d'échantillonnage.

Après avoir été collectées, les demandes ont été rendues anonymes par les ANC, puis envoyées aux auditeurs. Conformément à la méthodologie, les auditeurs n'ont pas reçu de demandes provenant de leur propre région/centre. Avant d'envoyer les demandes, il a été proposé à tous les auditeurs de participer à une session de formation en ligne sur l'ESR iGuide, les recommandations de bonne pratique de l'ESR en matière d'orientation vers l'imagerie dans un format d'aide à la décision clinique² utilisé comme norme pour les audits et fourni sous forme électronique pour être complété par chaque auditeur.

En janvier 2023, tous les audits avaient été réalisés dans tous les pays et l'analyse des données a pu commencer.

La méthodologie d'audit utilisée dans le cadre du projet est accessible au public³ afin d'encourager et de faciliter les audits sur la justification des examens de TDM dans d'autres États membres et régions.

Analyse des données

Les données fournies par les auditeurs ont été analysées par deux radiologues spécialisés dans l'audit de la justification des examens de TDM, avec l'aide d'une équipe de statisticiens. L'analyse a permis de déterminer les taux de pertinence dans le pays/la région, dans la population adulte et pédiatrique, dans les secteurs public et privé, en fonction de la région anatomique, de l'hospitalisation ou de la consultation externe et, le cas échéant, de la spécialité du médecin référent. L'analyse a également évalué quel aurait été l'examen le plus approprié en cas d'imagerie de TDM inappropriée et si le service d'imagerie dispose ou non d'une IRM.

Lors de l'analyse, les demandes ont été classées en fonction du score de pertinence de l'examen demandé à l'origine selon l'ESR iGuide. Les demandes avant obtenu un score de 7 à 9 ont été considérées comme tout à fait appropriées. Les demandes ayant obtenu un score de 4 à 6 ont été considérées comme modérément/partiellement appropriées. Les demandes ayant reçu un score de 1 à 3 ont été considérées comme inappropriées, et celles n'ayant reçu aucun score (en raison d'un manque de données) ont été considérées comme non justifiées en raison de l'absence ou de l'insuffisance de données cliniques. Lorsque les auditeurs ont attribué des scores différents à une demande. l'analyse a porté sur la question de savoir si leurs scores plaçaient la demande dans la même catégorie (auquel cas les auditeurs ont été considérés comme étant en accord), dans des catégories adjacentes (auquel cas les auditeurs ont été considérés comme étant en désaccord partiel) ou dans des catégories opposées (c'est-à-dire qu'un auditeur a noté la demande comme étant justifié et l'autre comme n'étant pas justifié). Dans ce dernier cas, les auditeurs ont été considérés comme étant en désaccord important. En cas de désaccord important ou partiel entre les deux auditeurs au sujet d'une demande, les deux radiologues experts supervisant l'analyse ont tenu le rôle d'arbitres. Dans les cas où un seul auditeur a évalué une demande donnée, l'un d'entre eux a tenu le rôle de second auditeur.

Les ANC ont reçu l'analyse détaillée de leurs données d'audit ainsi que les résultats de l'enquête menée auprès des centres d'imagerie participants.

Document d'orientation pour aider les services de radiologie à améliorer la justification

Un élément clé du projet a été l'élaboration d'un document d'orientation pour les radiologues comprenant des conseils concrets, des exemples de bonnes pratiques et des lignes directrices sur la manière de mettre en œuvre le processus de justification des procédures d'imagerie individuelles utilisant la TDM pour les patients adultes et pédiatriques dans un hôpital ou un cabinet privé. Les éléments du document d'orientation comprennent : les exigences de la BSSD en matière de justification, les définitions associées ainsi qu'une description du processus de justification, une description des parties prenantes impliquées et une description de leurs responsabilités, l'éducation et la formation ainsi que des exemples pratiques et des outils pour faciliter le processus de justification et une vue d'ensemble des défis associés.

Le document d'orientation est accessible au public⁴ et il s'appuie sur les informations fournies par les inspections effectuées par les autorités compétentes en radioprotection (au niveau national et international par l'intermédiaire d'HERCA), les audits réalisés par les organismes agréés et les sociétés professionnelles, ainsi que sur l'expérience des radiologues et des manipulateurs d'électroradiologie médicale en exercice qui ont participé au projet. Les résultats et les conclusions de la revue de littérature, de l'enquête et des audits pilotes, ainsi que les contributions des principales parties prenantes, ont apporté une contribution essentielle au document d'orientation.

Atelier européen

L'atelier EU-JUST-CT a eu lieu au Luxembourg en septembre 2023 et a permis aux représentants des sociétés nationales de radiologie, des autorités nationales de radioprotection, des autorités nationales de santé, des professionnels de santé et des représentants des patients des États membres de l'UE de s'informer sur l'état d'avancement de la justification des examens de TDM dans l'UE.

L'atelier a suscité un intérêt considérable (103 participants), ce qui renforce l'espoir que les résultats encourageront d'autres États membres à effectuer des audits sur la justification de leurs examens de TDM grâce à la méthodologie développée et employée dans le cadre du projet EU-JUST-CT, qui est disponible gratuitement sur le site Web d'EU-JUST-CT. Ceci serait d'autant plus important que le niveau de conformité avec la BSSD peut encore être amélioré et que la sensibilisation aux aspects juridiques de la radioprotection et de la justification doit être accrue parmi les États membres.

Pour ce qui est de l'avenir, les discussions animées et l'intérêt manifesté par le public pour la réalisation d'audits nationaux appliquant la méthodologie EU-JUST-CT nourrissent l'espoir que les résultats du projet EU-JUST-CT inciteront les autorités nationales à redoubler d'efforts en matière de justification, par exemple, par l'utilisation accrue des recommandations de bonne pratique, idéalement sous la forme d'un système CDS, par la formation des professionnels de la santé à la justification et par des activités de sensibilisation et autres menées par les ANC et les parties prenantes concernées.

Constats principaux, conclusions et recommandations du projet EU-JUST-CT

Résultats

- La sensibilisation aux aspects juridiques de la radioprotection et de la justification doit encore être renforcée dans les États membres.
- Le projet EU-JUST-CT a contribué à atteindre cet objectif en réalisant des audits pilotes sur la justification des examens de tomodensitométrie dans sept pays simultanément, avec l'ESR iGuide comme norme de référence.
- Les taux de pertinence des demandes évaluées dans les sept pays/régions pilotes varient de 57,9% à 85,9%, ce qui montre une grande disparité entre les pays et la nécessité d'une action supplémentaire pour améliorer la justification des examens de tomodensitométrie.
- La proportion d'examens dont la pertinence n'a pas pu être évaluée en raison de l'absence ou de l'insuffisance de données cliniques varie considérablement d'un pays à l'autre (de 0,3 % à 27 %).
- Très peu de pays ont effectué des audits sur la justification des procédures radiologiques.
- Un très faible nombre d'examens pédiatriques par tomodensitométrie a été observé dans tous les pays, ce qui témoigne d'une faible utilisation de la tomodensitométrie dans ce groupe d'âge.
- Les taux de pertinence étaient plus faibles pour les médecins généralistes que pour les (autres) médecins spécialistes.
- Des différences dans les taux de pertinence entre les régions du corps ont été observées et, dans six pays, la colonne vertébrale présentait des taux de pertinence assez faibles, suivie par les extrémités et le bassin. Les résultats sont comparables à ceux de l'étude d'audit menée au Luxembourg.
- Des différences dans les taux de pertinence ont été observées entre les établissements publics et privés, les taux de pertinence étant meilleurs dans les établissements publics.
- L'IRM était l'examen le plus approprié dans de nombreux cas où l'examen tomodensitométrique n'était pas approprié.
- Le taux de pertinence de la tomodensitométrie était meilleur pour les patients hospitalisés/en urgence que pour les patients ambulatoires.

Conclusions

- Les résultats obtenus permettent de conclure que, dans l'ensemble, il existe une corrélation entre les efforts de justification déployés dans certains pays et les résultats de l'audit. Des efforts de justification considérables ont été déployés jusqu'à présent en Belgique, au Danemark et en Finlande.
- La disponibilité et l'utilisation de recommandations de bonne pratique en matière d'imagerie sont cruciales dans le processus de justification des examens de tomodensitométrie, car elles permettent de s'assurer que le patient bénéficie de l'examen approprié.

- L'éducation et la formation à la justification et à l'audit clinique sont essentielles pour améliorer la mise en œuvre du processus de justification.
- L'inspection de la justification et l'audit clinique de la justification doivent avoir lieu.
- Les recommandations de bonne pratique en matière d'imagerie clinique et les systèmes CDS peuvent constituer des outils essentiels et leur élaboration, leur disponibilité et leur utilisation devraient être considérées comme une priorité par les hôpitaux et les organismes de soins de santé.
- Les auditeurs doivent avoir la volonté et la capacité de consacrer suffisamment de temps et d'énergie à la réalisation d'audits de qualité. L'effort attendu ainsi que la méthodologie à utiliser doivent être expliqués en détail au début du processus. Les efforts des auditeurs doivent être rémunérés.

Recommandations

- La qualité des demandes collectées auprès des centres d'imagerie participants était très variable. C'est pourquoi il est explicitement recommandé aux États membres de veiller à la qualité des demandes.
- La justification appropriée des procédures individuelles de tomodensitométrie reste un aspect clé de la sécurité des patients, des résultats pour les patients et de l'utilisation efficace et efficiente des ressources d'imagerie radiologique.
- Le dialogue avec les cliniciens référents est essentiel pour éviter les conflits entre les référents et les services d'imagerie radiologique.
- Les radiologues doivent être impliqués soit directement, soit dans la mise en place et l'approbation des politiques, des processus et des procédures lorsque d'autres spécialistes médicaux et professionnels de la santé les justifient.
- Dans tous les cas, les rôles et les responsabilités de toutes les personnes concernées dans le processus de justification doivent être clairs et identifiables.
- L'amélioration de la justification individuelle nécessite une approche multifactorielle, impliquant l'éducation et la formation, ainsi que l'ingénierie du flux de travail et l'audit clinique.
- L'accès direct aux dossiers des patients et à l'imagerie antérieure est essentiel pour que la justification soit correcte.
- La disponibilité de l'IRM peut jouer un rôle important concernant la pertinence des examens de tomodensitométrie.
- L'évaluation de la justification individuelle appropriée peut être fournie par un audit clinique.
- L'inspection est un processus important, mais sa portée et son objectif, ainsi que sa fréquence, peuvent limiter son impact au quotidien.
- L'atelier a démontré un intérêt considérable pour le sujet de la part de toutes les parties prenantes.
- Le groupe d'étude se félicite pour l'intention de la Commission européenne de continuer à soutenir les audits et les travaux sur la justification dans le cadre du plan d'action SAMIRA et soutient pleinement les efforts de la CE en vue d'une meilleure mise en œuvre et d'un engagement accru des États membres.

 Les États membres sont encouragés à tirer parti de la méthodologie et de l'expérience du projet EU-JUST-CT et à mener des campagnes d'audits similaires.

L'équipe du projet reste à votre disposition pour répondre à vos questions et vous conseiller.

1. Introduction

EU-JUST-CT stands for 'European co-ordinated action on improving justification of computed tomography' and is a European Commission Tender project that was awarded to the European Society of Radiology.

The three-year project started in April 2021 and aimed to improve justification of computed tomography in Europe through co-ordinated action.

The project pursued the following specific objectives:

- a) Collect up-to-date information about justification of CT examinations in Europe.
- b) Develop a common methodology for auditing justification of CT examinations.
- c) Carry out co-ordinated pilot audits of justification of CT examinations.
- d) Discuss the status of justification of CT examinations with the Member States and identify opportunities for further action.

The organisation of co-ordinated national or regional pilot audits in EU Member States or regions formed an essential part of the project and will be described in detail in the present report.

2. Literature Review and Survey on Status of CT Justification in Europe

As a first step, a literature search via PubMed, Science Direct and Google Scholar was performed. This review identified just 27 publications which investigated the appropriateness of CT referrals, which were predominantly European. Only few of these studies were categorised as major audits / surveys, organised at a national level collecting data from multiple centres. Surveys utilised a range of reviewer numbers to assess appropriateness / justification of CT referrals, with the most common being two reviewers who were typically radiologists. Most European publications used adult data, three focussed on paediatrics, five included both adults and paediatric patients while the remaining four did not describe their cohort. Most European audits were retrospective in nature. Although methodologies differed between studies depending on the specific CT examination, justification rates were consistently below 90% across studies, suggesting substantial scope for quality improvement. The project team therefore suggests that standardising the approach would better facilitate comparison between studies, imaging centres and even countries and guide resource allocation in this important area in the future.

In order to identify up-to-date information about justification of CT examinations in Europe, a survey was sent to national competent authorities of EU Member States, Norway, Switzerland and the UK in June 2021, as well as to the national radiology societies of these countries [9].

Questions related to the existence and details of justification processes as well as legal requirements for justification of individual CT examinations, the existence, nature and use

of referral guidelines, roles and responsibilities of the referrer and the radiology practitioner, whether health screening with CT takes place, whether an audit of justification of CT procedures was planned or had been performed in the country and if so, what the key learnings were.

Responses were received from 30 countries of both the national competent authorities and the national radiology societies. The results highlighted key areas for improvements, such as ensuring an earlier involvement of the radiology practitioner in the process of justification.

While referral guidelines were reported as being available in almost all countries, familiarity and use of same is lacking, suggesting the need to further encourage more regular use and incorporation into clinical decision support systems so that referrers are required to review such guidelines before submitting a referral, thus ensuring that patients receive the most appropriate imaging examination.

Justification of new CT practices appears to be largely regulated across Europe, although relevant processes vary between countries.

Results also suggested that further and more regular audits throughout EU Member States would contribute to ensuring that CT is used as efficiently and appropriately as possible. This was also corroborated by respondents reporting positive benefits from audits.

3. Audit Methodology and Tools

Individual justification of CT examinations is a process to ensure that the patient undergoes the appropriate examination in accordance with the clinical indications and the reason for the examination specified on the referral. The radiological practitioner decides whether the examination requested on the referral is the appropriate one or whether it should be changed or refused.

The EU-JUST-CT project team developed a common methodology and tools for carrying out co-ordinated national/regional audits.

The national competent authorities (NCAs) in radiological protection were responsible for organising the pilot audits in their countries with the aim to evaluate whether the justification process is implemented in the participating imaging centres. A pool of auditors was established with the support of the national radiology societies.

The hospitals provided the anonymised referrals (still containing age and sex of the patient) in paper or electronic format to the NCAs, who verified their quality and provided 500 anonymised referrals to each designated auditor. In order to evaluate the appropriateness of the CT examination, a set of data, including type of examination, patient gender, age, in/outpatient, referrer specialty etc., was obtained for each referral.

Each referral was assessed by two auditors, using the ESR imaging referral guidelines embedded in the ESR iGuide as a standard for the audits. If the ESR iGuide did not include recommendations for a specific indication, auditors were given the possibility of evaluating justification based on their expert opinion. In total, over 6,400 referrals were audited in the framework of the project.

Limitations of the methodology include the fact that appropriateness of a diagnostic CT examination was evaluated based on the information provided on the referral only, as the auditors did not have access to the patient history nor to previous imaging examinations. Referrals that were rejected were not part of the audit.

The document "Audit Methodology and Tools" is available on the EU-JUST-CT project website and is provided in Annex 2 of this report.

4. Workshop

Following the conclusion of the audits of CT justification, a project workshop was held in Luxembourg and remotely on 28-29 September 2023. The major aim was to share the results of the audits with representatives of the European Commission, national radiology societies, national radiation protection authorities, national health authorities, health professionals and patient representatives from various EU member states and to discuss the state of justification as well as the Guidance Document for radiology departments which the project has developed and which is provided in Part 2 of the present report. The high attendance number and lively interaction from the audience fostered the project consortium's hope that the results will enhance activities on clinical audit, improve justification of CT and thereby advance the quality of medical care for patients Europe.

The workshop proceedings can be accessed on the project website.5

5. Results of the Pilot Audits

5.1. Introduction and Background

The co-ordinated pilot audits followed the above-mentioned methodology and were carried out in EU Member States or regions that had not performed any (external / centralised) audits of justification of CT examinations in the past five years. The national / regional competent authorities and radiology societies were strongly involved in the process in order to guarantee representative results and coverage of adult and paediatric populations, public and private institutions, and CT referrals from general practitioners, emergency rooms and clinical specialists.

The list of National Competent Authority (NCA) and radiology society (NRS) lead contacts is provided in Annex 1.

To select the participating countries, a call for expressions of interest was launched among HERCA members by the HERCA WGMA during July/August 2020. The following countries finally agreed to participate in the pilot programme: Belgium (BE), Denmark (DK), Estonia (EE), Finland (FI), Greece (GR), Hungary (HU), Slovenia (SI).

The National Competent Authorities (NCAs) of the seven countries were invited to a meeting in July 2021 for a detailed introduction of the project, including the draft audit methodology and the role of the NCAs, and were asked to set up the pilot liaison group and timeline. Following this meeting, the NCAs were provided with a template and were asked to set up a list of participating centres, indicating for each centre whether it was public or private and if it performed CTs for the adult and/or paediatric population.

⁵ http://www.eurosafeimaging.org/eu-just-ct/wp-7

5.2. Final List of Pilot Countries/Regions

The NCAs of each participating country provided the project team with a list of diagnostic radiology departments proposed for participation together with information on the approximate number of CT procedures per day, whether the facility was public or private, and whether it performed adult, paediatric or both types of procedures (table 1).

Table 1 List of pilot countries/regions

Country	Level of Participation (country/ region)	No. of partici- pating hospitals (sites)	Of which public/ private	Of which adult/paediatric/both	CTs per country per year	Estimated CTs per day
BE	Representative selection of centres across the country	11	8 public, 3 private*	11 adult & paediatric	2,349,442	835 (Brussels region)
DK	Region of Southern Denmark	12	11 public, 1 private	10 adult, 1 adult & paediatric	1,057,470 adult 12,243 paed	1,000 (region)
EE	Entire country	19	17 public, 2 private	Mainly adult (only 1,200 paediatric CTs/per year in the entire country)	153,227 adult 1,287 paed	618 (country)
FI	Helsinki district	2 (17)	1 public, 1 private	16 both, 1 paediatric	570,000	892 (region)
GR	Thessaloniki region	26	8 public, 18 private	19 adult, 7 adult & paediatric	1,500,000	950 (region)
HU	4 counties: Baranya, Csongrád, Hajdú-Bihar, Borsod-Abaúj- Zemplén	4 (21)	4 public, 0 private	adult & paediatric	1,500,000	500-1,000 (region)
SI	Entire country	20	16 public, 4 private	17 mostly adult, 3 adult & paediatric	165,000	660 (country)

^{*} None of the hospitals in Belgium can be considered as fully private or fully public. See also Section 5.4.1.1

As a next step, the NCAs sent a letter to the participating centres in Q4 2021 with information on the project, explanation of the audit and the timeline. In parallel, the pilot liaison group was consulted on the draft audit methodology and tools prepared by the project.

In addition, the participating centres were provided with detailed explanations of the methodology in an online briefing. However, not all centres that initially agreed to supply referrals were ultimately able to collect and supply the agreed referrals. A full list of those that did participate is included in section 5.3 (below). Information about the public vs

private nature of the centres was adjusted later in the process following further enquiries with the NCAs in case of doubt as well as in the course of requests for information from the NCAs about the country's health system (section 5.7).

5.3. Participating Centres

A total of 125 centres ultimately supplied referrals for the pilot audits. The table below lists the centres of those participating countries whose NCAs agreed for the names of the centres to be published.

Table 2 List of participating centres

Country	Name of centre
Denmark	Odense University Hospital (3 centres/sites)
Denmark	Lillebaelt Hospital (3 centres/sites)
Denmark	Sønderjylland Hospital (3 centres/sites)
Denmark	Sydvestjysk Hospital (2 centres/sites)
Denmark	Private Hospital Molholm
Estonia	Hiiumaa Hospital
Estonia	East Tallinn Central Hospital
Estonia	East-Viru Central Hospital
Estonia	Järvamaa Hospital
Estonia	Jõgeva Hospital
Estonia	Kuressaare Hospital
Estonia	Läänemaa Hospital
Estonia	West Tallinn Central Hospital
Estonia	South Estonian Hospital
Estonia	Medicum Healthcare Services
Estonia	Narva Hospital
Estonia	Confido Medical Centre
Estonia	Pärnu Hospital
Estonia	North Estonia Medical Centre

Estonia	Põlva Hospital
Estonia	Rakvere Hospital
Estonia	Tartu University Hospital
Estonia	Valga Hospital
Estonia	Viljandi Hospital
Finland	Hospital District of Helsinki and Uusimaa (16 hospitals/sites)
Finland	Mehiläinen
Hungary	Borsod-Abaúj-Zemplén Megyei Központi Kórház és Egyetemi Oktatókórház, Képalkotó Diagnosztikai Centrum (represents 7 sites operated by the hospital)
Hungary	Debreceni Egyetem Klinikai Központ, Kenézy Gyula Campus Központi Radiológiai Diagnosztika (represents 5 sites operated by the University)
Hungary	Pécsi Tudományegyetem, Általános Orvostudományi Kar, Orvosi Képalkotó Klinika (represents 5 sites operated by the University)
Hungary	Szent-Györgyi Albert Klinikai Központ, Radiológiai Klinika (represents 4 sites operated by the University)
Slovenia	UMC Ljubljana
Slovenia	UMC Maribor
Slovenia	Institute of Oncology Ljubljana
Slovenia	GH Izola
Slovenia	GH Celje
Slovenia	GH Novo Mesto
Slovenia	GH Nova Gorica
Slovenia	GH Murska Sobota
Slovenia	GH Jesenice
Slovenia	GH Brežice
Slovenia	GH Trbovlje
Slovenia	GH Ptuj
Slovenia	GH Slovenj Gradec

Slovenia	Orthop. Hosp. Valdoltra
Slovenia	Hospital Topolšica
Slovenia	Primary health centre ZD Maribor
Slovenia	Medilab
Slovenia	MTC Fontana
Slovenia	Radiomed / Dvorec Lanovž*
Slovenia	Digitalna slikovna diagnostika

^{*}Technically two legal entities but same staff and CT unit, data merged

5.4. Survey of Participating Centres

A survey seeking to understand the implementation of the process of justification was conducted in the participating centres. The questions of the survey are included in Annex 2 "Final Audit Methodology and Tools" to this report.

5.4.1 Summary of the Results of the Survey of Participating Centres

A total of 78 responses to the survey were received from the 125 centres participating in the pilot audits. During data cleaning it was found that in some cases more than one respondent answered for the same centre, in which case the more complete answer was considered for analysis.

After analysis of the relevant replies, incomplete entries, duplicates as well as answers from respondents from centres that did not participate in the audit were removed.

Three of the hospitals in Denmark represented three centres (sites) each, and one hospital represented two centres (sites). Including one additional hospital, the responses reflected all 12 participating sites from Denmark.

One of the two responding centres in Finland represented 16 sites, totalling in 17 sites from Finland. One of the three replying hospitals from Hungary represented seven sites and two of the hospitals represented five sites each, resulting in a total of 17 sites where CT facilities are located; even if the equipment is not located in the same site, it belongs to the same hospital in one region organisation-wise. All analysed parameters below are based on the number of survey responses considered, i.e., five in the case of Denmark, two for Finland and three for Hungary. The overview of responses received and considered for the analysis following the cleaning process is represented in table 3.

Table 3 Responses per country

Overview of survey responses received and analysed following cleaning

Country	Survey responses received	Removed from analysis	Number of responses considered for analysis	Number of centres (sites) reflected by responses	Reasons for removal from analysis
Belgium	12	1	11	11	1 duplicate
Denmark	5	0	5	12	
Estonia	20	3	17	17	1 duplicate, 1 incomplete, 1 respondent has not participated in audit
Finland	2	0	2	17	
Greece	14	2	12	12	1 duplicate, 1 incomplete
Hungary	4	1	3	17	1 duplicate
Slovenia	21	1	20	20	1 respondent has not participated in audit
	78	8	70	106	

The centres (among those who agreed to published) that answered the survey and were considered for the analysis are listed below:

Table 4 List of centres considered for analysis

Country	Name of centre
Denmark	Odense University Hospital
Denmark	Lillebaelt Hospital
Denmark	Sønderjylland Hospital
Denmark	Sydvestjysk Hospital
Denmark	Private Hospital Molholm
Estonia	Hiiumaa Hospital
Estonia	East Tallinn Central Hospital

Estonia	East-Viru Central Hospital
Estonia	Järvamaa Hospital
Estonia	Jõgeva Hospital
Estonia	Kuressaare Hospital
Estonia	Läänemaa Hospital
Estonia	West Tallinn Central Hospital
Estonia	South Estonian Hospital
Estonia	Medicum Healthcare Services
Estonia	Narva Hospital
Estonia	Confido Medical Centre
Estonia	Pärnu Hospital
Estonia	North Estonia Medical Centre
Estonia	Põlva Hospital
Estonia	Rakvere Hospital
Estonia	Viljandi Hospital
Finland	Hospital District of Helsinki and Uusimaa (16 hospitals)
Finland	Mehiläinen
Hungary	Borsod-Abaúj-Zemplén Megyei Központi Kórház és Egyetemi Oktatókórház, Képalkotó Diagnosztikai Centrum (represents 7 sites operated by the hospital)
Hungary	Debreceni Egyetem Klinikai Központ, Kenézy Gyula Campus Központi Radiológiai Diagnosztika (represents 5 sites operated by the University)
Hungary	Pécsi Tudományegyetem, Általános Orvostudományi Kar, Orvosi Képalkotó Klinika (represents 5 sites operated by the University)
Slovenia	UMC Ljubljana
Slovenia	UMC Maribor
Slovenia	Institute of Oncology Ljubljana
Slovenia	GH Izola
Slovenia	GH Celje

Slovenia	GH Novo Mesto
Slovenia	GH Nova Gorica
Slovenia	GH Murska Sobota
Slovenia	GH Jesenice
Slovenia	GH Brežice
Slovenia	GH Trbovlje
Slovenia	GH Ptuj
Slovenia	GH Slovenj Gradec
Slovenia	Orthop. Hosp. Valdoltra
Slovenia	Hospital Topolšica
Slovenia	Primary health centre ZD Maribor
Slovenia	Medilab
Slovenia	MTC Fontana
Slovenia	Radiomed / Dvorec Lanovž*
Slovenia	Digitalna slikovna diagnostika

^{*}Technically two legal entities but same staff and CT unit, data merged

All countries except Hungary had a mix of public and private centres – see table 5 below:

Table 5 Public vs private centres

Country	Number of responses considered for analysis	Of which public	Of which private
Belgium*	11	8	3
Denmark	5	4	1
Estonia	17	15	2
Finland	2	1	1

Greece	12	6	6
Hungary	3	3	0
Slovenia	20	16	4
	70	53	17

^{*8} of the hospitals in Belgium were indicated by the respondents as public and 3 as private. However, as explained in section 5.4.1.1, none of the hospitals in Belgium can be considered as fully private or fully public.

Responses were obtained from 53 public and 17 private centres. Hungary is the only country without private centres analysed. In Greece 75% of the audited centres were private, but responses to the survey were sent from the same number of private and public centres. In Finland, one of the two centres was the hospital district of Helsinki, a public institution which comprises 16 hospitals, altogether performing over 100,000 CT examinations annually, while the other of the two facilities was a small private hospital with CT examinations in the range of 1,000-10,000 per year.

A summary of the answers to the key questions of the survey is provided below.

Table 6 Number of diagnostic CT examinations performed per year by centre

Country (No. of responses)	Number of diagnostic CT examinations performed per year by centre:								
Table	<1,000	1,001- 10,000	10,001- 30,000	30,001- 50,000	50,001- 100,000	>100,001	No data		
Belgium (11)	0	0	3	7	1	0	0		
Denmark (5)	1	0	1	2	1	0	0		
Estonia (17)	1	8	6	2	0	0	0		
Finland (2)	0	1	0	0	0	1	0		
Greece (12)	1	7	4	0	0	0	0		
Hungary (3)	0	0	2	1	0	0	0		
Slovenia (20)	0	14	4	1	1	0	0		
Total = 70	3	30	20	13	3	1	0		

Out of the 70 responses, only one response was related to a centre performing over 100,000 CT examinations annually (namely the group of 16 medical institutions in Finland with centralised administration, which is therefore considered as one large organisation/centre). Three responses were from centres performing 50,000-100,000 examinations (one each in Belgium, Denmark and Slovenia), 13 responses were from centres performing 30,000-50,000 examinations, 21 responses from centres performing

10,000-30,000 examinations annually, 30 responses from centres performing 1,000 to 10,000 examinations, and 3 responses from small centres performing less than 1,000 examinations annually.

Table 7 Availability of written procedures describing the justification process

Country (No. of responses)		Are there written procedures describing the justification process available in the imaging facility's Quality Assurance system?						
	yes	No	Partly	Don't know	Didn't answer	% Yes		
Belgium (11)	6	1	4	0	0	55		
Denmark (5)	5	0	0	0	0	100		
Estonia (17)	6	1	9	1	0	35		
Finland (2)	2	0	0	0	0	100		
Greece (12)	4	5	2	1	0	33		
Hungary (3)	1	1	1	0	0	33		
Slovenia (20)	8	6	4	2	0	40		
Total = 70	33	14	19	4	0			

In Denmark and Finland written procedures exist in all centres which responded. In Belgium, written procedures do not exist in the smallest regional hospital with 20,000 CT examinations per year. They exist partly in two large regional hospitals performing 27,500 to 37,500 CT examinations annually and two university hospitals with around 40,000 and 51,000 examinations annually. Written procedures exist in six hospitals with 27,000 to 44,000 examinations annually. In Estonia, Greece, Hungary and Slovenia written procedures exist in 33-40% of centres which responded. It was not possible to determine that the existence of written procedures correlates with the number of CT examinations annually. According to the received responses, the major university centres in Ljubljana and Maribor, which perform the highest number of examinations in Slovenia, do not have written procedures in place.

The tables below show the answers to the questions if the following issues addressed and described in the procedures:

Table 8 Evaluation of justification and appropriateness of referral

Country (No. of responses)	Evaluation of justification and appropriateness of referral?							
	Yes	No	Partly	Don't know	Didn't answer	% Yes		
Belgium (11)	7	1	2	0	1	63		
Denmark (5)	4	1	0	0	0	80		
Estonia (17)	8	0	6	1	2	47		
Finland (2)	1	0	1	0	0	50		
Greece (12)	4	0	1	0	7	33		
Hungary (3)	0	1	1	0	1	0		
Slovenia (20)	7	0	5	0	8	35		
Total = 70	31	3	16	1	19			

In the written procedures describing the justification process in the imaging facility's quality assurance system the issue of evaluation of justification and appropriateness of referral is addressed in detail in only 31 (44.3%) of 70 facilities and partly in 16 out of 70 (22.9%). Interestingly, 19 out of the 70 respondents did not answer this question, indicating that they are not familiar with such procedures. The highest percentages of positive responses were received from Denmark and Belgium.

Table 9 Previous images or clinical information/history

Country (No. of responses)	Seek previous images or clinical information/history?							
	Yes	No	Partly	Don't know	Didn't answer	% Yes		
Belgium (11)	9	1	0	0	1	82		
Denmark (5)	5	0	0	0	0	100		
Estonia (17)	11	2	2	0	2	65		
Finland (2)	2	0	0	0	0	100		
Greece (12)	5	0	0	0	7	42		
Hungary (3)	1	1	0	0	1	33		

Slovenia (20)	9	0	3	0	8	45
Total = 70	42	4	5	0	19	

In Denmark and Finland previous images or clinical information/history are sought in all cases, in Belgium in 82% and in Estonia in 65% of cases, while in Greece, Hungary and Slovenia this rate is below 50%. Again, 19 out of 70 respondents did not answer this simple question.

Table 10 Contact between referrer and radiological practitioner

Country (No. of	Contact between referrer and radiological practitioner when more information is required?						
responses)	Yes	No	Partly	Don't know	Didn't answer	% Yes	
Belgium (11)	7	2	1	0	1	64	
Denmark (5)	5	0	0	0	0	100	
Estonia (17)	12	1	2	0	2	71	
Finland (2)	2	0	0	0	0	100	
Greece (12)	5	0	0	0	7	42	
Hungary (3)	1	1	0	0	1	33	
Slovenia (20)	11	0	1	0	8	55	
Total = 70	43	4	4	0	19		

In Denmark and Finland, contact between referrer and radiological practitioner is established in all cases when more information is required, in Estonia in 71%, in Belgium in 64%, in Slovenia in 55% of cases, while in Greece and Hungary this rate is below 50%. Again, 19 out of 70 respondents did not answer this simple question.

Table 11 Self-assessments/peer reviews/audits evidence or indications

Country (No. of responses)	Have self-assessments/peer reviews/audits shown evidence or indications that these procedures are implemented in daily work?						
responses	Yes	No	Partly	Don't know	Didn't answer	% Yes	
Belgium (11)	5	1	3	1	1	46	

Denmark (5)	3	1	1	0	0	60
Estonia (17)	5	4	6	0	2	29
Finland (2)	1	0	1	0	0	50
Greece (12)	5	0	0	0	7	42
Hungary (3)	2	0	0	0	1	67
Slovenia (20)	9	1	2	0	8	45
Total = 70	30	7	13	1	19	

In Denmark positive answers were given in 60% of responses, in Finland in 50%, while in other countries less than 50% responded positively. Again, 19 out of 70 respondents did not answer the question if self-assessments/peer reviews/audits have shown evidence or indications that these procedures are implemented in daily work.

Table 12 Assignation of responsibilities and tasks for the referring physician

Country (No. of responses)	Are the responsibilities and tasks for the referring physician clearly assigned and documented?							
responses	Yes	No	Partly	Don't know	Didn't answer	% Yes		
Belgium (11)	6	1	2	2	0	55		
Denmark (5)	5	0	0	0	0	100		
Estonia (17)	10	2	4	1	0	58		
Finland (2)	2	0	0	0	0	100		
Greece (12)	5	3	2	1	1	42		
Hungary (3)	2	0	1	0	0	67		
Slovenia (20)	13	3	3	1	0	65		
Total = 70	43	9	12	5	1			

Tasks and responsibilities for the referring physician are clearly assigned and documented in all cases in Denmark and Finland. Only for Greece less than 50% of the answers were positive.

Table 13 Assignation of responsibilities and tasks for the radiological practitioner

Country (No. of responses)	Are the responsibilities and tasks for the radiological practitioner responsible for diagnostic CT examinations clearly assigned and documented?						
	Yes	No	Partly	Don't know	Didn't answer	% Yes	
Belgium (11)	8	1	2	0	0	73	
Denmark (5)	4	0	1	0	0	80	
Estonia (17)	12	0	3	2	0	71	
Finland (2)	2	0	0	0	0	100	
Greece (12)	7	2	2	0	1	58	
Hungary (3)	3	0	0	0	0	100	
Slovenia (20)	17	1	0	2	0	85	
Total = 70	53	4	8	4	1		

Tasks and responsibilities for the radiological practitioner responsible for diagnostic CT examinations are clearly assigned and documented according to over 70% of responses in all countries, except in Greece where 58% of the responses were positive. In Finland and Hungary all responses were positive. This question received the highest proportion of positive answers in the survey.

Table 14 Evaluation of appropriateness of referred examination

Country (No. of responses)	Is the appropriateness of referred examination evaluated before it is performed?							
responses	Yes	No	Partly	Don't know	Didn't answer	% Yes		
Belgium (11)	9	1	1	0	0	82		
Denmark (5)	4	1	0	0	0	80		
Estonia (17)	13	1	3	0	0	76		
Finland (2)	2	0	0	0	0	100		
Greece (12)	10	0	1	0	1	83		

Hungary (3)	1	0	2	0	0	33
Slovenia (20)	11	1	7	0	1	52
Total = 70	50	4	14	0	2	

^{*}The 4 that responded 'no' were: 1 public university hospital, 2 large public regional hospitals and 1 other (private diagnostic practice)

In all countries except Hungary, the appropriateness of referred examinations is evaluated fully before the latter are performed in over 50% of cases, in all cases in Finland and in over 80% in Denmark, Belgium and Greece. Out of the four negative responses, three came from large public hospitals (two regional, one university hospital), which can be considered surprising. 50 out of 70 respondents indicated full evaluation and 14 partial evaluation, meaning that in 64 out of 70 cases full or partial evaluation is performed.

Table 14 Examination request and rejection

Country (No. of	If the examination requested is inappropriate, is the examination rejected?							
responses)	Yes	No	Partly	Don't know	Didn't answer	% Yes		
Belgium (11)	4	0	7	0	0	36		
Denmark (5)	5	0	0	0	0	100		
Estonia (17)	14	0	3	0	0	82		
Finland (2)	2	0	0	0	0	100		
Greece (12)	8	1	2	0	1	67		
Hungary (3)	1	0	2	0	0	33		
Slovenia (20)	11	0	8	0	1	55		
Total = 70	45	1	22	0	2			

The answers indicate that inappropriate requests are rejected in 45 out of 70 cases overall (64.3%), and in all cases in Finland and Denmark. They are partially rejected in 22 of 70 cases (31.4%).

Table 15 Referral guidelines: Availability at the facility

Country (No. of	Are referral guidelines available at the facility?							
responses)	Yes	No	Partly	Don't know	Didn't answer	% Yes		
Belgium (11)	8	3	0	0	0	73		
Denmark (5)	5	0	0	0	0	100		
Estonia (17)	8	4	5	0	0	47		
Finland (2)	2	0	0	0	0	100		
Greece (12)	3	3	2	3	1	25		
Hungary (3)	0	1	2	0	0	0		
Slovenia (20)	7	6	3	3	1	35		
Total = 70	33	17	12	6	2			

Referral guidelines are available in all responding facilities in Denmark and Finland and in over 70% of facilities in Belgium, while they are not or only partly available in Hungary and available in 25%-47% of facilities in Greece, Slovenia and Estonia. It is interesting to note that 6 out of 70 responders indicated that they did not know if guidelines are available, 12 of the respondents indicated that referral guidelines are partly available, and two respondents did not answer this question. In 17 of 70 responses the answer was no, meaning that in 24.3% of facilities the legal requirements were not respected.

Table 16 Referral guidelines: Awareness

Country (No. of responses*)	Regarding the referral guidelines available at the facility: Are the referrers aware of the guidelines?							
responses /	Yes	No	Partly	Don't know	Didn't answer	% Yes		
Belgium (8)	0	0	6	2	0	0		
Denmark (5)	1	1	0	3	0	20		
Estonia (13)	7	1	3	2	0	54		
Finland (2)	1	0	1	0	0	50		
Greece (5)	2	0	1	1	1	40		

Hungary (2)	1	0	1	0	0	50
Slovenia (10)	5	0	4	1	0	50
Total = 45	17	2	16	9	1	

^{*}Respondents must have answered 'yes' or 'partly' to 'Are referral guidelines available at the facility?'

The replies demonstrate that even if guidelines are at least partly available at the facility, referrers are aware of their existence in only 37.8% (17 out of 45) cases, while they are partly aware of their existence in 35.6% (16 out of 45) of cases. This means that more than 20% of referrers are not aware that guidelines exist in their facility, even though they should be the principal users of the guidelines.

Table 17 Referral guidelines: Routine use

Country (No. of responses*)	Regarding the referral guidelines available at the facility: Is there evidence that the guidelines are in routine use by the referrer?									
responses ;	Yes	No	Partly	Don't know	Didn't answer	% Yes				
Belgium (8)	1	3	2	2	0	13				
Denmark (5)	3	1	0	1	0	60				
Estonia (13)	3	3	5	2	0	23				
Finland (2)	0	2	0	0	0	0				
Greece (5)	2	0	2	0	1	40				
Hungary (2)	0	1	1	0	0	0				
Slovenia (10)	4	2	4	0	0	40				
Total = 45	13	12	14	5	1					

^{*}Respondents must have answered 'yes' or 'partly' to 'Are referral guidelines available at the facility?'

Even if referrers are aware that guidelines exist, they use them only in 13 out of 45 cases (28.9%). However, the responses in the table above show that in Finland, referrers do not use the guidelines, and they use them in 60% of facilities in Denmark. These responses are in considerable contrast to the results obtained in the project and the high proportion of appropriate exams performed in Finland and Denmark. Possible reasons for this discrepancy might be that respondents either did not answer properly or could not demonstrate the evidence that referrers use the guidelines.

Table 18 Referral guidelines: Availability to the referrer

Country (No. of responses)	Regarding the referral guidelines available at the facility: Are the referral guidelines implemented in the Clinical Decision Support system available to the referrer?									
	Yes	No Partly Don't know			Didn't answer	% Yes				
Belgium (8)	0	6	1	1	0	0				
Denmark (5)	3	1	0	1	0	60				
Estonia (13)	2	7	1	3	0	15				
Finland (2)	0	1	1	0	0	0				
Greece (5)	3	0	0	1	1	60				
Hungary (2)	0	2	0	0	0	0				
Slovenia (10)	4	1	3	2	0	40				
Total = 45	12	18	6	8	1					

^{*}Respondents must have answered 'yes' or 'partly' to 'Are referral guidelines available at the facility?'

Even if guidelines are available at the facility, they are implemented in the clinical decision support system available to the referrer completely in only 26.7% (12 out of 45) cases and partially in 13.4% (6 cases), so the clinical decision support is at least partially available in only 40% of facilities that have referral guidelines available. It seems that clinical decision support systems are not available in Hungary and not or only partly in Belgium and Finland, while they are available in 60% of cases in Denmark and Greece.

Table 19 MRI availability

Country (No. of responses)	Is MRI available in your facility?									
	Yes	No	Partly	Don't know	Didn't answer	% Yes				
Belgium (11)	11	0	0	0	0	100				
Denmark (5)	5	0	0	0	0	100				
Estonia (17)	9	6	2	0	0	53				
Finland (2)	2	0	0	0	0	100				
Greece (12)	7	3	0	0	2	58				

Hungary (3)	3	0	0	0	0	100
Slovenia (20)	15	4	0	0	1	75
Total = 70	52	13	2	0	3	

MRI is available in 74% of facilities (52 out of 70). It is available in all facilities in Belgium, Denmark, Finland and Hungary, in 75% of facilities in Slovenia, in 58% in Greece and in 53% of facilities in Estonia.

The numbers of respondents indicated in the following sections reflect the numbers of responses considered for analysis.

5.4.1.1 Belgium

Respondents: 10 were medical doctors (MDs), 1 medical imaging technician

Institutions: 8 Public, 3 Private

Type of responding facility: 5 Large regional hospitals, 1 Small local hospital, 5 University Hospitals

None of the hospitals in Belgium should be considered as fully private or fully public, according to the project's NCA contact from the Federal Agency for Nuclear Control of Belgium. In the context of justification, the attribution of private and public might incorrectly influence the interpretation of data. Even if the owners of hospitals are private, they fall under the same financial structure regarding CT examinations. For patients, Belgium has a national reimbursement system independent of the hospital. Doctors are either paid by act, and they have to give a certain amount of this money to the hospital, or the hospital receives the money that is paid for each act and pays the medical doctors a salary (in university hospitals medical doctors receive a salary). In both situations there might be a financial benefit of performing more radiological acts. There is also public money for equipment purchases, regardless of the owner of the hospital. Public vs private ownership has an impact e.g., in cases of retirement or financing hospital buildings.

The project leaders suggest that no distinction can be made between private and public ownership in Belgium for this project, as all hospitals belong to the similar reimbursement system and follow similar administrative rules.

From 11 centres responding to the survey from Belgium it is visible that the majority, namely 7, perform 30,001–50,000 CT examinations annually, one centre performs 50,001–100,000 examinations annually, and three centres perform 10,001 – 30,000 examinations. Compared to other countries, responses from Belgium are from larger centres.

In Belgium written procedures describing the justification process are available in imaging facilities' quality assurance (QA) system in 6 out of 11 (54.5%) centres that responded and are partly available in 4 of 11 (36.4%) centres. Written procedures do not exist in the smallest regional hospital with 20,000 CT examinations per year. They exist partly in two large regional hospitals with 27,500 and 37,500 CT examinations annually and in two university hospitals with around 40,000 and 51,000 examinations annually. Written procedures exist in six hospitals with 27,000–44,000 examinations annually.

The justification and appropriateness of referral is addressed in detail in 7 out of 11 centres in Belgium, and partly in 2 of 11. It is not addressed in one institution, and no answer was provided in one case. In this context, Belgium is second best-performing after Denmark. Previous images or clinical information/history are sought in 9 out of 11 (82%)

centres in Belgium. Contact between referrer and radiological practitioner is established when more information is required in 64% of cases. Self-assessment, peer reviews or audits have shown evidence that these procedures are implemented in the daily work in 5 of 11 (46% of) cases.

Tasks and responsibilities for the referring physician are clearly assigned and documented in 6 out of 11 centres (55%) in Belgium. Tasks and responsibilities for the radiological practitioner responsible for diagnostic CT examinations are clearly assigned in 8 of 11 centres and partly assigned and documented in 2 of 11 centres, reflecting a very high rate of positive answers.

The appropriateness of referred examinations is evaluated fully before it is performed in 9 out of 11 centres (81.8%) in Belgium. The inappropriate examination requests are fully rejected in 4 out of 11 (36% of) centres and partly rejected in 7 of 11 (64%) centres.

Referral guidelines are available in 8 out of 11 (73%) centres in Belgium, but according to the survey respondents, referrers are only partly aware of their availability in 6 of 8 centres, and in 2 of 8 centres respondents did not know if referrers were aware of the availability of guidelines. Out of 8 centres with guidelines available, they are in routine use by referrers in only 1, and partly in 2 centres. In 8 centres where guidelines are available, they are partially implemented in the clinical decision support (CDS) system in only one centre, while in the others they are not implemented in the CDS. Finally, MRI is available in all 11 centres in Belgium that responded.

As a conclusion, evaluation of justification and appropriateness is quite advanced in Belgium, with clearly assigned tasks and responsibilities of referring physicians and radiological practitioners in the majority of centres. Even though referral guidelines are available in most centres they are seldom used in clinical practice and in most cases not implemented in the clinical decision support system.

5.4.1.2 Denmark

Respondents: 2 MDs (radiologists), 2 radiographers, 1 quality control administrator

Institutions: 4 Public, 1 Private

Type of responding facility: 1 Large regional hospital, 1 Small local hospital, 2 University Hospitals, 1 Other (private hospital)

In five centres from Denmark responding to the survey, two centres (one university hospital and one large regional hospital) perform 30,001–50,000 CT examinations annually, one centre performs 50,001–100,000 examinations annually (large university centre), one small hospital performs 10,001–30,000 examinations, and one private hospital performs below 1,000 examinations annually.

In Denmark written procedures describing the justification process are available in all imaging facilities' QA systems. Denmark and Finland performed best in this regard among the countries analysed. Evaluation of justification and appropriateness of referral is addressed in detail in 4 out of 5 centres in Denmark, which is the highest proportion of positive responses among the countries considered. Previous images or clinical information/history are sought in all centres in Denmark, and in all centres contact between referrer and radiological practitioner is established when more information is required.

Tasks and responsibilities for the referring physician are clearly assigned and documented in all centres in Denmark, while tasks and responsibilities for the radiological practitioner responsible for diagnostic CT examinations are clearly assigned in 4 out of 5 centres and

partly assigned in 1 centre. These are very high rates of positive answers compared to other countries.

The appropriateness of the referred examination is evaluated fully before the examination is performed in 4 out of 5 (80%) centres and inappropriate examination requests are fully rejected in all centres in Denmark.

Referral guidelines are available in all centres in Denmark, however respondents in 3 of 5 centres do not know if their availability is known to referrers, and one respondent indicated that referrers are not aware of their availability. However, in the next question, 3 out of 5 answered that guidelines are in routine use by referrers. Also, in 3 out of 5 centres guidelines are implemented in the clinical decision support system.

Finally, MRI is available in all five centres that responded.

As a conclusion, the evaluation of justification and appropriateness is quite advanced in Denmark, with clearly assigned tasks and responsibilities of referring physicians and radiological practitioners and guidelines available in all centres, with implementation of guidelines in the clinical decision support systems in 60% of centres, and guidelines in clinical use in 60% of centres.

These survey responses are reflected by the excellent results for Denmark in the present project.

5.4.1.3 Estonia

Respondents: 6 MDs (radiologists), 11 profession unknown, most likely radiographers

Institutions: 15 Public, 2 Private

Type of responding facility: 2 Large regional hospitals, 11 Small local hospitals, 4 Other (2 central hospitals, one small medical centre, 1 outpatient clinic)

A summary of the answers to the key questions of the survey is provided below.

From 17 centres in Estonia responding to the survey, the majority, namely 14 centres, perform 1,001–30,000 examinations annually; 2 out of 17 centres perform 30,001–50,000 CT examinations annually, 6 of 17 centres 10,001–30,000 examinations, 8 out of 17 centres perform 1,001–10,000 examinations, and 1 small centre performs less than 1,000 examinations. There are no centres with more than 50,000 annual examinations, which reflects the country's small population number.

In Estonia written procedures describing the justification process are available in the imaging facilities' QA systems in 6 out of 17 (35%) centres that responded, and partly available in 9 out of 17 (53%) centres. One centre where written procedures are not available is private, and one response was "I don't know" (respondent from a very small public hospital with 812 annual CTs performed). Evaluation of justification and appropriateness of referrals is addressed and described in the procedures in 8 of 17 centres in Estonia, and partly in 6 out of 17. Previous images or clinical information/history are sought in 11 out of 17 (65%) centres. Contact between referrer and radiological practitioner is established when more information is required in 12 of 17 (71%) cases, and partly in an additional 2 of 17. Self-assessment, peer reviews or audits have shown evidence that these procedures are implemented in the daily work completely in 5 out of 17 (29%) and partly in 6 of 17 (35%) cases. Tasks and responsibilities for the referring physician are clearly assigned and documented in 12 out of 17 (71%) centres in Estonia and partly in a further 4 of 17 centres (23.5%). Tasks and responsibilities for the radiological practitioner responsible for diagnostic CT examinations are clearly assigned in 12 of 17 centres (71%) and partly assigned and documented in 3 of 17 centres in Estonia (17.6%), reflecting a high rate of positive answers.

The appropriateness of referred examinations is evaluated fully before examinations are performed in 13 of 17 (76.5%) and partially in a further 3 of 17 (17.6%) centres in Estonia. The inappropriate examination requests are fully rejected in 14 out of 17 (82.4%) centres and partly rejected in 3 of 17 (17.6%) centres.

Referral guidelines are available in 8 out of 17 (47%) centres in Estonia fully, and in 5 of 17 (29.4%) partially, positioning Estonia in the middle among the analysed countries. In those centres where guidelines are available, referrers are fully aware of their availability in 7 of 13 (54%) and partly aware in 3 out of 13 centres. Out of 13 centres with guidance available, these guidelines are in routine use by referrers in only 3 of 13 and partly in 5 of 13 centres. In only one of the 8 centres where guidelines are available, the latter are fully implemented in the clinical decision support system, and in two centres partly, while in the other centres they are not implemented in the CDS.

Finally, MRI is available in 9 of 17 centres in Estonia, partially available in 2, and not available in 6 of the 17 centres.

As a conclusion, evaluation of justification and appropriateness in Estonia is moderately to quite advanced, with clearly assigned tasks and responsibilities of referring physicians and radiological practitioners in most centres and a high rejection rate of inappropriate examinations. Even though referral guidelines are available in many centres, they are seldom used in clinical practice and in a large proportion of centres they are not implemented in the clinical decision support system.

5.4.1.4 Finland

Respondents: 1 medical physicist, 1 unknown profession

Institutions: 1 Public, 1 Private

Type of responding facility: 0 Large regional hospital, 0 Small local hospital, 1 University Hospital (very large facility with 16 centres and centralised administration), 1 Other

A summary of the answers to the key questions of the survey is provided below.

Regarding the number of annual diagnostic CT examinations, a large university centre in Finland with multiple sites performs around 200,000 examinations per year and is the only among the audited centres with over 100,000 annual examinations. The second facility in Finland is a small private clinic performing 1,350 CT examinations per year. Both facilities provided responses to the survey.

Written procedures describing the justification process are available the QA systems in both institutions in Finland. Evaluation of justification and appropriateness of referral are addressed and described in procedures in the large centre and partly in the small one. Previous images or clinical information/history are sought in both centres. Contact between referrer and radiological practitioner is established when more information is required in both of the two centres. Self-assessment, peer reviews or audits have shown evidence that these procedures are implemented in the daily work completely in the small centre and partly in the large centre.

Tasks and responsibilities for the referring physician are clearly assigned and documented in both Finnish centres. Tasks and responsibilities for the radiological practitioner responsible for diagnostic CT examinations are clearly assigned in both cases/centres. In both centres in Finland, the appropriateness of referred examinations is evaluated fully before examinations are performed, and inappropriate examination requests are fully rejected in both centres. Referral guidelines are available in both centres in Finland. In the small centre referrers are fully aware and in the large centre partly aware of the availability

of guidelines. Evidence of guideline use is not available (probably reflecting the fact that the utilisation is not recorded). Guidelines are not implemented in the clinical decision support system in the large centre and partially in the small centre. Finally, MRI is available in both centres in Finland.

In conclusion, evaluation of justification and appropriateness in Finland is very advanced and procedures are followed with clearly assigned tasks and responsibilities of referring physicians and radiological practitioners and a high rejection rate of inappropriate examinations. Even though referral guidelines are available they are not or only partly embedded/implemented in the clinical decision support system.

5.4.1.5 Greece

Respondents: 4 MDs, 1 CEO, 7 profession unknown

Institutions: 6 Public, 6 Private

Type of responding facility: 4 Large regional hospitals (three public, one private), 2 Small local public hospitals, 6 Other (four small to medium private imaging centres, one public cancer hospital, one private primary healthcare service), no University Hospital

A summary of the answers to the key questions of the survey is provided below.

From the 12 centres from Greece responding to the survey, only four large regional hospitals are in the range of 10,001–30,000 CT examinations performed annually (one private large regional hospital performing 10,000–12,000, two public large regional hospitals perform 12,000 each, and one public large regional hospital performs 18,000 CT examinations per year – the latter representing the highest number of CTs performed annually). Seven centres performed 1,001–10,000 examinations and one below 1,000 CT examinations per year.

In Greece written procedures describing the justification process are available in imaging facilities' QA systems in 4 of 12 (33%) centres that responded and are partly available in 2 of 12 (16.7%) centres. Surprisingly, written procedures do not exist in three large public regional hospitals with >10,000 CT examinations annually. Evaluation of justification and appropriateness of referral is addressed in detail in 4 out of 12 centres in Greece, and partly in 1 out of 12.

Previous images or clinical information/history are sought in 5 of 12 (42%) centres in Greece, while the other centres did not answer this question. Likewise, in 5 out of 12 (42%) cases, contact between referrer and radiological practitioner is established when more information is required, while 7 of 12 centres did not answer this question. Self-assessment, peer reviews or audits have provided evidence that these procedures are implemented in the daily work in 5 of 12 (42%) cases, and 7 out of 12 did not respond, which is in accordance with previous answers.

Tasks and responsibilities for the referring physician are clearly assigned and documented in 5 of 12 (42%) and partly assigned and documented in 2 of 12 (16.7%) centres in Greece. Tasks and responsibilities for the radiological practitioner responsible for diagnostic CT examinations are clearly assigned in 7 of 12 (58%) centres and partly assigned and documented in 2 of 12 (16.7%) centres in Greece, reflecting a better rate of positive answers than for the previous question.

Interestingly, the appropriateness of referred examinations is evaluated fully before these are performed in 10 out of 12 (83.3%) centres in Greece. Inappropriate examination requests are fully rejected in 8 of 12 (67%) centres and partly rejected in 2 of 12 (16.7%) centres.

Referral guidelines are available in 3 out of 12 (25%) centres in Greece (and partly in 2 of 12, 16.7%), but referrers are only aware of their availability in 2 of 5 centres (40%). In 2 of

5 centres they are in routine use by referrers. In three out of the five centres where guidelines are available, the latter are implemented in the clinical decision support system. Finally, MRI is available in 7 of 12 (58%) centres in Greece that responded to the survey.

As a conclusion, evaluation of justification and appropriateness is not yet fully implemented in Greece, with tasks and responsibilities of referring physicians and radiological practitioners clearly defined in 42-58% of cases. Availability of referral guidelines in Greece is low, but where available they are implemented in the clinical decision support system in 60% of the centres.

5.4.1.6 Hungary

Respondents: 3 (MDs, radiologists)

Institutions: 3 Public, 0 Private

Type of responding facility: 0 Large regional hospital, 0 Small local hospital, 3 public University Hospitals (with 17 facilities overall under their administration), 0 Other

A summary of the answers to the key questions of the survey is provided below.

Three out of four Hungarian centres in the project responded to the survey. According to the answers, one centre performs 30,001–50,000 CT examinations annually (45,800), while two centres perform 10,001–30,000 examinations (25,880 and 15,000–20,000) per year.

Responses from the largest university centre were quite incomplete, with several unanswered questions. In Hungary written procedures describing the justification process are available in one centre, partly in one centre and not available in the third centre. Evaluation of justification and appropriateness of referrals is addressed partly in one centre, not addressed in one centre, and one centre did not provide an answer. Previous images or clinical information/history as well as contact between referrer and radiological practitioner when more information is required are sought/established in 1 of the 3 centres in Hungary and not sought in 1 of the 3 centres. One centre did not provide an answer. Self-assessment, peer reviews or audits have shown evidence that these procedures are implemented in the daily work in 2 of 3 (67%) centres, and no response was given for one centre. Tasks and responsibilities for the referring physician are clearly assigned and documented in 2 of 3 (67%) centres in Hungary and are partly assigned and documented in one centre. Tasks and responsibilities for the radiological practitioner responsible for diagnostic CT examinations are clearly assigned in all three Hungarian centres.

The appropriateness of the referred examination is evaluated fully before it is performed in 1 of the 3 centres and partly in 2 of the centres in Hungary. Inappropriate examination requests are fully rejected in 1 of 3 centres and partly rejected in 2 centres.

Referral guidelines are partly available in 2 of 3 centres in Hungary and not available in 1 centre. In those two centres where guidelines are partly available, referrers are aware of their presence in one and partly aware in the second centre. Guidelines are routinely used only partly in one centre and not routinely used in the other centre. The guidelines are not implemented in the clinical decision support system in any of two centres where they are available. Finally, MRI is available in all three centres in Hungary.

As a conclusion, responses from Hungarian centres were quite insufficient (especially from the major county hospital BAZ Miskolc). While evaluation of justification and appropriateness is moderate, tasks and responsibilities of referring physicians and radiological practitioners are well defined in the majority of centres. Even though referral guidelines are partly available in some centres, they are seldom used in clinical practice and are not implemented in the clinical decision support system.

5.4.1.7 Slovenia

Respondents: 10 MDs (radiologists), 5 radiographers, 1 IT expert owner of private

facility, 1 LL.M, 3 profession unknown

Institutions: 16 Public, 4 Private

Type of responding facility: 5 Large regional hospitals, 5 Small local hospitals, 2 University Hospitals, 8 Other (1 primary public health care facility, 4 private diagnostic centres, 3 small public hospitals)

A summary of the answers to the key questions of the survey is provided below.

The majority of the 20 centres in Slovenia that responded to the survey, namely 14, perform 1,001–10,000 CT examinations annually, 4 perform 10,001–30,000, one centre performs 30,001–50,000 CT examinations, and one centre in this relatively small country performs 50,001–100,000 examinations annually.

In Slovenia written procedures describing the justification process are available in imaging facilities' QA systems in 8 of 20 (40%) centres that responded. They are partly available in 4 of 20 (20%) centres, including the largest university centre. Procedures are not available in 6 out of 20 centres, including the second largest university centre and largest regional hospital. Evaluation of justification and appropriateness of referral is addressed in detail in 7 out of 20 centres and partly in 5 of 20, while 8 of the 20 centres did not answer the relevant question. Procedures are performed in daily practice in 9 of 20 (45%) centres.

Previous images or clinical information/history are sought in only 9 of 20 (45%) centres in Slovenia and contact between referrer and radiological practitioner when more information is required is established in 55% of cases (11 of 20 centres). Tasks and responsibilities for the referring physician are clearly assigned and documented in 13 out of 20 (65%) and partly assigned and documented in 3 of 20 (15%) centres. Tasks and responsibilities for the radiological practitioner responsible for diagnostic CT examinations are clearly assigned in 17 of 20 (85%) centres in Slovenia, reflecting the third highest rate of positive answers.

The appropriateness of referred examinations is evaluated fully before it is performed in 11 of 20 (55%) and partially in 7 of 20 (35%) centres in Slovenia. Inappropriate examination requests are fully rejected in 11 of 20 (55%) centres and partly rejected in 8 of 20 (40%) centres.

Referral guidelines are available in 7 out of 20 (35%) centres in Slovenia and partially available in 3 of the 20 centres (15%). Referrers are aware completely (5 of 10) or partly (4 of 10) of the availability of referral guidelines. Guidelines are in routine use in 4 of 10 centres and in partial use in another 4 of the 10 centres. In 4 of the 10 centres where guidelines are available, they are implemented in the clinical decision support system, and in an additional 3 centres they are partially implemented. Finally, MRI is available in 15 out of 20 (75%) centres in Slovenia.

In conclusion, while evaluation of justification and appropriateness is only moderately developed in Slovenia so far, clearly assigned tasks and responsibilities of referring physicians and radiological practitioners are available in most centres. Even though referral guidelines are available in some centres, they are not frequently used in clinical practice and are seldom implemented in the clinical decision support system.

5.6. Collection of Referrals and the Audit Process

Table 20 Overview of referrals provided to the auditors

Country	Total number of referrals provided to the auditors	f referrals public centres provided to the		Percentages Public / Private referrals	
Belgium	1006	614	392	61% / 39%	
Denmark*	1001*	991	10	99% / 1%	
Estonia	1013	971	42	96% / 4%	
Finland	745	729	16	98% / 2%	
Greece	909	288	621	32% / 68%	
Hungary	1027	1027	0	100% / 0%	
Slovenia	1021	801	220	78% / 22%	

^{*}For Denmark, the auditors returned 1010 audited data sets to the project office, duplicates were removed accordingly prior to analysis

Some delays were encountered by NCAs in some countries struggling to collect and send referrals to auditors as per the originally planned schedule. Deadlines were extended accordingly to try to ensure that all auditors would be allowed three months from receipt of the referrals to complete their work.

After referrals had been collected by the NCAs and, in cases where less than 1,000 referrals had been collected, attempts were made to collect further referrals. The referrals were anonymised and then sent to the auditors. According to the methodology, the auditors would not be assigned referrals from their own region/centre. Prior to sending the referrals, all auditors were offered participation in an online training session on the ESR iGuide. The recording of this training session was also made available on the EU-JUST-CT website⁶, and auditors were encouraged to ask the project team should they encounter any difficulties.

For various reasons, some auditors were unable to complete the assigned work and replacement auditors had to be sought in Belgium (4), Denmark (1), and Finland (1). In the case of Belgium, it was ultimately necessary to complete the audit with only three auditors. Each auditor in Belgium therefore audited more than the originally planned 500 referrals. It was necessary to extend deadlines for submission of the audited referrals for some auditors, especially those that stepped in at the last minute as replacement auditors. This led to significant delays in the start of the analysis work. Nevertheless, by January 2023 all audits had been completed in all countries and analyses of the data was able to begin. The results of these analyses are presented in section 5.6 of this report.

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⁶ http://www.eurosafeimaging.org/eu-just-ct/wp-4

5.6. Audit Results

Slovenia was chosen as a test case for a full analysis by the project's radiologist in charge of implementing the coordinated pilot audits of justification of CT examinations in the selected countries, supported by a team of expert statisticians from the Gertner National Institute for Epidemiology and Health Policy Research in Israel. It was decided not to anonymise countries in order to allow the presentation of country-specific background information on the healthcare system, efforts to improve justification etc., including relevant references.

During the analysis, referrals were categorised according to the appropriateness score of the originally matched ESR iGuide exam. Referrals given a score of 7-9 were considered fully appropriate (ESR iGuide: Usually Appropriate). Referrals given a score of 4-6 were considered moderately/partially appropriate (ESR iGuide: May Be Appropriate). Referrals given a score of 1-3 were considered inappropriate (ESR iGuide: Usually Not Appropriate), and those given no score (due to lack of data) were considered not justified due to no or insufficient clinical data. Where auditors scored a referral differently, analysis was conducted as to whether their scores placed the referral in the same category (in which case the auditors were considered to be in agreement), adjacent categories (in which case the auditors were considered to be in partial disagreement), or opposite categories (i.e. one auditor scored the referral as justified and the other scored it as not justified). In the latter case, the auditors were considered to be in significant disagreement. In cases of significant or partial disagreement between the two auditors over a referral, the two radiologists in charge of the audits within the project acted as arbitrators, according to the methodology. They also acted as the second auditor(s) in those cases where only one auditor audited a given referral. In such cases, if there was disagreement between the first (national) auditor and the second (project) auditor, the second assessment was considered authoritative.

Additionally, it was revealed that some referrals collected by the NCAs and sent to auditors were duplicates or part of research studies or projects. These cases were removed from the analysis. Consequently, fewer referrals were included in the final analysis than collected and audited by the auditors.

Two countries had high numbers of referrals with no or insufficient clinical data and these referrals were therefore not scored. Finland, Belgium and Denmark had low numbers of such referrals.

Table 21 Overview of collected CT referrals vs scored referrals

Country	Belgiu	ım	Denma	ırk	Eston	ia	Finla	nd	Gree	ce	Hunga	ry	Slove	nia
	N	% of total	N	% of total	N	% of total	N	% of total	N	% of total	N	% of total	N	% of total
Number of audited referrals (total)	1,006	100%	1,012	100%	1,013	100%	744	100%	909	100%	1,026	100%	1,024	100%
Of which removed from analysis (duplicates, invalid data)	22	2.19%	71	7.02%	10	0.99%	22	2.96%	49	5.39%	19	1.85%	9	0.88%
Of which unscored referrals (no/ insufficient clinical data)	10	1,02%	19	2,02%	57	5,68%	2	0,28%	193	22,44%	86	8,54%	266	26,21%
Of which scored	974	98,98%	922	97,98%	946	94,32%	720	99,72%	667	77,56%	921	91,46%	749	73,79%

Table 22 Scored vs unscored due to insufficient or no clinical data in % of analysed referrals

Country	Belg	ium	Denn	nark	Eston	ia	Finle	and	Gree	ce	Hung	gary	Slove	nia
	N	% of total	N	% of total	N	% of total	N	% of total	N	% of total	N	% of total	N	% of total
No. of analysed audited referrals	984	100%	941	100%	1003	100%	722	100%	860	100%	1007	100%	1015	100%
Of which unscored (no/ insufficient clinical data)	10	1.02%	19	2.02%	57	6.06%	2	0.28%	193	22.44%	86	8.54%	266	26.21%
Of which scored	974	98.98%	922	97.98%	946	94.32%	720	99.72%	667	77.56%	921	91.46%	749	73.79%

An overview of the appropriateness in percent according to the ESR iGuide and arbitration is provided below.

Table 23 Results of Appropriateness according to ESR iGuide and arbitration in % of scored audited referrals

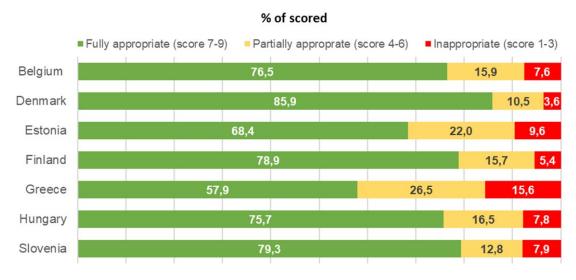


Table 24 Appropriateness according to ESR iGuide and arbitration in % considering unscored referrals due to no/insufficient clinical data

% of analysed



The full, in-depth analysis of all seven countries was presented in the project workshop in September 2023 and is provided in the following sections of the present report.

5.6.1 Belgium

5.6.1.1 General overview

A sample overview is provided below:

Table 25 Sample overview - BE

	N	% of total	% of scored
Number of audited referrals (Total)	1,006*	100	
Of which removed from analysis (duplicates, invalid data)	22	2.2	
Of which unscored referrals (no/insufficient clinical data)	10	1.0	
Of which scored	974	96.8	100
Fully appropriate (score 7-9)	745	74.1	76.5
Partially appropriate (score 4-6)	155	15.4	15.9
Inappropriate (score: 1-3, 0**)	74	7.4	7.6

^{* 1,006} were audited out of the 1,586 referrals on one day which had been provided

Percentage of scored/unscored referrals - BE

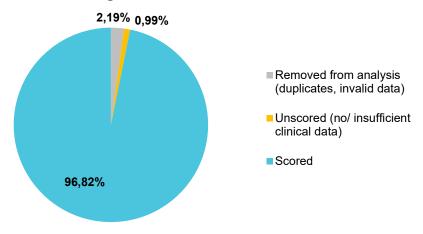


Figure 1 Percentage of scored/unscored referrals – BE

 $^{^{**}}$ 0 – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

[⇒] Data quality in Belgium was found to be generally good with only 1% of referrals unscored due to insufficient clinical data.

- ⇒ The source file included 1,006 records. Of these, 32 records (3.2%) were removed from the study or unscored due to insufficient clinical data, leaving 974 records that were included in the statistical analysis.
- ⇒ 76.5% of the <u>scored population</u> (745 out of 974) were rated as "Fully appropriate" (score between 7-9).
- ⇒ 23.5% of the <u>scored population</u> (229 out of 974) resulted in a score less than 7 and were classified as "Non-appropriate" according to a binary variable (7-9 appropriate, <7 inappropriate).

Table 26 Details of referrals removed from analysis – BE

Reason for exclusion	n (N = 32)	% of total
Not CT	12	37.5
No data	10	31.3
Research	5	15.6
Double entry	3	9.4
Biopsy	1	3.1
No age	1	3.1

⇒ For most of the removed referrals the removal reason was the fact the requested test was not a CT or due to lack of data (37.5% and 31.3%, respectively).

The table below lists the more Appropriate examinations in case of inappropriate (score less than 7) requested CT imaging, according to both auditors, for BE.

Table 27 More Appropriate examinations if CT was inappropriate – BE

More appropriate exam	n (N = 229)	%
No other exam was recommended	28	12.2
Another exam was recommended	201	87.8
MRI	79	39.3
X-ray	53	26.4
US	23	11.4
Other CT	16	8.0

MRI/X-ray	7	3.5
X-ray/other CT	6	3.0
US/X-ray	3	1.5
MRI/other CT	2	1.0
NUC/other CT	3	1.5
PET-CT/MRI	2	1.0
US/MRI/other CT	2	1.0
US/other CT	2	1.0
MRI/other CT/INV/X-ray	1	0.5
Interventional radiology	1	0.5
MRI/US	1	0.5

- ⇒ In 87.8% of the referrals scored inappropriate (less than 7) another exam was recommended, while in 12.2% of referrals no other exam was recommended.
- ⇒ It should be noted that out of 201 more appropriate exams recommended, 70% (n=141) were in complete agreement by both auditors regarding the type of exam (data not shown).
- ⇒ The most frequent appropriate examination was MRI (39% of referrals scored inappropriate, less than 7) and in another 7.5%, the more appropriate recommendation was MRI combined with another exam.
- ⇒ In 26.4% of the referrals scored inappropriate (less than 7), the more appropriate recommendation was X-ray and in 8.5% of referrals, X-ray combined with another exam.
- ⇒ In 11.4% of the referrals scored inappropriate (less than 7), the more appropriate recommendation was US and only in 4%, a combination of US and another exam.
- ⇒ In 8% of the referrals scored inappropriate (less than 7), the more appropriate recommendation was another CT (different from the requested).
- ⇒ Of note is that in 14.5% of the referrals scored inappropriate (less than 7), the more appropriate recommendation was mainly a combination of at least two modalities.

5.6.1.2 Analysis of CT orders regarding ESR assessment of Appropriateness (summary tables)

The table below shows the association between explanatory variables and appropriateness according to ESR (N=974). Pearson Chi-Square Test/Fisher's Exact Test (a binary variable was used, Appropriate meaning a score 7-9 and Non-appropriate a score less than 7).³

Table 28 Association between explanatory variables and appropriateness – BE

Characteristic	Appropriate (n=745)	Appropriate (n=745)		Non-appropriate (n=229)		
	n/Total Row	% of Total Row	% of Total Row	% of Total Row		
Institution						
Private	203/290	70.0	87/290	30.0	0.002*	
Public	542/684	79.2	142/684	20.8	0.002	
Patient status						
Inpatient/emergency	242/298	81.2	56/298	18.8]	
Outpatient	452/592	76.4	140/592	23.6	0.058	
Undetermined ¹	51/84	60.7	33/84	39.3		
Gender						
Female	322/452	71.2	130/452	28.8]	
Male	421/518	81.3	97/518	18.7	<0.001*	
Undetermined ¹	2/4	50.0	2/4	50.0		
Patient age group						
Adult	729/947	77.0	218/947	23.0	0.032*	
Child	16/27	59.3	11/27	40.7	0.002	
Referrer specialty						
Family medicine	65/123	52.8	58/123	47.2]	
Brain related specialties	35/47	74.5	12/47	25.5	<0.001*	
Emergency Medicine	100/130	76.9	30/130	23.1		
Internal Medicine	275/339	81.1	64/339	18.9		
Oncology ²	62/70	88.6	8/70	11.4		
Surgical specialties	169/219	77.2	50/219	22.8		

Undetermined ¹	39/46	84.8	7/46	15.2		
Referrer specialty (grouped)						
Family medicine	65/123	52.8	58/123	47.2		
Specialist doctor	641/805	79.6	164/805	20.4	<0.001	
Undetermined ¹	39/46	84.8	7/46	15.2		

^{*} Statistically significant at the level of $p \le 0.05$.

Conclusions: Significant associations were found between degree of appropriateness according to the ESR iGuide and institution type (p=0.002), gender of patient (p<0.001), age group of patient (p=0.03), and the expertise of the referring physician (p<0.001). Higher appropriateness rates were found in the public sector (79%) and for males (81%) compared to the private sector (70%) and females (71%). The appropriateness rate was much lower among children compared to adults (59% vs 77%, respectively), although only 27 children were included, and for general practitioner compared to specialist doctor (53% vs 80%, respectively).

A borderline significant association was found between the degree of appropriateness according to the ESR iGuide and status of the patient, with higher appropriateness rates for hospitalisation compared to ambulatory (outpatient) care (81% vs 76%, respectively; p=0.058).

The table below shows the number of appropriate and inappropriate requests and appropriateness rates (AR) for CT according to the type of CT examination (N=974):

Table 29 No. of Appropriate and Non-appropriate requests and AR according to type of CT examination – BE

Anatomical area	Appropriate (N = 745)	Non-appropriate (N=229)	AR (%)
Abdomen	54	21	72.0
Abdomen-Pelvis	91	16	85.1
Chest	158	36	81.4
Chest-Abdomen	39	13	75.0
Chest-Abdomen-Pelvis	91	6	93.8
Coronarography	35	3	92.1
Extremities	44	36	55.0
Head and neck	174	40	81.3

¹ Undetermined or missing values may be due to missing data or inconsistencies between auditors in respect to that variable that could not be resolved by arbitration.

² Oncology includes one referrer specialty of Nuclear Medicine.

³ All statistical tests in this report were performed without the "Undetermined" category.

Pelvis	12	3	80.0
Spine	35	51	41.0
Whole-body / Polytrauma	10	3	67.0
Undetermined	2	1	75.0

Conclusions: No significant association was found for anatomical area and ESR iGuide appropriateness due to the low expected counts of some of the cells (Fisher's Exact Chisquare did not converge). A large variation was found in appropriateness rates, ranging from 41% (spine) to 94% (chest-abdomen-pelvis). The anatomical areas with the highest appropriateness rates were chest-abdomen-pelvis (94%), coronarography (92%), and, far behind, abdomen-pelvis (85%). The appropriateness rate was lower than 80% for half of all exam types.

5.6.1.3 Institution: Public vs private

The figure below shows the proportion of Appropriate, Partially appropriate and Non-appropriate exams in the scored population as function of being a private/public institution (note: Public vs private refers to the hospital owner – see also 5.6.1.10 Demographics and health system – Belgium.)

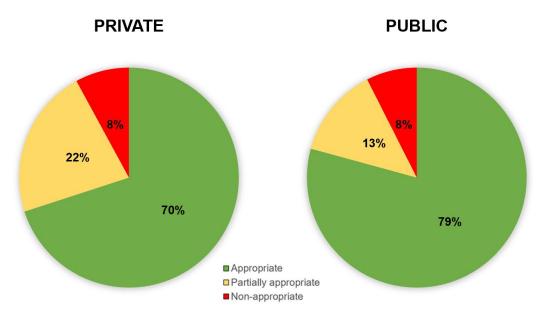


Figure 2 AR as function of public/private – BE

The table below shows the association between private/public institution and Appropriateness according to the ESR iGuide (N=974) for BE.

Table 30 Association between private/public institution and Appropriateness – BE

					There were 684
					CTs performed in
Frequency	Ар	Appropriateness level			public institutions,
Expected Row % Col %	Appr (7-9)	Partially appr (4-6)	Non-appr (0*-3)	Total	51 of them were Non-appropriate (7.5%).
	203	64	23	290	la tatal there were
Deixata	221.8	46.1	22.0	/	In total, there were 74 Non-appropriate
Private	4 70.0%	22.1%	7.9%		CTs, 51 of them
	27.2%	41.3%	31.1%		from public
	542	91	51	684	institutions (68.9%).
Public	523.2 79.2% 72.8%	108.9 13.3% 58.7%	52.0 7.5% 68.9%		52 is the estimated expected value in public institutions,
Total	745	155	74	974	under the
Frequency Missing = 0					hypothesis of independence.
AR					independence.

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 31 Pearson Chi-Square Test - BE

Pearson Chi-Square Test				
	Value	df	Asymptotic Significance (2-sided)	
Pearson Chi-Square	12.165*	2	0.002	
Likelihood Ratio	11.628	2	0.003	
N of Valid Cases	974			

^{*0} cells (0.0%) have an expected count of less than 5. The minimum expected count is 22.03.

Conclusions: The appropriateness rate was higher when the CT examinations concerned public institutions as compared to private institutions (79% vs 70%, respectively; p=0.002).

5.6.1.4 Patient status: Inpatient vs outpatient

The figure below shows the proportion of Appropriate, Partially appropriate and Non-appropriate exams in the scored population as function of inpatient/outpatient status for BE.

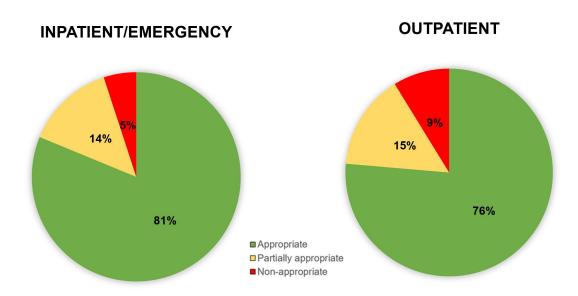


Figure 3 AR as function of inpatient/outpatient status – BE

The table below shows the association between Patient Status and Appropriateness according to the ESR iGuide (N=974).

Table 32 Association between patient status and Appropriateness – BE

Frequency Expected	Appropriateness			Total
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	
Inpatient/emergency	242 227.9 81.2% 32.5%	41 47.4 13.8% 26.5%	15 22.6 5.0% 20.3%	298
Outpatient	452 452.8 76.4% 60.7%	88 94.2 14.9% 56.8%	52 45.0 8.8% 70.3%	592
Total	745	155	74	890

 $^{^{*}}$ 0 – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 33 Pearson Chi-Square Test – BE

Pearson Chi-Square Test				
	Value	df	Asymptotic Significance (2-sided)	
Pearson Chi-Square	4.470*	2	0.107	
Likelihood Ratio	4.733	2	0.096	
N of Valid Cases	890			

^{* 0} cells (0.0%) have an expected count of less than 5. The minimum expected count is 6.38.

Conclusions: The appropriateness rate was higher when the CT examinations were performed during hospitalisation as compared to ambulatory care, although the difference is not statistically significant (81% vs 76%; p=0.107).

5.6.1.5 Patient gender

The figure below shows the proportion of Appropriate, Partially appropriate and Non-appropriate exams in the scored population as function of gender for BE.

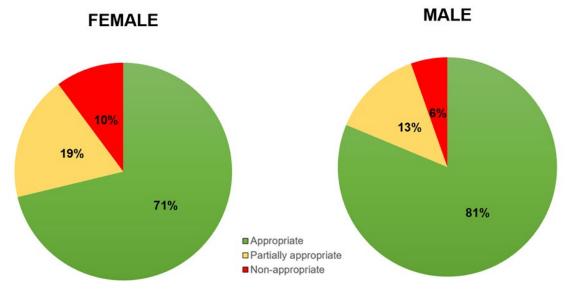


Figure 4 AR as function of gender – BE

The association between gender and appropriateness according to the ESR iGuide (N=974) for BE is provided below.

Table 34 Association between gender and appropriateness – BE

Frequency Expected	Appropriateness			Total
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	
Female	322 345.7 71.2% 43.2%	84 71.9 18.6% 54.2%	46 34.3 10.2% 62.2%	452
Male	421 396.2 81.3% 56.5%	69 82.4 13.3% 44.5%	28 39.4 5.4% 37.8%	518
Total	745	155	74	970
Frequency Missing = 4				

^{* 0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 35 Pearson Chi-Square Test: gender - BE

Pearson Chi-Square Test				
	Value	df	Asymptotic Significance (2-sided)	
Pearson Chi-Square	14.617*	2	<0.001	
Likelihood Ratio	14.632	2	<0.001	
N of Valid Cases	970			

^{*0} cells (0.0%) have an expected count of less than 5. The minimum expected count is 34.48.

Conclusions: The appropriateness rate was significantly higher when the CT examinations concerned the male population as compared to the female population (81% vs 77%; p<0.001).

5.6.1.6 Patient age group: Adult vs paediatric

The proportion of Appropriate, Partially appropriate and Non-appropriate exams in the scored population as function of age group for BE is shown below.

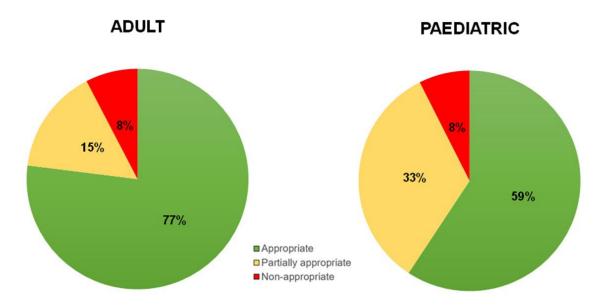


Figure 5 AR as function of age group – BE

The table below shows the association between patient age group and Appropriateness according to the ESR iGuide (N=974) for BE.

Table 36 Association between patient age group and Appropriateness – BE

Frequency Expected	Appropriateness		Total	
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	
Adult	729 724.3 77.0% 97.9%	72 71.9 7.6% 97.3%	146 150.7 15.4% 94.2%	947
Child	16 20.7 59.3% 2.1%	2 2.1 7.4% 2.7%	9 4.3 33.3% 5.8%	27
Total	745	74	155	974
Frequency Missing = 0				

 $^{^{*}0}$ – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 37 Pearson Chi-Square test: age group – BE

Pearson Chi-Square Test						
	Value	df	Asymptotic significance (2-sided)	Exact significance (2-sided)		
Pearson Chi-Square	6.374*	2	0.041	0.042		
Likelihood Ratio	5.218	2	0.074	0.092		
Fisher-Freeman-Halton Exact Test	5.578			0.045		
N of Valid Cases	974					

^{*2} cells (33.3%) have an expected count of less than 5. The minimum expected count is 2.05.

Conclusions: The appropriateness rate was significantly higher when the CT examination was for adults as compared to children (77% vs 59%, respectively; p=0.04). However, there were only 27 children, a small percentage of the sample, which might not represent the paediatric population in the country.

5.6.1.7 Exam requested (grouped)

The following radar chart shows the appropriateness rate (AR) as function of the exam requested in the scored population in BE.

Appropriateness rate

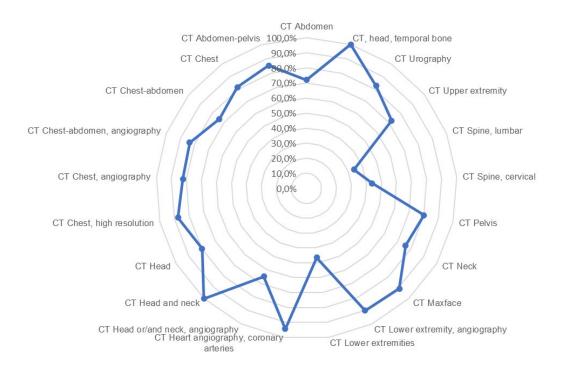


Figure 6 AR as function of exam requested – BE

Note: Exams with less than 5 observations were omitted from the figure.

The table below shows the number of Appropriate, Partially appropriate and Non-appropriate requests and AR (%) for CT according to type of CT examination (N=974) for BE.

Table 38 No. of Appropriate, Partially appropriate and Non-appropriate requests and AR according to type of CT examination – BE

Anatomical area	Appropriateness			
Exam requested (grouped)	Appr (7-9)	Partially appr (4-6)	Non-appr (0*-3)	(%)
Abdomen	54	5	16	72
CT Abdomen	54	5	16	72
Abdomen-pelvis	91	5	11	85
CT Abdomen-pelvis	75	4	9	85.2
CT Colon	2	0	0	100
CT Urography	14	1	2	82.4
Chest	158	11	25	81.4
CT Chest	113	9	17	81.3
CT Chest, angiography	37	1	7	82.2
CT Chest, high resolution	7	1	0	87.5
CT Neck-chest	1	0	1	50.0
Chest-abdomen	39	9	4	75.0
CT Chest-abdomen	34	9	3	73.9
CT Chest-abdomen, angiography	5	0	1	83.3
Chest-abdomen-pelvis	91	2	4	93.8
CT Chest-abdomen-pelvis	90	2	4	93.8
CT Chest-abdomen-pelvis, angiography	1	0	0	100.0
Coronarography	35	0	3	92.1
CT Heart	1	0	1	50.0
CT Heart angiography, coronary arteries	34	0	2	94.4

Extremities	44	10	26	55
CT Lower extremities	13	4	11	46.4
CT Lower extremity, angiography	18	1	1	90.0
CT Lower extremity, arthrography	0	1	0	0.0
CT Upper extremity	13	3	2	72.2
CT Upper extremity, arthrography	0	1	12	0.0
Head and neck	174	10	30	81.3
CT Head	97	10	14	80.2
CT Head and neck	6	0	0	100.0
CT Head or/and neck, angiography	13	0	7	65.0
CT Maxillofacial	30	0	3	90.9
CT Neck	19	0	6	76.0
CT, head, temporal bone	9	0	0	100.0
Pelvis	12	1	2	80.0
CT Pelvis	12	1	2	80.0
Spine	35	17	34	40.7
CT quantitative, spine-lower extremity, lumbar-hip	3	1	4	37.5
CT Spine	1	0	1	50.0
CT Spine, cervical	7	5	4	43.8
CT Spine, cervical-thoracic	1	0	1	50.0
CT Spine, lumbar	18	11	24	34.0
CT Spine, thoracic	4	0	0	100.0
CT Spine, thoracic-lumbar	1	0	0	100.0
Undetermined	2	1	0	66.7
Undetermined	2	1	0	66.7

Whole body/polytrauma	10	3	0	76.9
CT Neck-chest-abdomen	3	0	0	100.0
CT Neck-chest-abdomen-pelvis	0	1	0	0.0
CT Whole body/polytrauma	1	2	0	33.3
CT, head; CT spine, cervical; CT, chest-abdomen-pelvis	4	0	0	100.0
CT, head-C-spine-chest-abdomen	2	0	0	100.0
Total	745	74	155	76.5

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Conclusions: Because there were many cells with very low expected frequency (n < 5) and exact Chi-square did not converge, no definitive conclusions could be made about type of CT examination concerning appropriateness.

After omitting cells with a frequency of less than 5 cases, the appropriateness rate was 100% in CT examinations for chest and neck or temporal bones of the head. The appropriateness rate was higher for CT examinations of heart angiography, coronary arteries and chest-abdomen-pelvis (94%), maxillofacial region (91%), angiography of lower extremity (90%), CT chest in high resolution (88%), CT abdomen-pelvis (85%), angiography of chest-abdomen (83%), CT chest or head or pelvis (about 80.5%); rather than CT neck (76%), chest-abdomen (74%), lower extremities (46%) and CT spine cervical/lumbar (36.2%).

5.6.1.8 Referrer specialty (detailed)

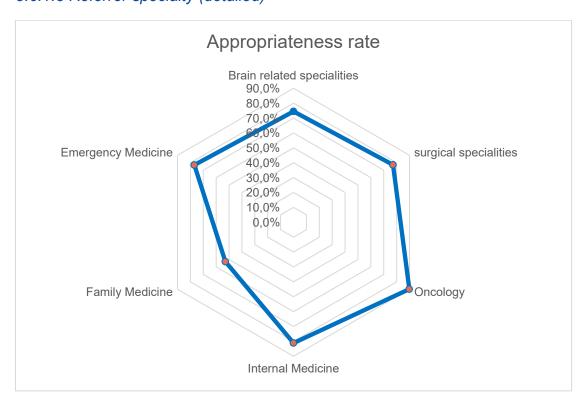


Figure 7 Radar chart: AR as function of referrer specialty - BE

The table below shows the association between Referrer Specialty and CT Appropriateness according to the ESR iGuide (N=974) in BE.

Table 39 Association between referrer specialty and Appropriateness – BE

Frequency Expected	Appropriatene	ess	Total	
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	
Brain related specialties	35 35.9 74.5% 4.7%	1 3.6 2.1% 1.4%	11 7.5 23.4% 7.1%	47
Emergency Medicine	100 99.4 76.9% 13.4%	5 9.9 3.8% 6.8%	25 20.7 19.2% 16.1%	130
Family Medicine	65 94.1 52.8% 8.7%	27 9.3 22.0% 36.5%	31 19.6 25.2% 20.0%	123
Internal Medicine	275 259.3 81.1% 36.9%	23 25.8 6.8% 31.1%	41 53.9 12.1% 26.5%	339
Oncology	62 53.5 88.6% 8.3%	5 5.3 7.1% 6.8%	3 11.1 4.3% 1.9%	70
Surgical Specialties	169 167.5 77.2% 22.7%	10 16.6 4.6% 13.5%	40 34.9 18.3% 25.8%	219
Total	706	71	151	928
Frequency Missing = 46				

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 40 Pearson Chi-Square Test: referrer specialty - BE

Pearson Chi-Square Test						
	Value	df	Asymptotic significance (2-sided)			
Pearson Chi-Square	70.198*	10	<0.001			
Likelihood Ratio	63.651	10	<0.001			
N of Valid Cases	928					

^{*1} cell (5.6%) has an expected count less than 5. The minimum expected count is 3.60.

Conclusions: In general, appropriateness rates were higher for requests referred by medical specialists (oncology 89%, internal medicine 81%, surgical specialties and emergency medicine 77%, brain related specialties 74.5%,) rather than by general practitioners (AR=53%), p<0.001. Of note, undetermined specialists show a relatively high appropriateness rate (85%), data not shown.

5.6.1.9 Referrer specialty (GP vs Medical specialist)

The proportion of Appropriate, Partially appropriate and Non-appropriate requests in the scored population as function of referrer specialty (Family doctor/General practitioner vs. Specialist doctor) in BE is shown below.

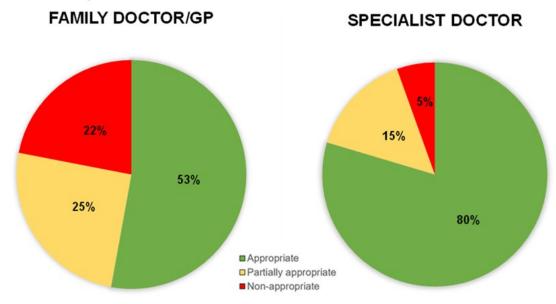


Figure 8 AR as function of referrer specialty – BE

The table below shows the association between referrer specialty (Family doctor/General practitioner vs. Specialist doctor) and Appropriateness according to the ESR iGuide (N=974) for BE.

Table 41 Association between referrer specialty (GP vs specialist) and Appropriateness – BE

Frequency Expected	Appropriateness			Total
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	
General practitioner	65 94.1 52.8% 8.7%	31 19.6 25.2% 20.0%	27 9.3 22.0% 36.5%	123
Medical specialist	641 615.7 79.6% 86.0%	120 128.1 14.9% 77.4%	44 61.2 5.5% 59.5%	805
Total	706	151	71	928
Frequency Missing = 46				

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 42 Pearson Chi-Square Test: referrer specialty - BE

Pearson Chi-Square Test						
	Value	df	Asymptotic significance (2-sided)			
Pearson Chi-Square	54.911*	2	<0.001			
Likelihood Ratio	44.521	2	<0.001			
N of Valid Cases	928					
*0 cells (0.0%) have an expected count less than 5. The minimum expected count is 9.41.						

Conclusions: The appropriateness rate was higher for requests referred by medical specialists than for requests referred by general practitioners (80% vs. 53%, p < 0.001).

5.6.1.10 Demographics and health system – Belgium

Population

Approx. 11.5 million inhabitants

Flanders (Northern part): approx. 6.65 million Wallonia (Southern part): approx. 3.65 million

Brussels: approx. 1.2 million

Healthcare system

Belgium has a compulsory health insurance system with 99% of the population covered for health services. Belgium's compulsory health insurance is managed by the National Institute of Health and Disability Insurance (INAMI-RIZIV). This public body determines, e.g., reimbursement criteria and establishes and controls the budget.

Belgian hospitals are either owned by public or private organisations. In both cases, access is unlimited, costs are similar and the same reimbursement criteria apply.

Belgium has a per-act payment system. In most hospitals medical doctors work as independent doctors or in an association of medical doctors. In that case the medical doctor receives the per-act payment. Typically, a certain part of the amount, which is based on negotiations, is transferred to the hospital to cover certain working cost. In some hospitals, like university hospitals, medical doctors receive a salary. Still, the revenues of the acts performed by the doctors, in this case for the hospital, are based on a per-act system.

There are conventions on the rates a medical doctor can charge for a certain act. However, medical doctors can charge supplements. Medical doctors are supposed to announce whether they work (parttime) by following the convention.

As per 1 January 2023, Belgium had 26 CT devices and 12 MRI devices per million inhabitants (see also 2022 figures below). CT and MRI devices need to be correctly registered to be eligible for reimbursement. This registration includes for instance licensing with the Belgian Federal Agency for Nuclear Control (FANC).

Equipment financing depends partly on the specific organisation of the hospitals, however, independent of the ownership of the hospitals, national and regional budgets can be applied.

Equipment base

CT scanners per million population (2022): 25.65

MRI units per million population (2022): 11.71

PET scanners per million population (2022): 2.847

Number of radiologists per million population

1388

Rationale for selection / representativeness of participating centres

A representative sample of centres across the entire country was chosen, including

- small and large hospitals
- university and regular hospitals
- hospitals in Flanders, Wallonia and Brussels with spreading based on population density
- Dutch and French speaking hospitals

Efforts regarding implementation of justification

⁷ https://stats.oecd.org/Index.aspx?DatasetCode=HEALTH_STAT (accessed on 10 July 2023)

⁸ EC-funded EU-REST study (Q1 2023)

In 2020 a national audit on the use of CT and MRI equipment took place, with the following aspects being reviewed: the patient care pathway, prescription, substitution, management, the national register of heavy medical equipment, regulations in relation to the FANC, the use of radiopharmaceuticals and medical imaging devices. This audit focused specifically on CT and MRI of the skull and spinal column, which are the most frequently charged examinations.

The audit did not focus on justification as such but provided a good overview of the situation in Belgium, e.g., some currently unexplained regional differences are observed, upon which further studies or actions can be initiated.

A large effort in raising awareness of radiologists, general practitioners and the public has been taken by the Belgian Medical Imaging Platform (BELMIP). Specific magazines on medical imaging for certain indications, such as lower back pain but also peripheral trauma in children, have been published and spread among all Belgian medical doctors. Public awareness campaigns with slogans such as "X-rays are no holidays pictures" are carried out.

In 2015 a study was performed, initiated by the Belgian college of medical imaging, in which for a limited set of hospitals justification of examinations was evaluated for X-ray, CT and MRI lumbar spine and X-ray, CT and US abdomen.

5.6.2 Denmark

5.6.2.1 General Overview

Table 43 Sample overview – DK

	N	% of total	% of scored
Number of audited referrals (Total)	1012	100%	
Of which removed from analysis (duplicates, invalid data)	71	7.02%	
Of which unscored referrals (no/insufficient clinical data)	19	1.88%	
Of which scored	922	91.11%	
Fully appropriate (score 7-9)	792	78.26%	85.9%
Partially appropriate (score 4-6)	97	9.58%	10.52%
Inappropriate (score: 1-3, 0*)	33	3.26%	3.58%

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Percentage of scored/unscored referrals - DK

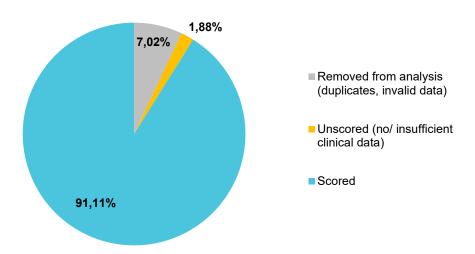


Figure 9 Percentage of scored/unscored referrals – DK

- Data quality in Denmark is relatively high with about 91% of referrals scored. However, arbitration was required in about 30% of the referrals due to disagreement between auditors (data not shown).
- From the 8.89% unscored population, 7% (n=71) of the records were removed from the analysis and 1.88% of the population was unscored due to insufficient clinical data (these are considered inappropriate)
- ⇒ 85.9% of the <u>scored population</u> (792 out of 922) were rated "Fully appropriate" (score between 7-9)
- ⇒ 14.1% of the <u>scored population</u> (130 out of 922) resulted in a score of less than 7 and were classified as "Inappropriate" according to a binary variable (7-9 appropriate, <7 inappropriate)

Table 44 Details of referrals removed from analysis – DK

Delete reason	N	%
Duplicate entry	38	53.52
Research project	10	14.08
INV, biopsy, chest	10	14.08
Double & Image guided nerve/root block	4	5.63
Empty line	3	4.23
PET-CT	2	2.82
NUC, bone scan, whole body, Tc-99m	1	1.41

US	1	1.41
No ID	1	1.41
No exam requested	1	1.41
Total	71	100%

[⇒] About half of the removed referrals (53.52%) were due to duplicate entries. Ten out of 71 were research projects and 18 out of 71 (25%) involved modalities and procedures beyond the scope of the present project, such as biopsy, US or PET-CT.

The table below shows the more appropriate examinations in those cases where CT imaging was marked inappropriate (score less than 7), according to both auditors:

Table 45 More Appropriate examinations if CT was inappropriate – DK

More appropriate exam	n (N=130)	%
No other exam was recommended	11	8.46%
Another exam was recommended	119	91.53%
MRI	23	17.69
Other CT	22	16.92
X-ray	16	12.31
US	12	9.23
US/other CT	10	7.69
Other CT /X-ray	9	6.92
MRI /other CT	7	5.38
PET-CT/NUC	4	3.08
MRI/US	3	2.31
MRI/X-ray	3	2.31
PET-CT/MRI	2	1.54
PET-CT/other CT	2	1.54
MRI/X-ray/CT	1	0.77

NUC/MRI	1	0.77
NUC/other CT	1	0.77
PET-CT	1	0.77
PET-CT/US	1	0.77
US/X-ray	1	0.77

- ⇒ In 8.5% of referrals scored inappropriate (less than 7), no other exam was recommended by either of the auditors. Accordingly, in 91.5% of the referrals, at least one more appropriate recommendation was suggested by one or both auditors. In 34.6% of the referrals more than one test modality was suggested as more appropriate.
- ⇒ The most frequent "more appropriate examination" was another CT. In 40% of referrals scored inappropriate (less than 7), the "more appropriate" recommendation was another CT (different from the one referred to) or a combination of CT and another exam modality.
- ⇒ In 30.7% of referrals scored inappropriate (less than 7), the more appropriate recommendation was MRI or a combination of MRI and another exam modality.
- ⇒ In 23% of referrals scored inappropriate (less than 7), the more appropriate recommendation was X-ray or a combination of X-ray and another exam modality.
- ⇒ In 20.7% of referrals scored inappropriate (less than 7), the more appropriate recommendation was US or a combination of US and another exam modality.
- ⇒ In 7.7% of referrals scored inappropriate (less than 7), the more appropriate recommendation was PET-CT or a combination of PET-CT and another exam modality.

5.6.2.2 Analysis of CT orders regarding ESR assessment of appropriateness (summary tables)

The table below shows the association between explanatory variables and Appropriateness according to the ESR iGuide (N=922). Pearson Chi-Square Test/Fisher's Exact Test (a binary variable was used, Appropriate denotes score 7-9 and Non-appropriate score less than 7)¹.

Table 46 Association between explanatory variables and Appropriateness – DK

Variable	Appropriate (AR) (N=792)	Non- appropriate (N=130)	P-value
Institution: Private Public	7/9 (77.8%) 785/913 (86%)	2/9 (22.2%) 128/913 (14.02%)	0.622
Patient Status: Inpatient (/emergency) Outpatient Missing ² =11	417/477 (87.4%) 365/434 (84.1%) 10/11 (91%)	60/477(12.6%) 69/434 (15.9%) 1/11 (9%)	0.1511
Gender:	404/458 (88.2%)	54/458 (11.8%)	0.0602

Female Male Missing ² =4	386/460 (83.9%) 2/4 (50%)	74/460 (16.1%) 2/4 (50%)	
Patient Age group: Adult Child	788/917 (85.9%) 4/5 (80%)	129/917 (14.1%) 1/5 (20%)	1.0000
Referrer Specialty: Brain related specialties Emergency Medicine Family Medicine Internal Medicine Oncology Surgical specialties Missing ² =15	47/55 (85.4%) 100/109 (91.7%) 77/102 (75.5%) 187/219 (85.4%) 163/174 (93.7%) 207/248 (83.5%) 11/15 (73.3%)	8/55 (14. 6%) 9/109 (8.3%) 25/102(24.5%) 32/219 (14.6%) 11/174 (6.3%) 41/248 (16.5%) 4/15 (26.6%)	0.0004*
Referrer Specialty (grouped): Family doctor/General practitioner Specialist doctor Missing ¹ =15	77/102 (75.5%) 704/805 (87.5%) 11/15 (73.3%)	25/102 (75.5%) 101/805 (12.6%) 4/15 (26.6%)	0.001*

^{*} Statistically significant at the level of p ≤ 0.05

The table below shows the numbers of appropriate and inappropriate requests and AR for CT according to type of CT examination (N=922, Missing=5) for DK.

Table 47 No. of Appropriate and Non-appropriate requests and AR according to type of CT examination – DK

Anatomical area	Appropriate (N=792)	Non- appropriate (N=130)	AR (%)
Abdomen	85	17	83.33%
Abdomen-Pelvis	111	27	80.43%
Chest	116	24	82.86%
Chest-Abdomen	140	10	93.33%
Chest-Abdomen-Pelvis	55	19	74.32%
Coronarography	47	1	97.92%
Extremities	23	3	88.46%
Head and neck	186	16	92.08%
Pelvis	3	6	33.33%

¹ All statistical tests in this report were performed without the "Missing" category.

² Missing values may be due to missing data or due to inconsistencies between auditors in respect to that variable that could not be resolved by arbitration.

Spine	18	6	75%
Whole-body / Polytrauma	4	0	100%

Conclusions: A significant association was found between the degree of appropriateness according to the ESR iGuide and the expertise of the referring physician (p=0.0004). Highest appropriateness rates were observed for oncology doctors (93.7%) and emergency medicine doctors (91.7%). The appropriateness rate was lower for Family/General physicians as compared to Specialist doctors (75.5% vs 87.5%, respectively, p=0.001).

No association was found for anatomical area and ESR appropriateness due to the low frequencies of some of the cells (Exact Chi-square did not converge). The anatomical areas with the highest appropriateness rates were Coronarography (98%), Chest-Abdomen (93%) and Head and neck (92%).

5.6.2.3 Institution: Public vs private

The figure below shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population as function of being a private/public institution for DK.

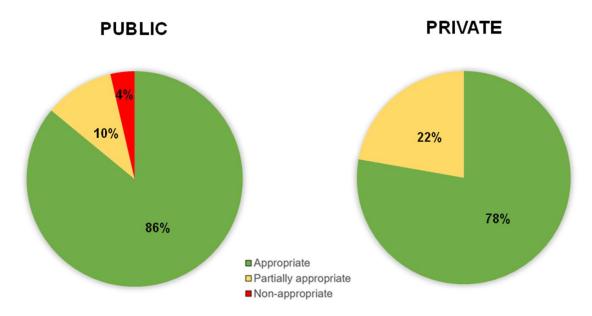


Figure 10 AR as function of private/public institution – DK

The table below shows the association between private/public institution and Appropriateness according to the ESR iGuide (N=922) for DK.

Table 48 Association between private/public institution and Appropriateness – DK

requency		Appropria	teness	
Expected Row Pct Col Pct	Appr (7-9)	Partially Appr (4-6)	Non-Appr (0*-3)	Total
rivate	7 7.731 77.78 0.88	2 0.9469 22.22 2.06	0 0.3221 0.00 0.00	9
blic	785 784.27 85.98 99.12	95 96.053 10.41 97.94	33 32.678 3.61 100.00	913
Total	792	97	33	922

There were 913
CTs performed in
Public institutions,
of which 33 were
Non-appropriate
(3.61%).
In total there were
33 Non-appropriate
CTs, all of which
occurred in public
institutions (100%).

32.678 is the
estimated expected
value in public
institutions under
the hypothesis of

dependence.

Table 49 Pearson Chi-Square Test: public/private - DK

Pearson Chi-Square Test	
Chi-Square	1.5780
DF	2
Asymptotic Pr > ChiSq	0.4543
Exact Pr ≥ ChiSq	0.3705

Conclusions: No significant association was found between the degree of appropriateness according to the ESR iGuide and belonging to a public or private institution (86% vs 78%; p=0.37).

5.6.2.4 Patient Status: Inpatient/emergency vs outpatient

The figure below shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population as function of inpatient/outpatient status for DK.

 $^{^{*}}$ 0 – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

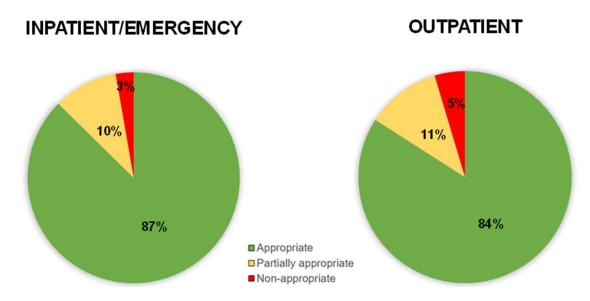


Figure 11 AR as function of inpatient/outpatient status – DK

The following table shows the Association between Patient Status and Appropriateness according to the ESR iGuide (N=922) for DK.

Table 50 Association between patient status and Appropriateness – DK

Frequency Expected	Appropriateness			
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total
Inpatient/emergency	417 409.46 87.42 53.32	47 50.266 9.85 48.96	13 17.279 2.73 39.39	477
Outpatient	365 372.54 84.10 46.68	49 45.734 11.29 51.04	20 15.721 4.61 60.61	434
Total	782	96	33	911
	Fred	quency Missing = 11		
AR				

 $^{^{*}0}$ – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor

Table 51 Pearson Chi-Square Test: patient status - DK

Pearson Chi-Square Test	
Chi-Square	2.9613
DF	2
Asymptotic Pr > ChiSq	0.2275
Exact Pr ≥ ChiSq	0.2231

Conclusions: No significant association was found between the degree of appropriateness according to the ESR iGuide and the status of the patient. The appropriateness rate was slightly higher when the CT examinations were performed during hospitalisation as compared to ambulatory (outpatient) care (87% vs 84%; p=0.23).

5.6.2.5 Patient Gender

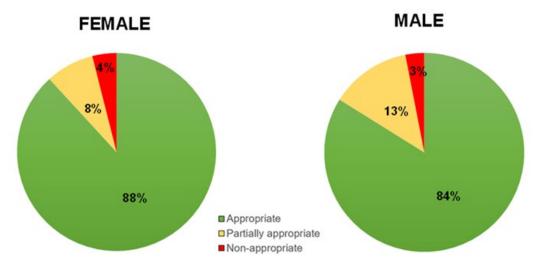


Figure 12 AR as function of gender – DK

The table below shows the association between gender and Appropriateness according to the ESR iGuide (N=922) for DK.

Table 52 Association between gender and Appropriateness – DK

Frequency Expected		Appropriateness			
Row % Col %		Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total
Female		404 394.14 88.21 51.14	36 47.895 7.86 37.50	18 15.965 3.93 56.25	458
Male	/	386 395.86 83.91 48.86	60 48.105 13.04 62.50	14 16.035 3.04 43.75	460
Total		790	96	32	918
		Fr	equency Missing = 4		
	AR				

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor

Table 53 Pearson Chi-Square Test: gender - DK

Pearson Chi-Square Test	
Chi-Square	6.9058
DF	2
Asymptotic Pr > ChiSq	0.0317
Exact Pr ≥ ChiSq	0.0299

Conclusions: The appropriateness rate was higher for CT examinations in female compared to male patients (88% vs 84%, respectively; p=0.03), although this association was not significant when using a binary variable for appropriateness (p=0.06), suggesting that the differences occur mainly in the ratio between partially appropriate and non-appropriate.

5.6.2.6 Patient age group: Adult vs paediatric

No further analysis was performed since children (less than 18 years old) were underrepresented. There were only 5 paediatric cases out of the 922 referrals scored. The appropriateness rate for adults was 86% (see figure below).

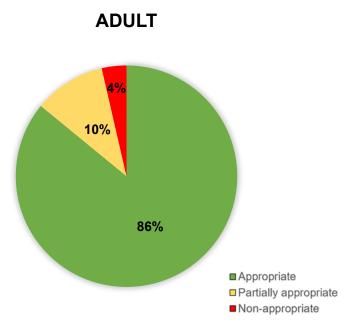


Figure 13 AR in the adult population - DK

5.6.2.7 Exam requested (detailed)

The radar chart below shows the appropriateness rate (AR) as function of the exam requested in the scored population in DK.

Appropriateness rate CT abdomen CT Abdomen-pelvis 100% CT pelvis 90% CT colon CT cervical spine 80% CT neck CT Urography 60% 50% 40% CT chest CT maxillofacial 30% 20% 10% CT chest angiography 0% CT head or/and neck angio CT Chest, high resolution CT head CT chest-abdomen CT, upper extremities CT Heart CT, lower extremities CT, angiography, hear T angio lower ext. coronary arteries CT chest-abdomen-pelvis

Figure 14 Radar chart: AR as function of exam requested – DK

Note: Exams with less than 5 observations were omitted from the figure.

The table below shows the numbers of Appropriate, Partially appropriate and Non-appropriate requests and AR for CT according to type of CT examination (N=922, Missing=5) for DK.

Table 54 No. of Appropriate, Partially appropriate and Non-appropriate requests and AR according to type of CT examination – DK

Anatomical area	Appropriate	Appropriateness			
Exam requested (grouped)	Appr (7-9)	Partially appr (4-6)	Non-appr (0*-3)	(%)	
Abdomen	85	13	4	83%	
CT Abdomen	85	13	4	83%	
Abdomen-Pelvis	111	20	7	80%	
CT Abdomen-pelvis	41	13	4	71%	
CT colon	8	0	0	100%	
CT Urography	62	7	3	86%	
Chest	116	20	4	83%	
CT Chest	84	20	4	78%	
CT Chest angiography	13	0	0	100%	
CT Chest, high resolution	19	0	0	100%	
Chest-Abdomen	140	6	4	93%	
CT Chest-abdomen	136	6	4	93%	
CT Neck-chest-abdomen	2	0	0	100%	
CT Angiography, chest-abdomen	2	0	0	100%	
Coronarography	47	1	0	98%	
CT Heart	15	1	0	94%	
CT, Angiography, heart, coronary arteries	32	0	0	100%	
Chest-Abdomen-Pelvis	55	12	7	74%	
CT Chest-abdomen-pelvis	55	12	7	74%	

Extremities	23	3	0	88%
CT Angiography lower extremities	5	0	0	100%
CT Angiography upper extremities	1	0	0	100%
CT, Lower extremities	12	2	0	86%
CT, Upper extremities	5	1	0	83%
Head and neck	186	13	3	92%
CT Head	159	10	3	92%
CT Head or/and neck angiography	5	0	0	100%
CT Maxillofacial	17	3	0	85%
CT Neck	5	0	0	100%
Pelvis	3	5	1	33%
CT Pelvis	3	5	1	33%
Spine	18	4	2	75%
CT Cervical spine	12	2	0	86%
CT Lumbar spine	1	2	1	25%
CT Spine	2	0	1	67%
CT Thoracic spine	2	0	0	100%
CT Thoracic-lumbar spine	1	0	0	100%
Whole-body/ Polytrauma	4	0	0	100%
CT Whole-body/ Polytrauma scan	4	0	0	100
TOTAL	788	97	32	

 $^{^{*}0}$ – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Conclusions: Because there were many cells with very low frequency and the Chisquare did not converge, no definitive conclusions could be made about the type of CT examination and appropriateness.

The appropriateness rate was higher for the following CT exam types: CT angiography, heart, coronary arteries (100%), CT heart (94%), CT chest, high resolution (100%), CT chest angiography (100%), CT chest-abdomen (93%) and CT head (92%).

5.6.2.8 Referrer specialty (detailed)

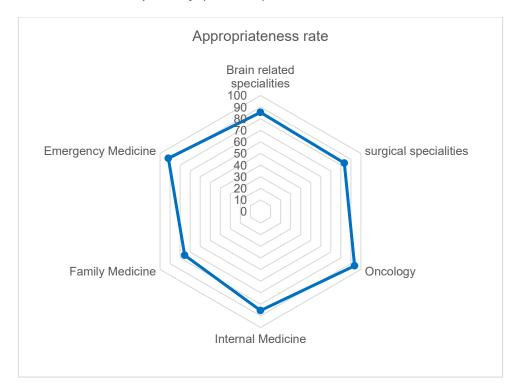


Figure 15 Radar chart: AR as function of referrer specialty – DK

The table below shows the association between referrer specialty and CT Appropriateness according to the ESR iGuide (N=922) for DK.

Table 55 Association between referrer specialty and Appropriateness – DK

Appropriateness by Referrer Specialty					
Frequency Expected		Approp	riateness		
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total	
Brain related specialties	47 47.359 85.45 6.02	7 5.7607 12.73 7.37	1 1.8798 1.82 3.23	55	
Emergency Medicine	100 93.858 91.74 12.80	6 11.417 5.50 6.32	3 3.7255 2.75 9.68	109	
Family Medicine	77 87.83 75.49 9.86	15 10.684 14.71 15.79	10 3.4862 9.80 32.26	102	
Internal Medicine	187 188.58 85.39	27 22.938 12.33	5 7.4851 2.28	219	

	23.94	28.42	16.13		
Oncology	163 149.83 93.68 20.87	7 18.225 4.02 7.37	4 5.9471 2.30 12.90	174	
Surgical specialties	207 213.55 83.47 26.50	33 25.976 13.31 34.74	8 8.4763 3.23 25.81	248	
Total	781	95	31	907	
Frequency Missing = 15					

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 56 Chi-Square: referrer specialty - DK

Statistic	DF	Value	Prob
Chi-Square	10	31.4379	0.0005
Likelihood Ratio Chi-Square	10	29.9046	0.0009

Conclusions: In general, the appropriateness rate was higher for requests referred by medical specialists (oncology 94%, emergency medicine 92%, brain related specialties 85%, internal medicine 85%, and surgical specialties 83%) than for those referred by general practitioners (AR=75%), p=0.0005.

5.6.2.9 Referrer specialty (GP vs other medical specialist)

The figure below shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population as function of referrer specialty (Family doctor/General practitioner vs. other medical specialties) for DK.

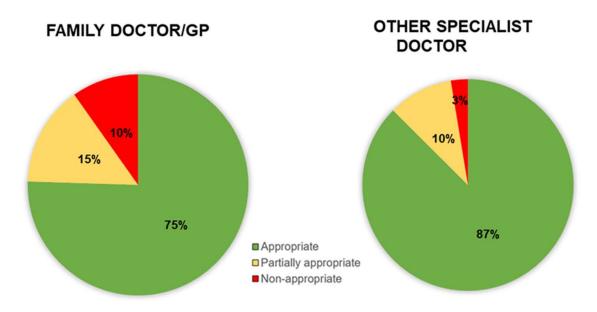


Figure 16 AR as function of referrer specialty – DK

Note: In Denmark, general medicine is a medical specialty.

The table below shows the association between referrer specialty (Family doctors/General practitioners vs. other medical specialists) and Appropriateness according to the ESR iGuide (N=922) for DK.

Table 57 Association between referrer specialty (GP vs specialist) and Appropriateness – DK

Frequency		Appropr	iateness	
Expected Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total
Family doctor/General practitioner	77 87.83 75.49 9.86	15 10.684 14.71 15.79	10 3.4862 9.80 32.26	102
Specialist doctor	704 693.17 87.45 90.14	80 84.316 9.94 84.21	21 27.514 2.61 67.74	805
Total	781	95	31	907
	Fre	quency Missing = 15		
AR				

Table 58 Pearson Chi-Square Test: referrer specialty – DK

Pearson Chi-Square Test	
Chi-Square	17.1823
DF	2
Asymptotic Pr > ChiSq	0.0002
Exact Pr ≥ ChiSq	0.0005

Conclusions: The appropriateness rate was higher for requests referred by other medical specialists than those referred by general practitioners (87% vs 75%, p=0.0005).

5.6.2.10 Demographics and health system – Denmark

Population

5,822,763 (mid-year estimate, 2020)9

Healthcare system

Health expenditure in Denmark has remained slightly above the EU average over the past decade and grew slightly below the EU average between 2015 and 2019⁷.

The Danish healthcare system is largely tax funded, and all Danish residents are automatically covered by the national healthcare system. The majority of hospitals are public, while some smaller private hospitals exist. Public hospitals are financed through state-level general taxes, from which the government allocates block grants to the five healthcare regions. General regulations etc. are provided by the national government, while the healthcare regions are responsible for defining and planning the delivery of health services. Some procedures are outsourced from public to private hospitals.

General practitioners and specialist clinics, including a few radiology clinics, are private practices, but they are still largely tax funded. No payment by the patient is required for visits to general practitioners, specialist clinics or hospital care funded by the healthcare regions. General medicine is a medical specialty in Denmark, meaning that general practitioners are classified as specialists.

Within radiology, about 95% of all examinations and 99% of all CT examinations are carried out in public hospitals¹⁰.

Equipment base

CT scanners per million population (2022): 43.59

⁹ State of Health in the EU, Denmark, Country Health Profile 2021, https://health.ec.europa.eu/system/files/2021-12/2021 chp da english.pdf (accessed on 11 July 2023)

¹⁰ The Danish Health Data Authority https://www.esundhed.dk/Emner/Operationer-og-diagnoser/Radiologiske-undersoegelser (accessed on 6 Oct 2023)

MRI units per million population (2021): 9.22

PET scanners per million population (2022): 8.857

Number of radiologists per million population

115⁸

Rationale for selection / representativeness of participating centres

The total number of CT examinations in Denmark is slightly below 5,000 per day. As the majority of radiology is carried out by the five healthcare regions, it seemed relevant to explore the feasibility of choosing one of the regions as the target of the audit. The population of the regions varies by a factor of approx..3, and the chosen region has a population close to the average. In addition, this region has a distribution of types of hospitals that was judged to match the average situation quite well.

Efforts regarding implementation of justification

Justification of radiological examinations is always addressed during inspections by the Radiation Protection Authority, in terms of reviews of procedures for justification. A separate series of inspections with this focus was also carried out as part of the HERCA Inspection Campaign in late 2016. Denmark also took part in the HERCA communication campaign "Getting the right image for my patient" in 2019.

5.6.3 Estonia

5.6.3.1 General overview

Table 59 Sample overview - EE

	N	% of total	% of scored
Number of audited referrals (Total)	1013	100%	
Of which removed from analysis (duplicates, invalid data)	10	0.99%	
Of which unscored referrals (no/insufficient clinical data)	57	5.63%	
Of which scored	946	93.39%	100%
Fully appropriate (score 7-9)	647	63.87%	68.39%
Partially appropriate (score 4-6)	208	20.53%	21.99%
Inappropriate (score: 1-3, 0*)	91	8.98%	9.62%

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

0,99% 5,63% Removed from analysis (duplicates, invalid data) Unscored (no/ insufficient clinical data) Scored 93,39%

Percentage of scored/unscored referrals - EE

Figure 17 Percentage of scored/unscored referrals – EE

- ⇒ Data quality in Estonia is relatively high with about 93% of referrals scored. Arbitration was required in about 16% of the referrals due to disagreement between auditors (data not shown).
- ⇒ From the 6.61% unscored population, 1% (n=10) of the records were removed from the analysis and 5.63% of the population was unscored due to insufficient clinical data (these are considered inappropriate).
- ⇒ 68% of the <u>scored population</u> (647 out of 946) were rated "Fully appropriate" (score between 7-9).
- ⇒ 31.6% of the <u>scored population</u> (299 out of 946) resulted in a score less than 7 and were classified as "Inappropriate" according to a binary variable (7-9 appropriate, <7 inappropriate). This is relatively high compared to the other countries in the project.

Table 60 Details of referrals removed from analysis – EE

Reason for exclusion	N	%
Duplicate entry	9	90
Not CT referral	1	10
Total	10	100%

⇒90% of removed referrals were due to duplicate entries.

The table below shows the number of more appropriate examinations in those cases where CT imaging was marked inappropriate (score less than 7), according to both auditors, for EE.

Table 61 More Appropriate examinations if CT was inappropriate – EE

More appropriate exam	n (N=299)	% of total
No other exam was recommended	52	17.39%
Another exam was recommended	247	82.6%
MRI	95	31.77
X-ray	55	18.39
Other CT	51	17.06
US	21	7.02
US/other CT	8	2.68
MRI/X-ray	6	2.01
Other CT /X-ray	5	1.67
INV	2	0.67
US/X-ray	2	0.67
PET-CT	1	0.33
PET-CT/MRI	1	0.33

- ⇒ In 17% of referrals scored inappropriate using a binary variable (score less than 7), no other exam was recommended by either of the auditors. Accordingly, in 83% of the referrals, at least one more appropriate examination was suggested by one or both auditors. In 7% of the referrals more than one modality was suggested as more appropriate.
- ⇒The most frequent "more appropriate examination" was MRI. In 34% of referrals scored inappropriate (less than 7), the "more appropriate" recommendation was MRI or a combination of MRI and another exam modality.
- ⇒ In 22.7% of referrals scored inappropriate (less than 7), the "more appropriate" recommendation was X-ray or a combination of X-ray and another exam modality.
- ⇒ In 21.4% of referrals scored inappropriate (less than 7), the more appropriate recommendation was another CT (different from the one referred to) or a combination of CT and another exam modality.
- ⇒ In 10.4% of referrals scored inappropriate (less than 7), the "more appropriate" recommendation was US or a combination of US and another exam modality.
- ⇒ In 2 of the referrals scored inappropriate (less than 7), the "more appropriate" recommendation was PET-CT or a combination of PET-CT and another exam modality and in two of the referrals the more appropriate recommendation was INV.

5.6.3.2 Analysis of CT orders regarding ESR assessment of Appropriateness (summary tables)

The table below shows the association between explanatory variables and Appropriateness according to the ESR iGuide (N=946). Pearson Chi-Square Test/Fisher's Exact Test (a binary variable was used, Appropriate denotes score 7-9 and Non-appropriate score less than $7)^1$ – EE.

Table 62 Association between explanatory variables and Appropriateness – EE

Variable	Appropriate (AR) (N=647)	P-value	Non-appr (N=299)
Institution: Private Public	14/36 (38.9%) 633/910 (69. 6%)	22/36 (61.11%) 277/910 (30.44%)	0.0001*
Patient Status: Emergency Inpatient Outpatient Undetermined ²	83/103 (80.6%) 267/377 (70.8%) 290/455 (63.7%) 7/11 (63.6%)	20/103 (19.4%) 110/377 (29.2%) 165/455 (36.3%) 4/11 (36.4%)	0.0018*
Gender: Female Male Undetermined ²	312/480 (65%) 333/464 (71.7%) 2/2 (100%)	168/480 (35%) 131/464 (28.2%) 0/2 (0%)	0.0255*
Patient Age group: Adult Child	641/939 (68.3%) 6/7 (85.7%)	298/939 (31.7%) 1/7 (14.3%)	0.4425
Referrer Specialty: Brain related specialties Emergency Medicine Family Medicine Internal Medicine Oncology Surgical specialties Undetermined ²	27/73 (36.9%) 126/161(78.3%) 2/2 (100%) 62/89 (69.7%) 35/43 (81.4%) 89/123 (72.4%) 306/455 (67.2%)	46/73 (63%) 35/161 (21.7%) 0/2 (0%) 27/89 (30.3%) 8/43 (18.6%) 34/123 (27.6%) 149/455 (32.7%)	<0.0001*
Referrer Specialty (grouped): Family doctor/General practitioner ³ Specialist doctor Undetermined ²	2/2 (100%) 339/489 (69.3%) 306/455 (67.2%)	0/2 (0%) 150/489 (30.7%) 149/455 (32.7%)].0.5748

^{*}Statistically significant at the level of $p \le 0.05$

The table below shows the number of appropriate and inappropriate requests and appropriateness rates (AR) for CT according to the type of CT examination (N=946, Missing=2) for EE.

¹ All statistical tests were performed without the "Undetermined" category.

² Undetermined values may be due to missing data or due to inconsistencies between auditors in respect to that variable that could not be resolved by arbitration.

³ In Estonia family physicians cannot refer to CT, classification is not relevant for this country.

Table 63 No. of Appropriate and Non-appropriate requests and AR according to type of CT examination – EE

Anatomical area	Appropriate (N=645)	Non- appropriate (N=299)	AR (%)
Abdomen	5	6	45.4
Abdomen-Pelvis	116	38	75.3
Chest	103	46	69.1
Chest-Abdomen	7	2	77.8
Chest-Abdomen-Pelvis	88	32	73.3
Coronarography	11	0	100
Extremities	29	11	72.5
Head and neck	187	93	66.8
Head/neck-chest	15	4	78.9
Pelvis	1	2	33.3
Spine	21	40	34.4
Whole body / Polytrauma	62	25	71.3

Conclusions: A significant association was found between the degree of appropriateness according to the ESR iGuide and public or private institution (69.6% vs 38.9%, respectively, p=0.0001), patient status (p=0.0018), patient gender (p=0.0255) and the expertise of the referring physician (p<0.0001), with a lower appropriateness rate in the private sector and ambulatory (outpatient) care compared to public sector and hospitalisation (inpatient/emergency). Since there were only two general practitioners in the sample, it was not possible to compare appropriateness rates between Family/General physicians and Specialist doctors. The appropriateness ratio was lower in female patients compared to male patients (65% vs 72%, respectively). The highest appropriateness rate was observed for oncologists (81.4%) and emergency medicine doctors (78.3%).

No association could be found for anatomical area and ESR appropriateness due to the low frequencies of some of the cells (Exact Chi-square did not converge). The anatomical areas with highest appropriateness rates were coronarography (100%), head/neck-chest (78.9%) and chest-abdomen (77.8%).

5.6.3.3 Institution: Public vs private

The figure below shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population as function of being a private/public institution for EE.

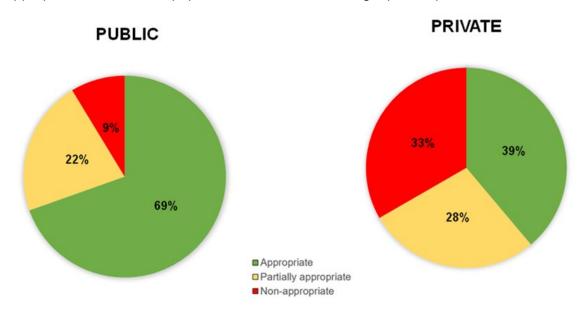


Figure 18 AR as function of private/public institution – EE

The table below shows the association between private/public institution and Appropriateness according to the ESR iGuide (N=946) for EE.

Table 64 Association between private/public institution and Appropriateness – EE

Frequency Expected		Appropria	teness	
Row Pct Col Pct	Appr (7-9)	Partially Appr (4-6)	Non-Appr (0*-3)	Total
Private	14 24.622 38.89 1 2.16	10 7.9154 27.78 4.81	12 3.463 33.33 13.19	36
Public	633 622.38 69.56 97.84	198 200.08 21.76 95.19	79 87.537 8.68 86.81	910
Total	647	208	91	946

There were 910 CTs performed in Public institutions, of which 79 were Non-appropriate (8.68%). In total, there were 91 Non-appropriate CTs, 87% of which occurred in public institutions. 87.537 is the estimated expected value in public institutions, under the hypothesis of independence.

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 65 Pearson Chi-Square Test: private/public – EE

Pearson Chi-Square Test	
Chi-Square	27.21
DF	2
Asymptotic Pr > ChiSq	<0.0001
Exact Pr ≥ ChiSq	<0.0001

Conclusions: The appropriateness rate was higher when the CT examinations occurred in public institutions as compared to private institutions (69.6% vs 38.9%; p<0.0001).

5.6.3.4 Patient status: Inpatient/emergency vs outpatient

The figure below shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population as function of inpatient/outpatient status for EE.

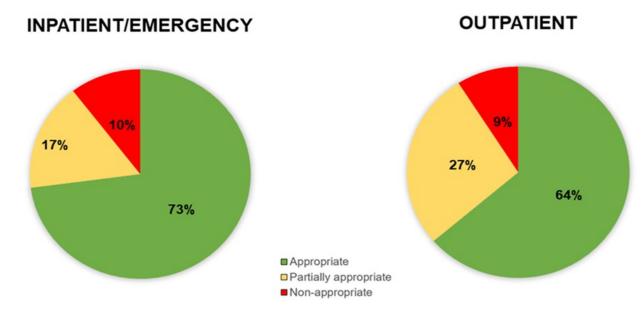


Figure 19 AR as function of inpatient/outpatient status – EE

The table below shows the association between patient status and Appropriateness according to the ESR iGuide (N=946) for EE.

Table 66 Association between patient status and Appropriateness – EE

Appropriateness by Patient Status				
Frequency Expected Row % Col %	Appropriateness			
	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total
Inpatient/emergency	350 328.56 72.92 54.69	80 104.73 16.67 39.22	50 46.717 10.42 54.95	480
Outpatient /	290 311.44 63.74 45.31	124 99.273 27.25 60.78	41 44.283 9.08 45.05	455
Total	640	204	91	935
Frequency Missing = 11				
AR				

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 67 Pearson Chi-Square Test: patient status – EE

Pearson Chi-Square Test	
Chi-Square	15.3478
DF	2
Asymptotic Pr > ChiSq	0.0005
Exact Pr ≥ ChiSq	0.0004

Conclusions: The appropriateness rate was higher when the CT examinations were performed during hospitalisation as compared to ambulatory care (73% vs 64%, respectively; p=0.0005)

5.6.3.5 Patient gender

The figure below shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population as function of gender – EE.

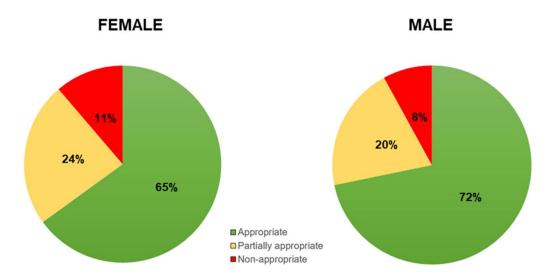


Figure 20 AR as function of gender – EE

The table below shows the association between gender and Appropriateness according to the ESR iGuide (N=946) for EE.

Table 68 Association between gender and Appropriateness – EE

Appropriateness by Gender					
Frequency Expected Row % Col %		Appropriateness			
	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total	
Female	312 327.97 65.00 48.37	114 105.76 23.75 54.81	54 46.271 11.25 59.34	480	
Male	333 317.03 71.77 51.63	94 102.24 20.26 45.19	37 44.729 7.97 40.66	464	
Total	645	208	91	944	
	Fre	equency Missing = 2			
AR					

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 69 Pearson Chi-Square Test: gender - EE

Pearson Chi-Square Test	
Chi-Square	5.5130
DF	2
Asymptotic Pr > ChiSq	0.0635
Exact Pr ≥ ChiSq	0.0632

Conclusions: The appropriateness rate was higher for CT examinations in male compared to female patients (72% vs 65%, respectively; p=0.06), the association being borderline significant.

5.6.3.6 Patient age group: Adult vs paediatric

No further analysis was performed since children (less than 18 years old) were underrepresented. There were only 7 paediatric cases out of the 946 (0.7%) referrals scored. The appropriateness rate for adults was 68% (see figure below, showing the proportions of Appropriate, Partially Appropriate and Non-appropriate referrals in the adult population in EE).

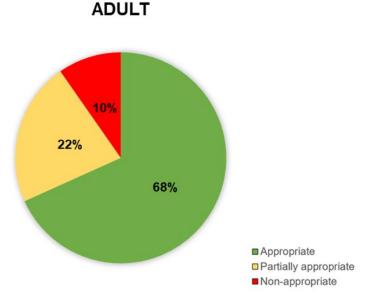


Figure 21 AR in the adult population – EE

5.6.3.7 Exam requested (detailed)

The radar chart below shows the appropriateness rates (AR) as function of the exam requested in the scored population in EE.

Appropriateness rate

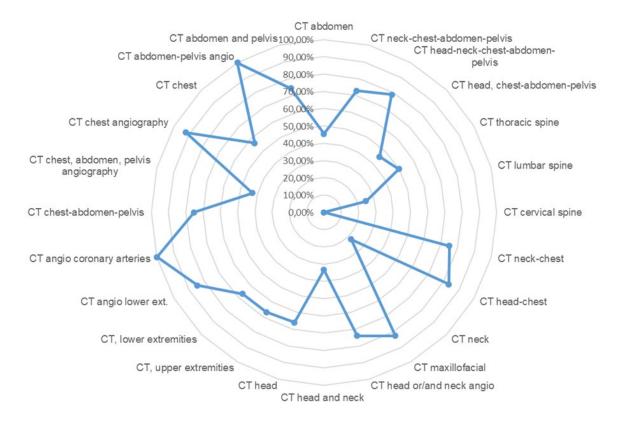


Figure 22 AR as function of exam requested - EE

Note: Exams with less than 5 observations were omitted from the figure.

The table below shows the numbers of Appropriate, Partially Appropriate and Non-appropriate requests and appropriateness rates (AR) for CT according to the type of CT examination (N=946, Missing=2) for EE.

Table 70 Appropriateness according to type of CT examination – EE

Anatomical area	Appropriateness			AR (%)
Exam requested (grouped)	Appr (7-9)	Partially appr (4-6)	Non-appr (0*-3)	
Abdomen	5	3	3	45.45
CT Abdomen	5	3	3	45.45
Abdomen-Pelvis	116	24	14	75.32
CT Abdomen and pelvis	110	24	14	74.32
CT Abdomen-pelvis angiography	6	0	0	100.00
Chest	103	37	9	69.13

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CT Chest	55	33	9	56.70
CT Chest angiography	48	4	0	92.31
Chest-Abdomen	7	1	1	77.78
CT Angiography chest and abdomen	2	0	0	100.00
CT Chest and abdomen	3	1	0	75.00
CT Head(/neck)-chest-abdomen	2	0	1	66.67
Chest-Abdomen-Pelvis	88	16	16	73.33
CT Chest, abdomen, pelvis angiography	3	2	2	42.86
CT Chest-abdomen-pelvis	85	14	14	75.22
Coronarography	11	0	0	100.00
CT Angiography coronary arteries	11	0	0	100.00
Extremities	29	5	6	72.50
CT Angiography lower extremities	11	0	2	84.62
CT, Lower extremities	8	3	1	66.67
CT, Upper extremities	10	2	3	66.67
Head and neck	187	67	26	66.79
CT Head	126	44	21	65.97
CT Head and neck	2	3	1	33.33
CT Head or/and neck angiography	37	10	3	74.00
CT Maxillofacial	19	4	0	82.61
CT Neck	2	6	1	22.22
CT Temporal bone	1	0	0	100.00
Head/neck-chest	15	3	1	78.95
CT Head-chest	5	0	1	83.33
CT Head-neck-chest	1	0	0	100.00

CT Neck-chest	9	3	0	75.00
Pelvis	1	2	0	33.33
CT Pelvis	1	2	0	33.33
Spine	21	33	7	34.43
CT Cervical spine	0	4	3	0.00
CT LS-spine and pelvis	2	0	0	100.00
CT Lumbar spine	10	26	4	25.00
CT Spine	2	0	0	100.00
CT Thoracic spine	3	3	0	50.00
CT Thoracic-lumbar spine	4	0	0	100.00
Whole-body/ Polytrauma	62	17	8	71.26
CT Chest-abdomen-pelvis, lower ext.	1	0	1	50.00
CT Head, chest-abdomen-pelvis	5	4	2	45.45
CT Head-abdomen-pelvis	2	0	0	100.00
CT Head-neck-chest-abdomen- pelvis	11	2	1	78.57
CT Neck-chest-abdomen-pelvis	40	11	4	72.73
CT Whole-body	3	0	0	100.00
Total	645	208	91	68.33

 $^{^{*}0}$ – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Conclusions: Because there were many cells with very low frequency and Chi-square did not converge, no definitive conclusions could be made about the type of CT examination concerning appropriateness.

The appropriateness rate was higher for the following CT exam types (CT with less than 5 observations are not considered): CT angiography coronary arteries (100%), CT abdomen-pelvis angiography (100%), CT chest angiography (92%), CT angiography lower extremities (85%), CT maxillofacial region (83%) and CT head-chest (83%).

5.6.3.8 Referrer specialty (detailed)

The radar chart below shows the appropriateness rate (AR) as a function of referrer specialty in the scored population in EE.

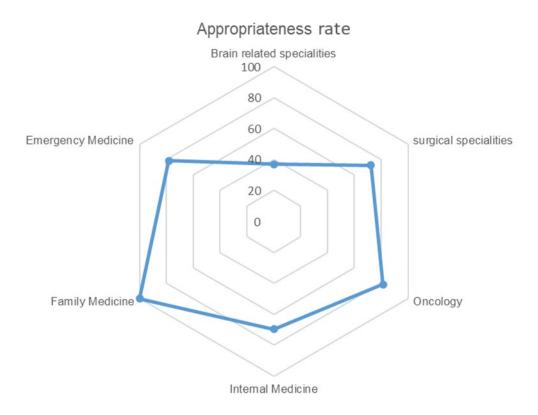


Figure 23 Radar chart: AR as function of referrer specialty – EE

The table below shows the association between referrer specialty and CT Appropriateness according to the ESR iGuide (N=946) in EE.

Table 71 Association between referrer specialty and Appropriateness – EE

Appropriateness by Referrer Specialty					
Frequency Expected		Approp	riateness		
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total	
Brain related specialties	27 50.699 36.99 7.92	41 17.544 56.16 34.75	5 4.7576 6.85 15.63	73	
Emergency Medicine	126 111.81 78.26 36.95	26 38.692 16.15 22.03	9 10.493 5.59 28.13	161	
Family Medicine	2 1.389 100.00 0.59	0 0.4807 0.00 0.00	0 0.1303 0.00 0.00	2	
Internal Medicine	62 61.811 69.66	17 21.389 19.10	10 5.8004 11.24	89	

	18.18	14.41	31.25		
Oncology	35 29.864 81.40 10.26	6 10.334 13.95 5.08	2 2.8024 4.65 6.25	43	
Surgical specialties	89 85.424 72.36 26.10	28 29.56 22.76 23.73	6 8.0163 4.88 18.75	123	
Total	341	118	32	491	
Frequency Missing = 455					

Table 72 Chi-Square: referrer specialty - EE

Statistic	DF	Value	Prob
Chi-Square	10	57.1184	<0.0001
Likelihood Ratio Chi-Square	10	51.6906	<0.0001

WARNING: 28% of the cells have expected counts of less than 5. (Asymptotic) Chi-Square may not be a valid test.

Conclusions: No association could be found for Referrer Specialty and ESR appropriateness due to the low frequencies of some of the cells (Exact Chi-square did not converge). In general, the appropriateness rate was higher for requests referred by oncology doctors (81%), emergency medicine doctors (78%), and surgical specialties doctors (72%). The lowest appropriateness rate was observed for brain related specialty doctors (37%). They were only two family doctors so no conclusion can be made.

We note the high percentage of unknown data for the referrer specialty variable (455 missing data representing 48% of the sample).

5.6.3.9 Referrer specialty (GP vs Medical specialist)

No further analysis was performed since general practitioners were underrepresented. There were only two family medicine doctors out of the 946 referrals scored. This is explainable since family physicians in Estonia cannot refer to CT, so classification is not relevant. Among medical specialists, the appropriateness rate was 69% (see figure below).

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

SPECIALIST DOCTOR

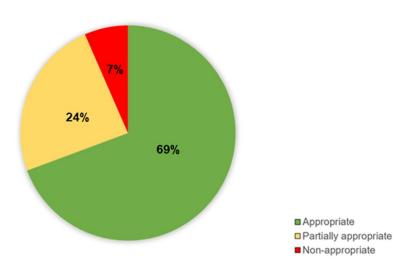


Figure 24 AR among medical specialists - EE

5.6.3.10 Demographics and health system - Estonia

Population

1,365,000 (preliminary data of Statistics Estonia as per 1 January 2023)

Proportion of age group 0-14 years: 16%

Healthcare system

The Estonian healthcare system is based on health insurance, which follows the principle of solidarity, i.e., healthcare is financed by the social tax paid by the employed population.

The management and supervision of the healthcare system and development of the health policy is under the scope of the Ministry of Social Affairs (hereafter MoSA). The Ministry operates in three main policy areas: health services, social services and employment. Public hospitals and private primary care institutions, professional associates are also part of the complex organisational structure of the healthcare system. The key tasks of the MoSA include health policy, monitoring of population health and organisation of the national healthcare system. The key tasks of the Estonian Health Board (hereinafter HB) include licensing healthcare providers, registering healthcare professionals, monitoring quality of healthcare services and funding the organisation of emergency care services.

The Estonian Health Insurance Fund (EHIF) is an active purchaser of services, with responsibilities including signing of contracts with healthcare providers, payment for healthcare services, compensating for the cost of medical products, payment of working benefits for temporary incapacity. The medical services insured by the EHIF are paid by the Fund to the medical institutions under a contract. Relevant agreements have been signed with the healthcare institutions all over Estonia.

In Estonia, medical care is divided into three levels:

- primary or family medical care,
- specialised medical care,

nursing care.

Primary medical care is a healthcare service provided by family physicians and healthcare professionals working together. If necessary, the family physician refers the patient to a medical specialist for consultation or to a hospital. Primary medical care is paid by EHIF, which uses the funds provided for health insurance in the state budget. Individuals who are not covered by health insurance shall pay for primary care themselves. Specialised medical care follows the same principles as primary medical care.

In Estonia, the provision of healthcare services is almost completely decentralised. Most hospitals are either public limited companies owned by local governments or foundations established by the state, local governments, or other public organisations.

In Estonia, hospitals are divided into regional, central, general, local, specialised and rehabilitation hospitals. (Source EHIF; HB)

Equipment base

CT scanners per million population (2021): 21.04 MRI units per million population (2021): 16,53 PET scanners per million population (2021): 2.25⁷

Number of radiologists per million population

154⁸

Rationale for selection / representativeness of participating centres

The requirement of clinical audit was established by the Radiation Act in 2018. According to the Act, holders of radiation practice licences shall ensure proper performance of the clinical audit of medical radiological procedures. Based on the document, clinical audit of medical radiological procedures is a purposeful review of medical exposure practices to improve clinical performance, safety and quality. The Act also includes adapting the standards and organising training and instructing of exposed workers or other employees related to medical radiological procedures. The implementation of clinical audit is established in the MoSA regulation of medical exposure.

There are 19 health care providers in Estonia, 17 of them public and 2 private, using 25 CT scanners. The decision to participate in the EU-JUST-CT project was made by the Environmental Board in collaboration with the Estonian Radiology Society after negotiations with the representatives of the hospitals and approvement by the Ethics Committee.

Efforts regarding implementation of justification

As the requirement of clinical audit was established, Estonia has plans to establish a body for conducting external audits as well as a national procedure for clinical audits.

Estonia participated in the HERCA communication programme "Getting the right image for my patient" in 2019. In 2021 a Workshop on establishing a programme of clinical audits in diagnostic radiology and nuclear medicine was carried out as a joint effort with the International Atomic Energy Agency, Tallinn Technical University, the Estonian Environmental Board, and the Estonian Society of Radiology.

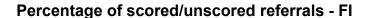
5.6.4 Finland

5.6.4.1 General overview

Table 73 Sample overview - FI

	N	% of total	% of scored
Number of audited referrals (Total)	744	100	
Of which removed from analysis (duplicates, invalid data)	22	3.0	
Of which unscored referrals (no/insufficient clinical data)	2	0.3	
Of which scored	720	96.8	100
Fully appropriate (score 7-9)	568	76.3	78.9
Partially appropriate (score 4-6)	113	15.2	15.7
Inappropriate (score: 1-3, 0*)	39	5.2	5.4

 $^{^{*}0}$ – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.



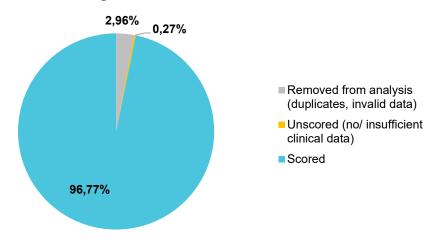


Figure 25 Percentage of scored/unscored referrals - FI

⇒ Data quality in Finland is relatively excellent with about 97% of referrals scored. To note, for Finland, less than 1,000 referrals were collected. However, arbitration was required in about 32% of the referrals due to disagreement between auditors (data not shown).

- ⇒ From the 3.3% unscored population, 3% (n=22) of the records were removed from the analysis and 0.3% of the population was unscored due to insufficient clinical data (these are considered inappropriate).
- ⇒ 78.9% of the <u>scored population</u> (568 out of 720) were rated "Fully appropriate" (score 7-9).
- ⇒ 21.1% of the <u>scored population</u> (152 out of 720) resulted in a score less than 7 and were classified as "Inappropriate" according to a binary variable (7-9 appropriate, <7 inappropriate).

Table 74 Details of referrals removed from analysis – FI

Reason for exclusion	Frequency (N = 24)	%
Duplicate	14	58.3
Not CT/ Interventional procedure	5	20.8
Project / research project	2	8.3
NO DATA (unscored)	2	8.3
No referral ID	1	4.2

➡ More than half of the removed referrals (58.33%) were due to duplicate entries. Two out of 24 were research projects and 5 out of 24 (20.8%) involved procedures beyond the scope of the present project.

The table below shows the more appropriate examinations in those cases where CT imaging was marked inappropriate (score less than 7), according to both auditors, for FI.

Table 75 More Appropriate examinations if CT was inappropriate - FI

More appropriate exam	n (N = 152)	%
No other exam was recommended	9	5.9
Other exam was recommended	143	94.1
Other CT	40	26.3
MRI	32	21.1
X-ray	16	10.5
MRI / other CT	13	8.6
US	13	8.6
Other CT / X-ray	8	5.3

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US / other CT	7	4.6
MRI / X-ray	3	2.0
NUC / MRI	2	1.3
NUC / other CT	2	1.3
PET-CT / NUC	2	1.3
INV / other CT	1	0.7
MRI / US	1	0.7
NUC	1	0.7
NUC / X-ray	1	0.7
US / X-ray	1	0.7

- ⇒ In 6% of referrals scored inappropriate (less than 7), no other exam was recommended by either of the auditors. Accordingly, in 94% of the referrals, at least one more appropriate examination was suggested by one or both auditors. In 48% of the referrals more than one test modality was suggested as more appropriate.
- ⇒ The most frequent "more appropriate examination" was another type of CT (different from the one referred to, 26%). In 46.7% of referrals scored inappropriate (less than 7), the more appropriate recommendation was another type of CT or a combination of other CT and another exam modality.
- ⇒ In 33.6% of referrals scored inappropriate (less than 7), the more appropriate recommendation was MRI (21.1%) or a combination of MRI and another exam modality (12.5%).
- ⇒ In 19.1% of referrals scored inappropriate (less than 7), the more appropriate recommendation was X-ray or a combination of X-ray and another exam modality (10.5% and 8.6%, respectively).
- ⇒ In 14.5% of referrals scored inappropriate (less than 7), the more appropriate recommendation was US or a combination of US and another exam modality.
- ⇒ In 1.3% of referrals scored inappropriate (less than 7), the more appropriate recommendation was a combination of PET-CT and NUC exam modalities.

5.6.4.2 Analysis of CT orders regarding ESR Assessment of Appropriateness (Summary Tables)

The following table shows the association between explanatory variables and Appropriateness according to the ESR iGuide (N=720). Pearson Chi-Square Test/Fisher's Exact Test (a binary variable was used, Appropriate denotes score 7-9 and Non-appropriate score less than 7)¹ for FI.

Table 76 Association between explanatory variables and Appropriateness – FI

Variable	Appropriate (AR) (N=568)	Non-appropriate (N=152)	P-value*
Institution: Private Public	8/11 (72.7%) 560/709 (79%)	3/11 (27.3%) 149/709 (21%)	0.18
Patient Status: Emergency Inpatient Undetermined ²	42/53 (79.2%) 24/27 (88.9%) 526/667 (78.9%)	11/53 (20.8%) 3/27 (11.1%) 141/667 (21.1%)	0.26
Gender: Female Male Undetermined ²	274/343 (79.9%) 291/373 (78%) 3/4(75%)	69/343 (20.1%) 82/373 (22%) 1/4 (25%)	0.24
Patient Age group: Adult Child	555/706 (78.6%) 13/14 (92.9%)	151/706 (21.4%) 1/14 (7.1%)	0.48
Referrer Specialty: Brain related specialties Internal Medicine Oncology Surgical specialties Undetermined ²	1/2 (50%) 1/2(50%) 1/1 (100%) 3/4 (75%) 562/711 (79%)	1/2 (50%) 1/2 (50%) 0/1 (0%) 1/4 (25%) 149/711 (21%)	_3
Referrer Specialty (grouped): Specialist doctor Undetermined ²	6/9 (66.7%) 562/711 (79%)	3/9 (33.3%) 149/711 (21%)	_4

^{*} Statistically significant at the level of $p \le 0.05$.

The table below shows the numbers of appropriate and inappropriate requests and appropriateness rates (AR) for CT according to the type of CT examination (N=720) for FI.

¹ All statistical tests in this report were performed without the "Undetermined" category.

² Undetermined values may be due to missing data or due to inconsistencies between auditors in respect to that variable that could not be resolved by arbitration.

³ No test could be done for referrer specialty and ESR appropriateness due to very low frequencies of all cells (Exact Chi-square did not converge).

⁴ No test could be done for referrer specialty (grouped) and ESR appropriateness since no general practitioners were represented in the sample. In Finland family physicians cannot refer to CT, therefore, classification is not relevant for this country.

Table 77 Appropriateness according to type of CT examination – FI

Anatomical area	Appropriate (N=568)	Non-appropriate (N=152)	AR (%)
Abdomen	54	15	78.3
Abdomen-Pelvis	49	13	79
Chest	79	12	86.8
Chest-Abdomen	11	2	84.6
Chest-Abdomen-Pelvis	91	33	73.4
Coronarography	12	2	85.7
Extremities	42	8	84.0
Head-neck	180	52	77.6
Neck-chest	1	2	33.3
Pelvis	3	0	100
Spine	13	0	100
Whole body/ Polytrauma	19	10	65.5
Undetermined	14	3	-

Conclusions: Approx. a third of the appropriate referrals for a CT were for a head-neck scan (n=180), the most common exam followed by a chest-abdominal-pelvis scan (16%). Of note, pelvic constitutes only 0.5% of appropriate referrals.

No significant associations were found between the degree of appropriateness according to the ESR iGuide and institution type, patient status, or gender. No association was found for age group, but only 14 paediatric cases were included in the study. No association was found for referrer specialty and ESR appropriateness, which might be due to low frequencies of some of the cells (Exact Chi-square did not converge).

No association was found for anatomical area and ESR appropriateness due to low frequencies of some of the cells (Exact Chi-square did not converge). The anatomical areas with the highest appropriateness rates were spine (100%), although frequency was low (n=13), followed by chest (86.8%), coronarography (85.7%), chest-abdomen (84.6%), and extremities (84%). The anatomical area with the lowest appropriateness rates (with expected counts >5) was whole body / polytrauma (65.5%).

5.6.4.3 Institution: Public vs private

The following figure shows the proportion of Appropriate, Partially appropriate and Non-appropriate in the scored population as function of being a private/public institution for FI.

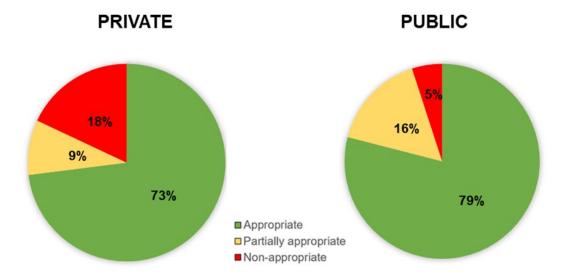


Figure 26 AR as function of private/public institutions - FI

The table below shows the association between private/public institution and Appropriateness according to the ESR iGuide (N=720) for FI.

Table 78 Association between private/public and Appropriateness – FI

Institution type		Appropriateness			Total
		Appr (7-9)	Partially appr (4-6)	Non-appr (0*-3)	
	Count	8	1	2	11
Private	Expected count	8.7	1.7	0.6	11.0
Private	% within Institute type	72.7%	9.1%	18.20%	100.0%
	% within Appropriateness	1.4%	0.9%	5.10%	1.5%
	Count	560	112	37	709
Dublio	Expected count	559.3	111.3	38.4	709.0
Public %	% within Institute type	79.0%	15.8%	5.20%	100.0%
	% within Appropriateness	98.6%	99.1%	94.90%	98.5%

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 79 Pearson Chi-Square Test: public/private - Fl

Pearson Chi-Square Test							
	Value	df	Asymptotic significance (2-sided)	Exact significance (2-sided)			
Pearson Chi-Square	3.725*	2	0.155	0.189			
Likelihood Ratio	2.508	2	0.285	0.289			
Fisher-Freeman-Halton Exact Test	3.313			0.151			
N of Valid Cases	720						

^{*2} cells (33.3%) have an expected count of less than 5. The minimum expected count is 0.60.

Conclusions: Most referrals were for a CT related to public institutions (98.5%). No significant association was found between the degree of appropriateness according to the ESR iGuide and public vs private institution (79% vs 73%, respectively; p=0.15).

5.6.4.4 Patient status: Inpatient vs emergency

All cases occurred during hospitalisation as is usual in Finland, thus no comparison could be made between inpatient and ambulatory/outpatient exams. The figure below shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population as function of inpatient-emergency status (N=53) for FI.

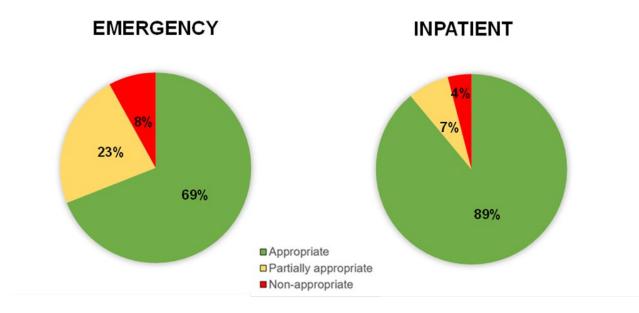


Figure 27 AR as function of inpatient-emergency status - FI

The table below shows the association between patient status and Appropriateness according to the ESR iGuide (N=720) for FI.

Table 80 Patient Status and Appropriateness – FI

Patient status			Appropriateness				
		Appr	Partially appr	Non-appr			
	Count	18	6	2	26		
Emergeney	Expected Count	20.5	4.1	1.4	26.0		
Emergency	% within Patient status	69.2%	23.1%	7.7%	100.0%		
	% within Appropriateness	3.2%	5.3%	5.1%	3.6%		
	Count	24	2	1	27		
Innationt	Expected Count	21.3	4.2	1.5	27.0		
Inpatient	% within Patient status	88.9%	7.4%	3.7%	100.0%		
	% within Appropriateness	4.2%	1.8%	2.6%	3.8%		
	Count	526	105	36	667		
	Expected Count	526.2	104.7	36.1	667.0		
Undetermined	% within Patient status	78.9%	15.7%	5.4%	100.0%		
	% within Appropriateness	92.6%	92.9%	92.3%	92.6%		

Table 81 Pearson Chi-Square Test: patient status - Fl

Pearson Chi-Square Test						
	Value	df	Asymptotic significance (2-sided)	Exact significance (2-sided)		
Pearson Chi-Square	3.173*	2	0.205	0.267		
Likelihood Ratio	3.274	2	0.195	0.304		
Fisher-Freeman-Halton Exact Test	3.131			0.204		
N of Valid Cases	53					
*4 cells (66.7%) have an expected count of less than 5. The minimum expected count is 1.47.						

Conclusions: Most of the data for this variable are missing (92.6%) and with no representation of ambulatory care. No significant association was found between the degree of appropriateness according to the ESR iGuide and the status of the patient. The

appropriateness rate was lower when the CT examinations were performed during emergency care as compared to hospitalisation (69% vs 89%; p=0.204), though the difference was not significant.

5.6.4.5 Patient gender

The following figure shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population as function of gender (N=716) for FI.

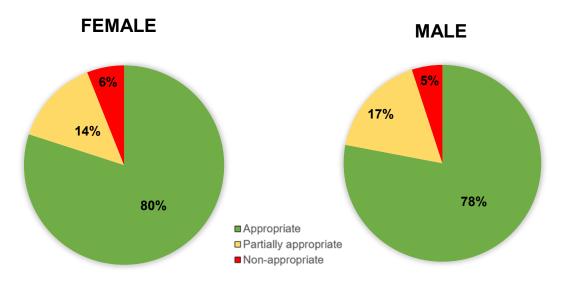


Figure 28 AR as function of gender - FI

The table below shows the association between gender and Appropriateness according to the ESR iGuide (N=720) for FI.

Table 82 Association between gender and Appropriateness – FI

Gender	ender		Appropriateness			
		Appr	Partially appr	Non-appr		
	Count	274	47	22	343	
Female	Expected Count	270.6	53.8	18.6	343.0	
	% within Gender	79.9%	13.7%	6.4%	100.0%	
	% within Appropriateness	48.2%	41.6%	56.4%	47.6%	
	Count	291	65	17	373	
Male	Expected Count	294.3	58.5	20.2	373.0	
	% within Gender	78.0%	17.4%	4.6%	100.0%	

	% within Appropriateness	51.2%	57.5%	43.6%	51.8%
Undetermined %	Count	3	1	0	4
	Expected Count	3.2	0.6	0.2	4.0
	% within Gender	75.0%	25.0%	0.0%	100.0%
	% within Appropriateness	0.5%	0.9%	0.0%	0.6%

Table 83 Pearson Chi-Square Test: gender - Fl

Pearson Chi-Square Test							
	Value	df	Asymptotic significance (2-sided)	Exact significance (2-sided)			
Pearson Chi-Square	2.793*	2	0.247	0.250			
Likelihood Ratio	2.802	2	0.246	0.250			
Fisher-Freeman-Halton Exact Test	2.782			0.250			
N of Valid Cases	716						

^{*0} cells (0.0%) have an expected count of less than 5. The minimum expected count is 18.68.

Conclusions: Men comprised 51.8% of the study sample. The appropriateness rate was higher for CT examinations in female compared to male patients (80% vs 78%, respectively), although this association was not significant (p=0.247).

5.6.4.6 Patient age group: Adult vs paediatric

The figure below shows the proportion of Appropriate, Partially appropriate and Non-appropriate exams in the scored population as function of age group (N=720) in FI.

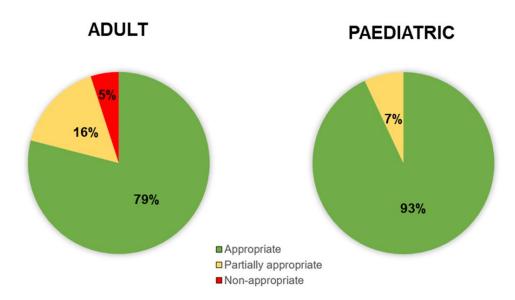


Figure 29 AR as function of age group - FI

The table below shows the association between age group and appropriateness according to the ESR iGuide (N=720) in FI.

Table 84 Association between age group and appropriateness - FI

Age group			Appropriateness			
		Appr	Partially appr	Non-appr		
	Count	555	112	39	706	
۸ ماریاد	Expected Count	557.0	110.8	38.2	706.0	
Adult	% within Age group	78.6%	15.9%	5.5%	100.0%	
	% within Appropriateness	97.7%	99.1%	100.0%	98.1%	
	Count	13	1	0	14	
Ob.it.d	Expected Count	11.0	2.2	0.8	14.0	
Child	% within Age group	92.9%	7.1%	0.0%	100.0%	
	% within Appropriateness	2.3%	0.9%	0.0%	1.9%	

Table 85 Pearson Chi-Square Test: age group - Fl

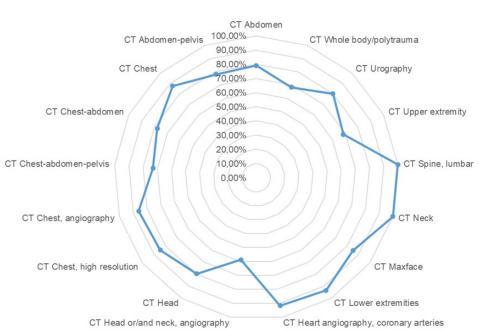
Pearson Chi-Square Test						
	Value	df	Asymptotic significance (2-sided)	Exact significance (2-sided)		
Pearson Chi-Square	1.792*	2	0.408	0.485		
Likelihood Ratio	2.699	2	0.259	0.341		
Fisher-Freeman-Halton Exact Test	0.703			0.656		
N of Valid Cases	720					

^{*2} cells (33.3%) have an expected count of less than 5. The minimum expected count is 0.76.

Conclusions: The appropriateness rate was higher for CT examinations in children compared to adult patients (93% vs 79%, respectively), although this association was not significant (p=0.656). Only 14 out of the 720 referrals scored were in children.

5.6.4.7 Exam requested (detailed)

The radar chart below shows the appropriateness rate (AR) as function of the exam requested in the scored population in FI.



Appropriateness rate

Figure 30 AR as function of exam requested – FI

Note: Exams with less than 5 observations in Appr were omitted from the figure.

The following table shows the numbers of Appropriate, Partially appropriate and Non-appropriate requests and appropriateness rates (AR) for CT according to the type of CT examination for FI.

Table 86 No. of Appropriate, Partially appropriate and Non-appropriate requests and AR according to type of CT examination – FI

Anatomical area		Appropriateness				
Exam requested (grouped)	Appr (7-9)	Partially appr (4-6)	Non-appr (0*-3)			
Abdomen	54	13	2	78.3%		
CT Abdomen	49	12	1	79.0%		
CT Liver	1	0	1	50.0%		
CT Abdomen-pancreas	4	1	0	80.0%		
Abdomen-Pelvis	49	10	3	79.0%		
CT Abdomen-pelvis	25	4	3	78.1%		
CT Urography	24	6	0	80.0%		
Chest	79	10	2	86.8%		
CT Chest	37	3	2	88.1%		
CT Chest, angiography	31	5	0	86.1%		
CT Chest, high resolution	11	2	0	84.6%		
Chest-Abdomen	11	2	0	84.6%		
CT Chest-abdomen	7	2	0	77.8%		
CT Chest-abdomen, angiography	3	0	0	100.0%		
CT Neck-chest-abdomen	1	0	0	100.0%		
Chest-Abdomen-Pelvis	91	26	7	73.4%		
CT Chest-abdomen-pelvis	89	26	7	73.0%		
CT Chest-abdomen-pelvis, angiography	2	0	0	100.0%		
Coronarography	12	0	2	85.7%		
CT Heart	1	0	1	50.0%		
CT Heart, coronary arteries, angiography	11	0	1	91.7%		

Extremities	42	5	3	84.0%
CT Lower extremities	28	1	1	93.3%
CT Lower extremity, angiography	1	0	0	100.0%
CT Upper extremities	13	4	2	68.4%
Head and neck	180	39	13	77.6%
CT Head	129	25	8	79.6%
CT Head and neck	3	0	1	75.0%
CT Maxillofacial	23	4	0	85.2%
CT Neck	5	0	0	100.0%
CT Head or/and neck, angiography	20	10	4	58.8%
Spine	13	0	0	100.0%
CT Spine	1	0	0	100.0%
CT Spine, lumbar	8	0	0	100.0%
CT Spine, cervical	3	0	0	100.0%
CT Spine, thoracic	1	0	0	100.0%
Whole body / Poly trauma	19	5	5	65.5%
CT Neck-chest-abdomen-pelvis	3	1	1	60.0%
CT Whole body / poly trauma	13	3	3	68.4%
CT Head-chest-abdomen-pelvis	3	1	1	60.0%
Pelvis	3	0	0	100.0%
CT Pelvis	3	0	0	100.0%
Neck-chest	1	2	0	33.3%
CT Neck-chest	1	2	0	33.3%
Undetermined	14	1	2	82.4%
Undetermined	14	1	2	82.4%
TOTAL	568	113	39	78.9%

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*0 – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Conclusions: Because there were many cells with very low frequency and Chi-square did not converge, no definitive conclusions could be made about the type of CT examination concerning appropriateness.

Appropriateness rates were higher for the following CT exam types: CT neck and CT lumbar spine (both with an appropriateness rate of 100%), CT lower extremities (93%) and CT heart angiography (92%). The range of appropriateness rates of 80-90% includes CT of the maxillofacial region (88%), chest as well as chest angiography and HRCT (about 86%), and CT urography (80%). The range of appropriateness rates of 70-80% includes CT of head (79.6%), abdomen (79%), abdomen-pelvis and chest-abdomen (78%), and chest-abdomen-pelvis (73%). The lowest appropriateness rate was found for CT head or/and neck as well as angiography (59%).

5.6.4.8 Referrer specialty (detailed)

The radar chart below shows the appropriateness rate (AR) as a function of referrer specialty in the scored population in FI.

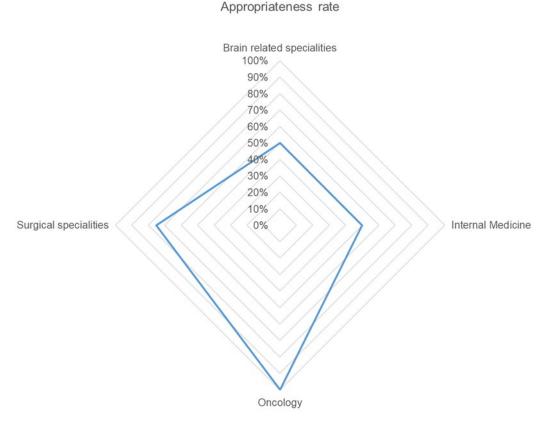


Figure 31 Radar chart: AR as function of referrer specialty - FI

The table below shows the association between Referrer Specialty and CT Appropriateness according to the ESR iGuide (N=922) for FI.

Table 87 Association between referrer specialty and Appropriateness – FI

Referrer specialty (grouped)			Total		
		Appr	Partially appr	Non-appr	
	Count	1	0	1	2
Brain related	Expected Count	1.6	0.3	0.1	2.0
specialties	% within Referrer specialty	50.0%	0.0%	50.0%	100.0%
	% within Appropriateness	0.2%	0.0%	2.6%	0.3%
	Count	1	1	0	2
Internal	Expected Count	1.6	0.3	0.1	2.0
Medicine	% within Referrer specialty	50.0%	50.0%	0.0%	100.0%
	% within Appropriateness	0.2%	0.9%	0.0%	0.3%
	Count	1	0	0	1
Openiany	Expected Count	0.8	0.2	0.1	1.0
Oncology	% within Referrer specialty	100.0%	0.0%	0.0%	100.0%
	% within Appropriateness	0.2%	0.0%	0.0%	0.1%
	Count	3	1	0	4
Surgical	Expected Count	3.2	0.6	0.2	4.0
specialties	% within Referrer specialty	75.0%	25.0%	0.0%	100.0%
	% within Appropriateness	0.5%	0.9%	0.0%	0.6%
	Count	562	111	38	711
l la data ::	Expected Count	560.9	111.6	38.5	711.0
Undetermined	% within Referrer specialty	79.0%	15.6%	5.3%	100.0%
	% within Appropriateness	98.9%	98.2%	97.4%	98.8%

Table 88 Pearson Chi-Square Test: referrer specialty - FI

Pearson Chi-Square Test							
	Value	df	Asymptotic significance (2-sided)	Exact significance (2-sided)			
Pearson Chi-Square	5.250*	6	0.512	0.746			
Likelihood Ratio	5.232	6	0.514	0.810			
Fisher-Freeman-Halton Exact Test	5.656			0.810			
N of Valid Cases	9						

^{*12} cells (100.0%) have an expected count of less than 5. The minimum expected count is 0.11.

Conclusions: No association was found between referrer specialty and CT Appropriateness according to the ESR iGuide, due to very low frequencies. In general, the appropriateness rate was higher for requests referred by oncologists (100%) and surgical specialists (75%).

5.6.4.9 Referrer specialty (GP vs Medical specialist)

The figure below shows the proportion of Appropriate, Partially appropriate and Non-appropriate in the scored population as function of Referrer Specialty (Specialist doctors only) – FI.

SPECIALIST DOCTOR

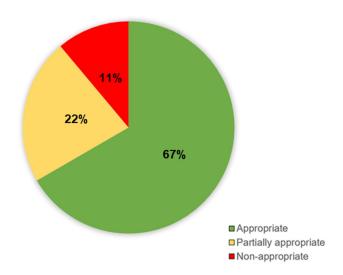


Figure 32 AR as function of referrer specialty - FI

Conclusions: Due to high rate of missing data for this parameter, comparison is not relevant. There was no representation of general physicians in the study and only nine specialist doctors were included in the study (AR = 67%).

5.6.4.10 Demographics and health system – Finland

Population

5,525,292 (mid-year estimate 2020)11

Selected region: 2.2 mio inhabitants

Healthcare system

Life expectancy in Finland increased over the past two decades. However, chronic diseases and disabilities due to an ageing population will raise the demand on health and long-term care in the future. A recently approved major reform foresees more centralisation of responsibilities and resources at the regional level to improve healthcare access while controlling costs.

The Finnish healthcare system is currently governed at the national and local levels. The Ministry of Social Affairs and Health is responsible for health reforms and policies. It is supported by expert advisory bodies, which inform decision-making. At the local level, municipalities were in charge of organising health and social care until the end of year 2022. Twenty hospital districts and five specialised care districts organised around the university centres provided the secondary and tertiary care.

Decentralisation has enabled the health system to meet the needs of a dispersed population but created certain inequalities and inefficiencies. A major administrative reform that was approved in 2021 aims to reduce inequalities, improve service quality and availability and contain expenditure growth. 21 well-being services counties, together with the City of Helsinki, have organised health and social care services from 2023 onwards.¹¹

Equipment base

CT scanners per million population (2021): 16.96

MRI units per million population (2022): 33,16

PET scanners per million population (2021): 3.617

Number of radiologists per million population

116⁸

Rationale for selection / representativeness of participating centres

The Hospital District of Helsinki and Uusimaa was selected as region for the audit, the largest region in Finland with 2.2 mio. inhabitants. This covers all 16 clinics that perform diagnostic CT examinations in public health care and 1 private clinic. One private clinic that performs only few CT examinations per week was excluded.

Efforts regarding implementation of justification

Considering the rising number of imaging procedures and costs, justification is considered a tool by the regulators and professional societies to have a positive impact on both. The main efforts in Finland regarding implementation of justification are as follows:

Education and training

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¹¹ https://health.ec.europa.eu/system/files/2021-12/2021_chp_fi_english.pdf

All Finnish radiology trainees are required to complete a special course on radiation protection and physics. Justification and appropriateness are among the major components of this course. Many cardiologists also take this course because it is practically a prerequisite for acting as a radiation protection officer in an organisation. Medical students are introduced to the concepts of justification and optimisation along with typical doses in most common medical imaging examinations. Some subfields like cardiology and orthopaedics have incorporated radiation protection in their curriculum.

There is a long tradition of over 40 years of an annual meeting of specialists around radiation protection in radiology organised jointly by the Radiological Society of Finland and the Radiation and Nuclear Safety Authority (STUK). Justification is a continuous key topic integrated in radiology sessions there. STUK arranges thematic workshops and webinars on radiation protection, where justification has been highlighted.

Research

Unjustified CT examinations in young patients has been a subject for research projects since 2005 in Finland. The first results were published from Oulu university hospital in 2009 [11]. This study motivated putting emphasis on training on justification in whole Finland. There have been follow-up studies as well.

<u>Guidelines</u>

STUK has co-operated with professional societies to establish guidelines such as

- STUK guideline on justification for referring physicians (2015) (in Finnish)
- STUK guideline on paediatric CTs (2012)

Clinical audits

In Finland clinical audits became mandatory in year 2000. The clinical audit programmes often have justification as one of the subtopics that are being audited.

5.6.5 Greece

5.6.5.1 General overview

Table 89 Sample overview - GR

	N	% of total	% of scored
Number of audited referrals (Total)	909	100	
Of which removed from analysis (duplicates, invalid data)	49	5.4	
Of which unscored referrals (no/insufficient clinical data)	193	21.2	
Of which scored	667	73.4	100
Fully appropriate (score 7-9	386	42.5	57.9
Partially appropriate (score 4-6)	177	19.5	26.5
Inappropriate (score: 1-3, 0*)	104	11.4	15.6

*0 – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Percentage of scored/unscored referrals - GR

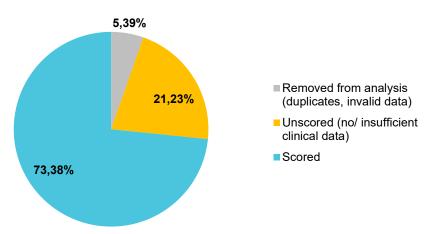


Figure 33 Percentage of scored/unscored referrals - GR

- ⇒ Data quality in Greece was found to be generally average, with only about 73% of referrals scored.
- ⇒ The source file included 909 records. Of these, 242 records (26.6%) were removed from the study or unscored due to insufficient clinical data, leaving 667 records that were included in the statistical analysis.
- ⇒ 58% of the <u>scored population</u> (386 out of 667) was rated as "Fully appropriate" (score between 7-9), which is generally low compared to other countries.
- ⇒ 42% of the <u>scored population</u> (281 out of 667) resulted in a score less than 7 and were classified as "Non-appropriate" according to a binary variable (7-9 appropriate, <7 inappropriate).

Table 90 Details of referrals removed from analysis - GR

Reason for exclusion	n (N = 242)	%
No data (unscored referrals)	193	79.7
No referral ID	28	11.6
Double entry	20	8.3
Not CT	1	0.4

⇒ Most of the removed referrals were mainly due to no data and partly because of missing referral IDs (about 80% and 12%, respectively), double entries and requested exam other than CT (8.7%).

The following table shows the more Appropriate examinations in case of inappropriate (score less than 7) requested CT imaging, according to both auditors (N=281), for GR.

Table 91 More Appropriate examinations if CT was inappropriate – GR

More appropriate exam	n (N = 281)	%
No other exam was recommended	31	11.0
Other exam was recommended	250	89.0
X-ray	82	32.8
MRI	38	15.2
Other CT	23	9.2
US	19	7.6
US/X-ray/other CT	16	6.4
MRI/other CT	10	4.0
MRI/X-ray	10	4.0
Other CT/X-ray	10	4.0
US/X-ray	8	3.2
NUC/other CT	4	1.6
US/other CT	4	1.6
MRI/US	3	1.2
MRI/X-ray/other CT	3	1.2
NUC/PET-CT/other CT	3	1.2
X-ray/other CT	3	1.2
US/MRI/other CT	3	1.2
INV/other CT	1	0.4
MRI/X-ray/US/other CT	1	0.4
NUC/PET-CT	1	0.4
NUC/PET-CT/MRI	1	0.4
NUC/INV/other CT	1	0.4

NUC/MRI/other CT	1	0.4
PET-CT	1	0.4
PET-CT/other CT	1	0.4
PET-CT/INV/other CT	1	0.4
PET-CT/MRI/other CT	1	0.4
PET-CT/US/other CT	1	0.4

- ⇒ In 89% of referrals scored inappropriate (less than 7) another exam was recommended, while in 11% of referrals neither of the auditors recommended another exam.
- ⇒ The most frequent appropriate examination was X-ray (33% of referrals scored inappropriate, less than 7) and in another 20%, the more appropriate recommendation was X-ray combined with another exam.
- ⇒ In 15% of referrals scored inappropriate (less than 7), the more appropriate recommendation was MRI and in 13% of referrals, MRI combined with another exam.
- ⇒ In 9% of referrals scored inappropriate (less than 7), the more appropriate recommendation was other CT (different from the requested) and in about 26%, a combination of other CT and another exam.
- ⇒ In about 8% of referrals scored inappropriate (less than 7), the more appropriate recommendation was US and in about 15%, a combination of US and another exam.
- ⇒ Of note is that in more than a third (34.5%) of referrals scored inappropriate (less than 7), the more appropriate recommendation was a combination of at least two modalities.

5.6.5.2 Analysis of CT orders regarding ESR assessment of Appropriateness (summary tables)

The following table shows the association between explanatory variables and appropriateness according to ESR (N=667). Pearson Chi-Square Test/Fisher's Exact Test (a binary variable was used, Appropriate meaning score 7-9 and Non-appropriate score less than 7)¹ for GR.

Table 92 Association between explanatory variables and appropriateness – GR

Characteristic	Appropriate (n=386)		Non-appropi (n=281)	riate	p-value			
	n/Total Row	% of Total Row	% of Total Row	% of Total Row				
Institution								
Private	221/439	50.3	218/439	49.7	<0.001*			
Public	165/228	72.4	63/228	27.6	.0.001			
Patient status								
Inpatient/emergency	215/262	82.1	47/262	17.9	<0.001*			
Outpatient	150/377	39.8	227/377	60.2	Ţ			
Undetermined ²	21/28	75.0	7/28	25.0				
Gender								
Female	165/303	54.5	138/303	45.5	0.13			
Male	206/341	60.4	135/341	39.6				
Undetermined ²	15/23	65.2	8/23	34.8				
Patient age group								
Adult	384/665	57.7	281/665	42.3	0.51			
Child	2/2	100.0	0/2	0.0	0.01			
Referrer specialty								
Brain related specialties	12/25	48.0	13/25	52.0]			
Emergency medicine	5/5	100.0	0/5	0.0				
Family medicine	8/20	40.0	12/20	60.0				
Internal Medicine	127/242	52.5	115/242	47.5	. 0.001*			
Oncology	49/64	76.6	15/64	23.4				
Surgical specialties	71/119	59.7	48/119	40.3				

Undetermined ¹	114/192	59.4	78/192	40.6	
Referrer specialty (grouped)					
Family medicine	8/20	40.0	12/20	60.0]
Specialist doctor	264/455	58.0	191/455	42.0	- 0.16
Undetermined ²	114/192	59.4	78/192	40.6	

^{*} Statistically significant at the level of p ≤ 0.05.

Conclusions: Significant associations were found between degree of appropriateness according to the ESR iGuide and institution type, patient status, and referrer specialty (all three with p<0.001). Higher appropriateness rates were found in the public sector (72%), in inpatient/emergency (82%) compared to private sector (50%), and ambulatory (outpatient) care (40%). Referrer specialty was also found to be associated with appropriateness rate, which was higher for oncology (76.6%) and surgical specialties (60%) compared to internal medicine (52.5%), brain related specialties (48%), and family medicine (40%). Although the appropriateness rate for emergency medicine was 100%, this group includes five cases.

The appropriateness rate was much lower among adults compared to children (60% vs. 100%, respectively; p=0.34), though this was not significant, and since only two paediatric cases were included in the study, no conclusion can be drawn regarding the association with the appropriateness rate.

No associations with referrer specialty (grouped) were found for general practitioner and for males compared to specialist physician (40% vs. 58%, respectively; p=0.16) and to females (55% vs. 60%, respectively; p=0.13). Of note is that the sample contained only 20 referrals from general physicians.

The table below shows the numbers of appropriate and inappropriate requests and appropriateness rates (AR) for CT according to the type of CT examination (N=667) for GR.

Table 93 No. of Appropriate and Non-appropriate requests and AR according to type of CT examination – GR

Anatomical area	Appropriate (N=386)	Non- appropriate (N=281)	AR (%)
Abdomen	19	17	52.8%
Abdomen-pelvis	65	43	60.2%
Chest	96	103	48.2%
Chest-abdomen	12	4	75.0%
Chest-abdomen-pelvis	62	22	73.8%

¹ All statistical tests in this report were performed without the "Undetermined" category.

² Undetermined or missing values may be due to missing data or inconsistencies between auditors in respect to that variable that could not be resolved by arbitration.

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Coronarography	16	1	94.1%
Extremities	2	12	14.3%
Head and/or neck	83	51	61.9%
Head-chest/abdomen/pelvis	1	3	25.0%
Head/neck-chest	8	0	100.0%
Pelvis	3	6	33.3%
Spine	11	16	40.7%
Whole-body / Polytrauma	5	1	83.3%
Undetermined	3	2	60.0%

Conclusions: No significant association was found for anatomical area and ESR appropriateness, probably be due to the low expected counts of some of the cells (Fisher's Exact Chi-square did not converge). A large variation was found in appropriateness rates, ranging from 14% (extremities) to 100% (head/neck-chest). While focusing on exams with 5+ counts in each appropriateness group, the appropriateness rate was generally low and the highest appropriateness rates were found for chest-abdomen-pelvis (74%), head and/or neck (62%), and abdomen-pelvis (60%). The appropriateness rate was lower than 80% for 10 of the 13 studied anatomical areas.

5.6.5.3 Institution: Public vs private

The graphic below shows the proportion of Appropriate, Partially appropriate and Non-appropriate exams in the scored population as function of being a private/public institution (N=667) for GR.

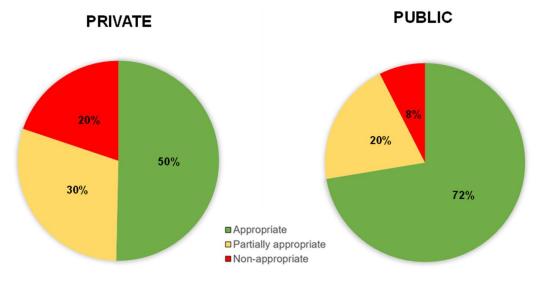


Figure 34 AR as function of private/public institution – GR

The table below shows the association between private/public institution and Appropriateness according to the ESR iGuide (N=667) for GR.

Table 94 Association between private/public institution and Appropriateness – GR

Frequency	A	propriateness level			There were 228 CTs performed in public
Row % Col %	Appr (7-9)	Partially ppr (4-6)	Non-appr (0*-3)	Total	institutions, 46 of which were Non-
	221	87	131	439	appropriate (20%).
Private	254.1	68.4	116.5		In total, there were
Filvate	50.3%	19.8%	29.8%		104 Non-appropriate
	57.3%	83.7%	74.0%		CTs, 46 of them in
	165	17	46	228	public institutions
Public	131.9	35.6	60.5		(26%).
Public	72.4%	7.5%	20.2%		60.5 is the estimated
/	42.7%	16.3%	26.0%		expected value in
Total /	386	177	104	667	public institutions,
Frequency Missing = 0					under the hypothesis of independence.
ÁR					

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 95 Pearson Chi-Square Test: private/public - GR

Pearson Chi-Square Test (without undetermined)						
	Value	df	Asymptotic significance (2-sided)	Exact significance (2-sided)		
Pearson Chi-Square	32.570*	2	<0.001	<0.001		
Likelihood Ratio	34.337	2	<0.001	<0.001		
Fisher-Freeman-Halton Exact Test	33.781			<0.001		
N of Valid Cases	667					

^{*0} cells (0.0%) have an expected count of less than 5. The minimum expected count is 35.55.

Conclusions: The appropriateness rate was higher when the CT examinations occurred in public institutions as compared to private institutions (72% vs. 50%, respectively; p<0.001).

5.6.5.4 Patient status: Inpatient vs outpatient

The figure below shows the proportion of Appropriate, Partially appropriate and Non-appropriate exams in the scored population as function of inpatient/outpatient status (N=667) for GR.

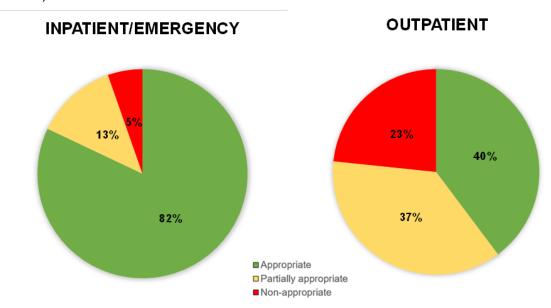


Figure 35 AR as function of inpatient/outpatient status - GR

The table below shows the association between patient status and Appropriateness according to the ESR iGuide (N=667) for GR.

Table 96 Association between patient status and Appropriateness – GR

Frequency Expected	Appropriateness						
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total			
Inpatient/emergency	215 151.6 82.1% 55.7%	33 69.5 12.6% 18.6%	14 40.9 5.3% 13.5%	262			
Outpatient	150 218.2 39.8% 38.9%	139 100.0 36.9% 78.5%	88 58.8 23.3% 84.6%	377			
Total	365	172	102	639			
Frequency Missing = 28							

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 97 Pearson Chi-Square Test: patient status - GR

Pearson Chi-Square Test (without undetermined)							
	Value	df	Asymptotic significance (2-sided)	Exact significance (2- sided)			
Pearson Chi-Square	113.569*	2	<0.001	<0.001			
Likelihood Ratio	120.898	2	<0.001	<0.001			
Fisher-Freeman-Halton Exact Test	119.758			<0.001			
N of Valid Cases	639						

^{*0} cells (0.0%) have an expected count of less than 5. The minimum expected count is 41.82.

Conclusions: The appropriateness rate was significantly much higher when the CT examinations were performed during hospitalisation (inpatient/emergency) as compared to ambulatory (outpatient) care (82% vs. 40%, respectively; p<0.001).

5.6.5.5 Patient gender

The figure below shows the proportion of Appropriate, Partially appropriate and Non-appropriate exams in the scored population as function of gender (N=667) for GR.

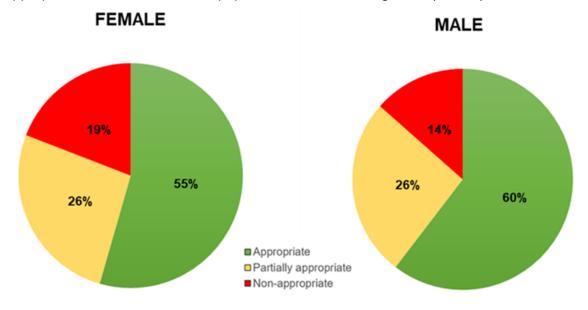


Figure 36 AR as function of gender – GR

The table below shows the association between gender and Appropriateness according to the ESR iGuide (N=667) for GR.

Table 98 Association between gender and Appropriateness – GR

Appropriateness by Gender								
Frequency Expected Row % Col %	Appropriateness							
	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total				
Female	165 175.3 54.5% 42.7%	80.4 26.4% 45.2%	58 47.2 19.1% 55.8%	303				
Male	206 197.3 60.4% 53.4%	89 90.5 26.1% 50.3%	46 53.2 13.5% 44.2%	341				
Total	371	169	104	644				
Frequency Missing = 23								

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 99 Pearson Chi-Square Test: gender - GR

Pearson Chi-Square Test (without undetermined)							
	Value	df	Asymptotic significance (2-sided)	Exact significance (2-sided)			
Pearson Chi-Square	4.167*	2	0.124	0.124			
Likelihood Ratio	4.164	2	0.125	0.126			
Fisher-Freeman-Halton Exact Test	4.154			0.124			
N of Valid Cases	644						

^{*0} cells (0.0%) have an expected count of less than 5. The minimum expected count is 48.93.

Conclusions: The appropriateness rate was higher when the CT examinations concerned the male population as compared to female population, although the difference is not statistically significant (60.4% vs. 54.5%, respectively; p=0.124).

5.6.5.6 Patient age group: Adult vs paediatric

ADULT

The following figure shows the proportion of Appropriate, Partially appropriate and Non-appropriate exams in the scored population as function of age group for GR.

16% 26% 58% Appropriate Partially appropriate Non-appropriate

Figure 37 AR as function of age group - GR

Conclusions: No further analysis was performed since children (less than 18 years old) were under-represented in the study. There were only two paediatric cases out of the 667 referrals scored in the study. The appropriateness rate was 60% for adults.

5.6.5.7 Exam requested (grouped)

The following radar chart shows the appropriateness rate (AR) as function of the exam requested in the scored population in GR.

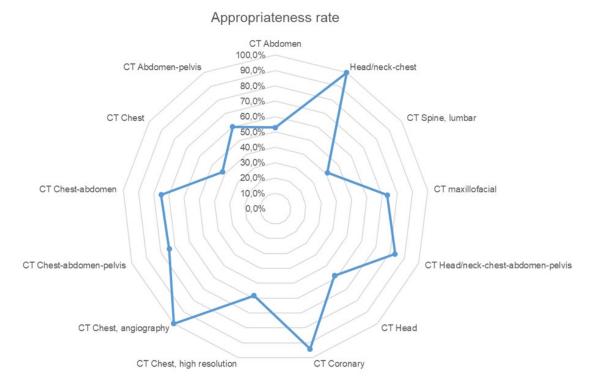


Figure 38 AR as function of exam requested - GR

Note: Exams with less than 5 observations in Appr group were omitted from the figure.

The table below shows the numbers of Appropriate, Partially appropriate and Non-appropriate requests and appropriateness rates (AR, %) for CT according to the type of CT examination (N=667) for GR.

Table 100 No. of Appropriate, Partially appropriate and Non-appropriate requests and AR according to type of CT examination – GR

Anatomical area	Appropriateness A		Appropriateness			
Exam requested (grouped)	Appr (7-9)	Partially appr (4-6)	Non-appr (0*-3)			
Abdomen	19	10	7	52.8%		
CT Abdomen	19	10	7	52.8%		
Abdomen-pelvis	65	27	16	60.2%		
CT Abdomen-pelvis	65	27	16	60.2%		
Chest	96	81	22	48.2%		
CT Chest	71	78	20	42.0%		
CT Chest, angiography	18	0	0	100.0%		
CT Chest, high resolution	7	3	2	58.3%		
CT Chest-abdomen	12	3	1	75.0%		
Chest-abdomen-pelvis	62	14	8	73.8%		
CT Chest-abdomen-pelvis	62	14	8	73.8%		
Coronarography	16	0	1	94.1%		
CT Coronary	16	0	1	94.1%		
Extremities	2	6	6	14.3%		
CT Lower extremities	1	3	5	11.1%		
CT Upper extremities	1	3	1	20.0%		
Head and/or neck	83	24	27	61.9%		

CT Head	57	20	21	58.2%
CT Head and neck	0	0	1	0.0%
CT Maxillofacial	22	4	4	73.3%
CT Neck	4	0	1	80.0%
Head/neck-chest	8	0	0	100.0%
Head/neck-chest	8	0	0	100.0%
Head-chest/abdomen/pelvis	1	1	2	25.0%
CT Head-chest/abdomen/pelvis	1	1	2	25.0%
Pelvis	3	0	6	33.3%
CT Pelvis	3	0	6	33.3%
Spine	11	9	7	40.7%
CT Spine	3	0	0	100.0%
CT Spine, cervical	1	3	3	14.3%
CT Spine, lumbar	7	6	4	41.2%
Whole body/polytrauma	5	1	0	83.3%
CT Head/neck-chest-abdomen-pelvis	5	1	0	83.3%
Undetermined	3	1	1	60.0%
Undetermined	3	1	1	60.0%
Total	386	177	104	57.9%

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Conclusions: Because there were many cells with very low expected frequency (n < 5) and exact Chi-square did not converge, no definitive conclusions could be made about the type of CT examination concerning appropriateness.

After omitting cells with a frequency of less than five in each category of appropriateness, the appropriateness rate was lower than 80%. Appropriateness rates were higher for CT examinations of chest-abdomen-pelvis (74%), maxillofacial region (73%), rather than CT abdomen-pelvis (60%), CT head (58%), CT abdomen (53%), CT chest (42%), and CT spine lumbar (41%).

5.6.5.8 Referrer specialty (detailed)

The radar chart below shows the appropriateness rate (AR) as a function of referrer specialty in the scored population (N=667) for GR.

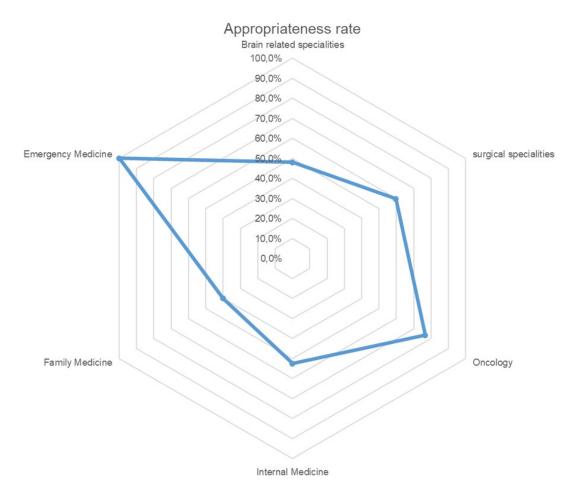


Figure 39 Radar chart: AR as function of referrer specialty – GR

The table below shows the association between referrer specialty and CT Appropriateness according to the ESR iGuide (N=667) for GR.

Table 101 Association between referrer specialty and Appropriateness – GR

Frequency Expected				
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total
Brain related specialties	12 14.5 48.0% 3.1%	6 6.6 24.0% 3.4%	7 3.9 28.0% 6.7%	25
Emergency Medicine	5	0	0	5

	2.9 100.0% 1.3%	1.3 0.0% 0.0%	0.8 0.0% 0.0%		
Family Medicine	8 11.6 40.0% 2.1%	6 5.3 30.0% 3.4%	6 3.1 30.0% 5.8%	20	
Internal Medicine	127 140.0 52.5% 32.9%	82 64.2 33.9% 46.3%	33 37.7 13.6% 31.7%	242	
Oncology	49 37.0 76.6% 12.7%	10 17.0 15.6% 5.6%	5 10.0 7.8% 4.8%	64	
Surgical Specialties	71 68.9 59.7% 18.4%	27 31.6 22.7% 15.3%	21 18.6 17.6% 20.2%	119	
Total	272	72	131	475	
Frequency Missing = 192					

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Conclusions: No association was found for referrer specialty and ESR appropriateness due to the low frequencies of some of the cells (Exact Chi-square did not converge).

The appropriateness rate was higher for requests referred by medical specialists (emergency medicine 100% with five cases, oncology 77%, surgical specialties 60%, internal medicine 52.5%, and brain related specialties 48%) than for requests by general practitioners (AR 40%). Differences were significant when association was examined in two categories of appropriateness instead of three categories (p<0.001, see table 92, Association between explanatory variables and appropriateness according to ESR (N=667).

5.6.5.9 Referrer specialty (GP vs Medical specialist)

The figure below shows the Proportion of Appropriate, Partially appropriate and Non-appropriate in the scored population as function of Referrer Specialty (Family doctor/GP vs. Specialist doctor) (N=667) for GR.

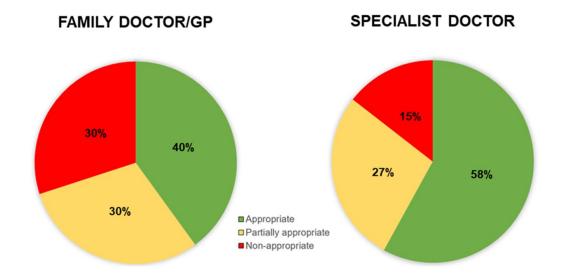


Figure 40 AR as function of referrer specialty – GR

The following table shows the association between referrer specialty (Family doctor/General practitioner vs. Specialist doctor) and Appropriateness according to the ESR iGuide (N=667) for GR.

Table 102 Association between referrer specialty (GP vs specialist) and Appropriateness – GR

Frequency Expected	Appropriateness				
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total	
General practitioner	8 11.6 40.0% 2.1%	6 5.3 30.0% 3.4%	6 3.1 30.0% 5.8%	20	
Medical specialist	264 263.3 58.0% 68.4%	125 120.7 27.5% 70.6%	66 70.9 14.5% 63.5%	455	
Total	272	131	72	475	
Frequency Missing = 192					

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 103 Pearson Chi-Square Test: referrer specialty – GR

Pearson Chi-Square Test (without undetermined)						
	Value	df	Asymptotic significance (2-sided)	Exact significance (2- sided)		
Pearson Chi-Square	4.165*	2	0.125	0.129		
Likelihood Ratio	3.638	2	0.162	0.177		
Fisher-Freeman-Halton Exact Test	4.08			0.133		
N of Valid Cases	475					

^{*1} cell (16.7%) has an expected count less than 5. The minimum expected count is 3.03.

Conclusions: The appropriateness rate was higher for requests referred by medical specialists than for requests referred by general practitioners, although the difference is not statistically significant (58% vs. 40%, respectively, p=0.133).

5.6.5.10 Demographics and health system – Greece

Population

10,718,565 (mid-year estimate, 2020)12

Healthcare system

The national health system of Greece is known as the National Health Service (ESY). It is a healthcare system designed to provide universal healthcare coverage and access to all Greek citizens and legal residents. The Greek healthcare system is primarily funded through public financing, with the government playing a central role in its administration and regulation. The main authority responsible for overseeing the system is the Ministry of Health, which sets policies, allocates resources, and ensures the delivery of healthcare services.

The system consists of seven health regions which administer three degrees of health care:

- 1. Primary health care consisting of Health Centres and Local Health Units providing prevention, treatment and rehabilitation of patients
- 2. Hospitals with the purpose of providing Secondary and Tertiary Health Care, i.e., inpatient care of patients
- 3. For the insured, the provision of health services is provided by the National Organization for the Provision of Health Services (EOPYY). EOPYY has been the main social security body of the country since January 2012. The EOPYY also contracts with private providers, mainly to deliver primary and outpatient care and diagnostic services. In the case of diagnostic examinations, the insured patients

¹² State of Health in the EU, Greece, Country Health Profile 2021, https://health.ec.europa.eu/system/files/2021-12/2021 chp gr english.pdf (accessed on 11 July 2023)

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pay 15% of the respective reimbursement price when referrals are executed by privately contracted providers. In cases when referrals are executed in the public sector the cost is fully covered (no patient participation).

Equipment base

CT scanners per million population (2022): 48.66 MRI units per million population (2021): 37.19 PET scanners per million population (2022): 1.43⁷

Number of radiologists per million population

264⁸

Rationale for selection / representativeness of participating centres

Due to the large number of diagnostic radiology centres, Greece could not participate at a national level. Hence, the region of Thessaloniki was selected because it is the second largest city (after Athens) in Greece and has a large and representative number of diagnostic radiology centres including both public and private centres. The vast majority of diagnostic radiology centres in Greece are located in Athens and Thessaloniki. The project itself requested an amount of 1,000 referrals per country. The number of diagnostic centres in Thessaloniki was the most appropriate one in order to get the requested number of referrals by including all the diagnostic centres.

In order to achieve optimal representation of the whole country, a different approach, i.e., collecting a sufficient number of referrals across the entire country, would have been preferable. However, this was not feasible considering the objectives and timeframe of this project.

Efforts regarding implementation of justification

In Greece there is no national committee performing audits on the justification of radiological examinations. However, the Greek NCA is not aware whether internal audits are performed at a hospital/local level. Greece had participated in HERCA's European communication campaign "Getting the right image for my patient" in 2019.

5.6.6 Hungary

5.6.6.1 General overview

Table 104 Sample overview – HU

	N	% of total	% of scored
Number of audited referrals (Total)	1026	100%	
Of which removed from analysis (duplicates, invalid data)	19	1.85%	
Of which unscored referrals (no/insufficient clinical data)	86	8.38%	
Of which scored	921	89.77%	
Fully appropriate (score 7-9)	697	67.93%	75.68%
Partially appropriate (score 4-6)	152	14.81%	16.50%
Inappropriate (score: 1-3, 0*)	72	7.02%	7.82%

 $^{^{*}0}$ – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Percentage of scored/unscored referrals - HU

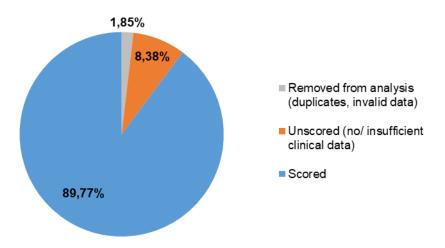


Figure 41 Percentage of scored/unscored referrals – HU

- ⇒ Data quality in Hungary is relatively high with almost 90% of referrals scored. However, arbitration was required in about 27% of the referrals due to disagreement between auditors (data not shown).
- From the 10% unscored population, 1.85% (n=19) of the records were removed from the analysis and 8.38% of the population was unscored due to insufficient clinical data (these are considered inappropriate).
- ⇒ 75.7% of the <u>scored population</u> (697 out of 921) were rated "Fully appropriate" (score 7-9).

⇒ 24.3% of the <u>scored population</u> (224 out of 921) resulted in a score of less than 7 and were classified as "Inappropriate" according to a binary variable (7-9 appropriate, <7 inappropriate).

Table 105 Details of referrals removed from analysis – HU

Delete reason	N	%
No data at all	8	42.11%
Duplicates	6	31.58%
Interventional radiology	3	15.79%
Not same patients	2	10.53%
Total	19	100%

⇒ About 42% of the removed referrals were due to not having data at all. Six out of 19 were due to duplicate entries.

The table below shows the more Appropriate examinations in those cases where CT imaging was marked inappropriate (score less than 7), according to both auditors, for HU.

Table 106 More Appropriate examinations if CT was inappropriate - HU

More appropriate exam	n (N = 224)	%
No other exam was recommended	10	4.46
Other exam was recommended	214	95.54
MRI	72	32.14
X-ray	49	21.88
Other CT	37	16.52
Other CT/MRI	22	9.82
US	6	2.68
Other CT/X-ray	5	2.23
US/other CT	3	1.34
US/X-ray	3	1.34

MRI/INV	2	0.89
MRI/X-ray	2	0.89
NUC	2	0.89
Other CT/INV	2	0.89
US/ECD	2	0.89
INV/X-ray	1	0.45
NUC/MRI	1	0.45
Other CT/MRI/US	1	0.45
Other CT/MRI/X-ray	1	0.45
Other CT/PET-CT	1	0.45
Other CT/US-X-ray	1	0.45
Other CT/MRI/US/NUC	1	0.45

- ⇒ In 4.5% of referrals scored inappropriate (less than 7), no other exam was recommended by either of the auditors. Accordingly, in 95.5% of the referrals, at least one more appropriate examination was suggested by one or both auditors. In 21.4% of the referrals more than one test modality was suggested as more appropriate
- ⇒ The most frequent "more appropriate examination" was MRI. In 45.5% of referrals scored inappropriate (less than 7), the "more appropriate" recommendation was MRI or a combination of MRI and another exam modality.
- ⇒ In 33% of referrals scored inappropriate (<7), the more appropriate recommendation was another CT (different from the one referred to) or a combination of CT and another exam modality.
- ⇒ In 27.7% of referrals scored inappropriate (less than 7), the more appropriate recommendation was X-ray or a combination of X-ray and another exam modality.
- ⇒ In 7.6% of referrals scored inappropriate (less than 7), the more appropriate recommendation was US or a combination of US and another exam modality.

5.6.6.2 Analysis of CT orders regarding ESR assessment of Appropriateness (summary tables)

The table below shows the association between explanatory variables and Appropriateness according to the ESR iGuide (N=921) for HU. Pearson Chi-Square Test/Fisher's Exact Test (a binary variable was used, Appropriate denotes a score 7-9 and Non-appropriate a score less than 7)¹.

Table 107 Association between explanatory variables and Appropriateness – HU

Variable	Appropriate (AR) (N=697)	Non-appropriate (N=224)	P-value*
Institution: Public	697/921 (75.7%)	224/921 (24.3%)	
Patient Status: Inpatient (/emergency) Outpatient Undetermined ²	208/246 (84.6%) 386/534 (72.3%) 103/141 (73.1%)	38/246 (15.4%) 148/534 (27.7%) 38/141 (26.9%)	0.0002*
Gender: Female Male Undetermined ²	365/473 (77.2%) 327/440 (74.3%) 5/8 (62.5%)	108/473 (22.8%) 113/440 (25.7%) 3/8 (37.5%)	0.3153
Patient Age group: Adult Child Undetermined ²	692/913 (75.8%) 4/5 (80%) 1/3 (33.3%)	221/913 (24.2%) 1/5 (20%) 2/3 (66.7%)] 0.8266
Referrer Specialty: Brain related specialties Emergency Medicine Family Medicine Internal Medicine Oncology Surgical specialties Undetermined ²	40/94 (42.5%) 143/182 (78.6%) 66/81 (81.5%) 150/199 (75.4%) 102/122 (83.6%) 146/185 (78.9%) 50/58 (86.2%)	54/94 (57.5%) 39/182 (21.4%) 15/81(18.5%) 49/199 (24.6%) 20/122 (16.4%) 39/185 (21.1%) 8/58 (13.8%)	<0.0001*
Referrer Specialty (grouped): Family doctor/General practitioner ³ Specialist doctor Undetermined ²	66/81 (81.5%) 581/782 (74.3%) 50/58 (86.2%)	15/81 (18.5%) 201/782 (25.7%) 8/58 (13.8%)	0.1553

^{*}Statistically significant at the level of $p \le 0.05$.

The table below shows the numbers of appropriate and inappropriate requests and appropriateness rates (AR) for CT according to the type of CT examination (N=921, Missing/Undetermined=4) for HU.

¹ All statistical tests in this report were performed without the "Undetermined" category.

² Undetermined values may be due to missing data or due to inconsistencies between auditors in respect to that variable that could not be resolved by arbitration.

³ In Hungary family physicians cannot refer to CT. Those referred to as family physicians in this table were actually residents in different clinical specialties who have not passed the board exam yet and were therefore counted as family doctors. Therefore, this classification is not relevant for Hungary.

Table 108 No. of Appropriate and Non-appropriate requests and AR according to type of CT examination – HU

Anatomical area	Appropriate (N=697)	Non- appropriate (N=224)	AR (%)
Abdomen	45	16	73.77%
Abdomen-Pelvis	16	7	69.57 %
Chest	219	69	76.04%
Chest-Abdomen	69	12	85.19 %
Chest-Abdomen-Pelvis	53	13	80.30%
Coronarography	37	6	86.05%
Extremities	12	4	75.00%
Head and neck	210	51	80.46%
Head-Abdomen	2	0	100.00%
Head/Neck-Chest	5	1	83.33%
Pelvis	12	1	92.31%
Spine	11	43	20.37%
Whole-body / Polytrauma	3	0	100.00%
Undetermined	3	1	75.00 %

Conclusions: A significant association was found between the degree of appropriateness according to the ESR iGuide and the status of the patient (p=0.0002) and the expertise of the referring physician (p<0.0001). Highest appropriateness rates were observed for oncology doctors (84%) and family medicine doctors (81.5%). For the grouped variable, the Appropriateness rate was higher in family/general physicians as compared to specialist doctors, but the difference was not significant (81.5% vs 74.3%, respectively, p=0.16). Moreover, residents in different specialties were counted as family/general physicians, as at the time of the referral they may have been conducting their studies. General practitioners and family physicians from their own practice cannot refer to CT examinations. Thus, this classification is not relevant for Hungary and may be misleading.

No association was found for anatomical area and ESR appropriateness due to the low frequencies of some of the cells (Exact Chi-square did not converge). The anatomical areas with highest AR were pelvis (92%), coronarography (86%), chest-abdomen (85%), and head and neck (80%). The lowest appropriateness rate was observed for spine (20.4%).

5.6.6.3 Institution: Public vs private

No further analysis was performed since there was no representation of private institutions. All 921 scored referrals belonged to public institutions. The appropriateness rate for public institutions was 76% (see figure below, which shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population for HU as function of being a private/public institution).

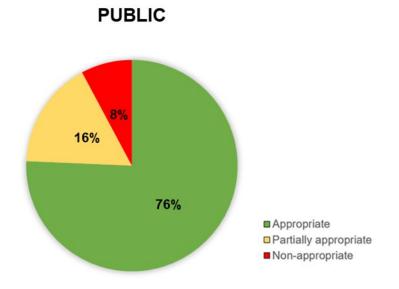


Figure 42 AR as function of private/public institution – HU

7.6.4 Patient status: Inpatient/emergency vs outpatient

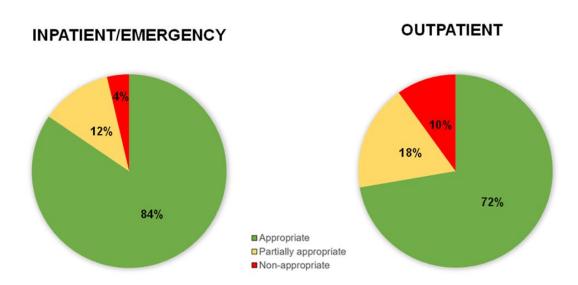


Figure 43 AR as function of inpatient/outpatient status – HU

The table below shows the association between patient status and Appropriateness according to the ESR iGuide (N=921) for HU.

Table 109 Association between patient status and Appropriateness – HU

Appropriateness by patient status					
Frequency Expected	Appropriateness				
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total	
Inpatient/emergency	208 187.34 84.55 35.02	29 39.108 11.79 23.39	9 19.554 3.66 14.52	246	
Outpatient	386 406.66 72.28 64.98	95 86.892 17.79 76.61	53 42.446 9.93 85.48	534	
Total	594	124	62	780	
Frequency missing = 141					
AR					

 $^{^{*0}}$ – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 110 Pearson Chi-Square Test: patient status - HU

Pearson Chi-Square Test		
Chi-Square	15.4648	
DF	2	
Asymptotic Pr > ChiSq	0.0004	
Exact Pr ≥ ChiSq	0.0004	

Conclusions: The appropriateness rate was higher when the CT examinations were performed during hospitalisation as compared to ambulatory (outpatient) care (85% vs 72%, respectively; p=0.0004).

5.6.6.5 Patient gender

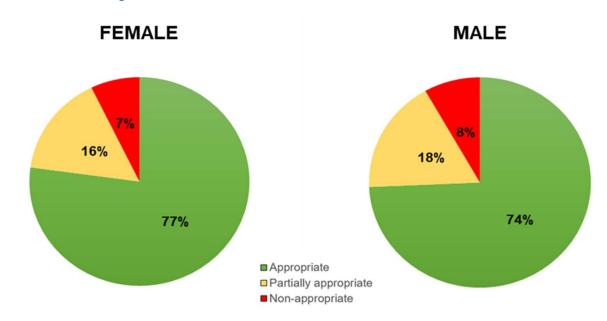


Figure 44 AR as function of gender – HU

The association between gender and appropriateness according to the ESR iGuide (N=921) for HU is shown below.

Table 111 Association between gender and Appropriateness according to ESR iGuide – HU

Appropriateness by gender Frequency Expected		Appropriateness				
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total		
Female	365 358.51 77.17 52.75	74 78.229 15.64 49.01	34 36.265 7.19 48.57	473		
Male	327 333.49 74.32 47.25	77 72.771 17.50 50.99	36 33.735 8.18 51.43	440		
Total	692	151	70	913		
Frequency missing = 8						

Table 112 Pearson Chi-Square Test: gender – HU

Pearson Chi-Square Test	
Chi-Square	1.0120
DF	2
Asymptotic Pr > ChiSq	0.6029
Exact Pr ≥ ChiSq	0.6087

Conclusions: No significant association was found between the degree of appropriateness according to the ESR iGuide and patient gender (77% vs 74%; p=0.6).

5.6.6.6 Patient age group: Adult vs paediatric

ADULT

No further analysis was performed since children (less than 18 years old) were underrepresented. There were only 5 paediatric cases out of the 921 referrals scored (4 appropriate, 1 non-appropriate). AR for adults was 76% (see figure 45, which shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the adult population in HU).

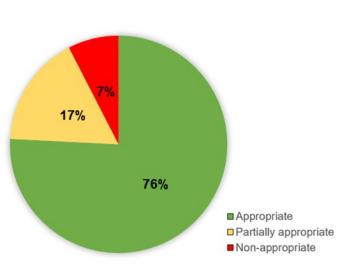


Figure 45 AR in the adult population – HU

5.6.6.7 Exam requested (detailed)

The radar chart below shows the appropriateness rate (AR) as function of the exam requested in the scored population in HU.

Appropriateness rate

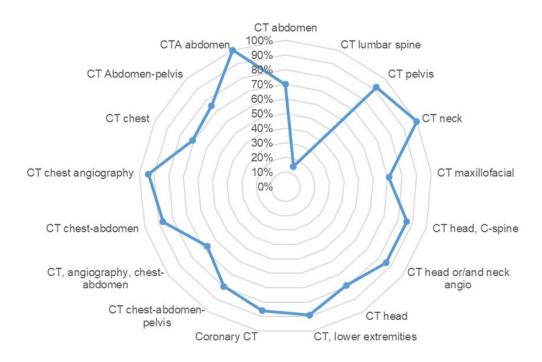


Figure 46 AR as function of the exam requested - HU

Note: Exams with less than 5 observations were omitted from the figure.

The table below shows the numbers of Appropriate, Partially appropriate and Non-appropriate requests and appropriateness rates (AR) for CT according to the type of CT examination (N=921, Missing/Undetermined=4) for HU.

Table 113 No. of Appropriate, Partially appropriate and Non-appropriate requests and AR according to type of CT examination – HU

Anatomical area	Appropriateness			AR (%)
Exam requested	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	
Abdomen	45	11	5	74%
CT Abdomen	38	11	5	70%
CTA Abdomen	7	0	0	100%
Abdomen-Pelvis	16	6	1	70%
CT Abdomen-pelvis	15	4	1	75%
CT Urography	1	2	0	33%

Chest	219	56	13	76%
CT Chest	156	53	12	71%
CT Chest angiography	63	3	1	94%
Chest-Abdomen	69	9	3	85%
CT Chest-abdomen	65	8	2	87%
CT, Angiography, chest- abdomen	4	1	1	67%
Chest-Abdomen-Pelvis	53	9	4	80%
CT Chest-abdomen-pelvis	53	9	4	80%
Coronarography	37	0	6	86%
Coronary CT	37	0	6	86%
Extremities	12	1	3	75%
CT Angiography lower extremities	2	0	2	50%
CT, Lower extremities	8	0	1	89%
CT, Upper extremities	2	1	0	67%
Head and neck	210	22	29	80%
CT Head	160	18	25	79%
CT Head or/and neck angiography	30	3	2	86%
CT Head, C-spine	6	0	1	86%
CT Maxillofacial	5	1	1	71%
CT Neck	8	0	0	100%
CT Neck + maxillofacial	1	0	0	100%
Head/Neck-Chest	5	1	0	83%
CT Head, CT pulmonary angiography	1	0	0	100%
CT Maxillofacial, neck, chest	0	1	0	0%
CT Neck, chest	4	0	0	100%

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Head-Abdomen	2	0	0	100%
CT Head, chest, abdomen	1	0	0	100%
CT Head, CT Abdomen	1	0	0	100%
Pelvis	12	0	1	92%
CT Pelvis	12	0	1	92%
Spine	11	36	7	20%
CT Cervical spine	1	1	0	50%
CT Lumbar spine	7	34	7	15%
CT Thoracic spine	0	1	0	0%
CT Thoracic-lumbar spine	3	0	0	100%
Whole-body / Polytrauma	3	0	0	100%
CT Whole-body / Polytrauma scan	3	0	0	100%
Undetermined	3	1	0	75%
Undetermined	3	1	0	75%
TOTAL	697	152	72	76%

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Conclusions: As there were many cells with very low frequency and Chi-square did not converge, no definitive conclusions could be made about the type of CT examination concerning appropriateness.

Appropriateness rates were higher for the following CT exam types: CT neck (100%), CT chest angiography (94%), CT pelvis (92%), CT chest-abdomen (87%), coronary CT (86%) and CT head or/and neck angiography (86%).

5.6.6.8 Referrer specialty (detailed)

The radar chart below shows the appropriateness rate (AR) as function of referrer specialty in the scored population in HU.

Appropriateness rate

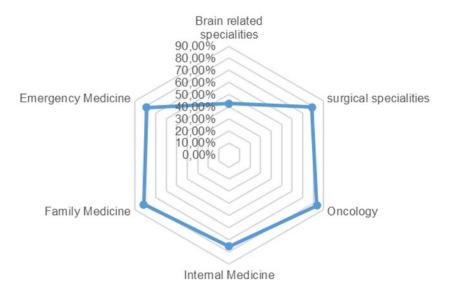


Figure 47 Radar chart: AR as function of referrer specialty – HU

The table below shows the association between referrer specialty and Appropriateness according to the ESR iGuide (N=921) for HU.

Table 114 Association between referrer specialty and Appropriateness – HU

Appropriateness by referrer speciality					
Frequency Expected	Appropriateness				
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total	
Brain related specialties	40 70.473 42.55 6.18	37 16.229 39.36 24.83	17 7.2978 18.09 25.37	94	
Emergency Medicine	143 136.45 78.57 22.10	32 31.423 17.58 21.48	7 14.13 3.85 10.45	182	
Family Medicine	66 60.727 81.48 10.20	12 13.985 14.81 8.05	3 6.2885 3.70 4.48	81	
Internal Medicine	150 149.19 75.38 23.18	27 34.358 13.57 18.12	22 15.45 11.06 32.84	199	
Oncology	102 91.465 83.61	16 21.064 13.11	4 9.4716 3.28	122	

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	15.77	10.74	5.97	
Surgical specialties	146 138.7 78.92 22.57	25 31.941 13.51 16.78	14 14.363 7.57 20.90	185
Total	647	149	67	863
Frequency Missing = 58				

Table 115 Pearson Chi-Square Test: referrer specialty - HU

Pearson Chi-Square Test		
Chi-Square	70.8912	
DF	10	
Asymptotic Pr > ChiSq	<0.0001	
Exact Pr ≥ ChiSq		

Conclusions: A significant association was found between the degree of appropriateness according to the ESR iGuide and the specialty of the referring physician (p<0.0001). Highest appropriateness rates were observed for oncology doctors (84%) and family medicine doctors (81.5%). The lowest appropriateness rate was observed for brain related specialties (43%).

5.6.6.9 Referrer specialty (GP vs Medical specialist)

The figure below shows the proportion of Appropriate, Partially Appropriate and Non-appropriate examinations in the scored population as function of referrer specialty (Family doctor/GP vs. Specialist doctor) in HU.

FAMILY DOCTOR/GP

SPECIALIST DOCTOR

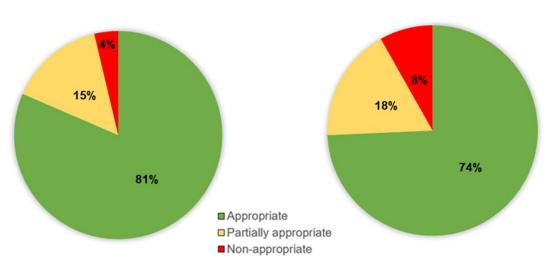


Figure 48 AR as function of referrer specialty – HU

Note: 55 out of 58 undetermined records for referrer specialty were set to undetermined because of discrepancies between the two auditors. The other 3 were unknown. In addition, general practitioners were actually residents in different specialties before board exam, especially in emergency medicine, so this classification is not relevant because general practitioners are not allowed to refer patients for CT examinations in Hungary.

The table below shows the association between referrer specialty (Family doctor/General practitioner vs. Specialist doctor) and Appropriateness according to the ESR iGuide (N=921) in HU.

Table 116 Association between referrer specialty (GP vs specialist) and Appropriateness – HU

Appropriateness by referrer specialty					
Frequency Expected	Appropriateness				
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total	
General practitioner	66 61.3 81.48 9.47	12 13.368 14.81 7.89	3 6.3322 3.70 4.17	81	
Medical specialist	581 591.81 74.30 83.36	137 129.06 17.52 90.13	64 61.134 8.18 88.89	782	
Total	647	149	67	863	
AR		Frequency missing =	58		

Table 117 Pearson Chi-Square Test: referrer specialty – HU

Pearson Chi-Square Test	
Chi-Square	2.7141
DF	2
Asymptotic Pr > ChiSq	0.2574
Exact Pr ≥ ChiSq	0.2461

Note: Two out of the four auditors used general practitioner/family doctor classification to identify medical doctors who had a working license as a GP/family doctor but at the time of the referral acted as doctors on behalf of the emergency department. The situation is the same if these medical doctors were residents just practicing for their specialisation and had recognition as a general physician. In Hungary, GPs/family doctors/general physicians are not permitted to refer patients to CT examinations.

Conclusions: No significant association was found between the degree of appropriateness according to the ESR iGuide and referrer specialty (grouped variable, emergency physician as presumed based on the note above vs medical specialist). In contrast to other countries, in Hungary the appropriateness rate was higher for requests referred by emergency physicians rather than by medical specialists (81% vs 74%; p=0.26), although the difference was not statistically significant.

5.6.6.10 Demographics and health system – Hungary

Population

9,769,526 (mid-year estimate, 2020)¹³ Inhabitants per county (2020)

Table 118 Population per county - HU

County	Population
Baranya	359,109
Borsod-Abaúj-Zemplén	637,064
Hajdú-Bihar	526,727
Csongrád-Csanád	398,332

-

¹³ State of Health in the EU, Hungary, Country Health Profile 2021. https://health.ec.europa.eu/system/files/2021-12/2021 chp hu english.pdf (accessed on 11 July 2023)

Healthcare system

Health spending in Hungary increased moderately in the years before the COVID-19 pandemic but remains below the EU average. Public funding accounts for two thirds of healthcare spending, which is below the EU average of 80 %, leading to high levels of outof-pocket spending.

The Hungarian health care system has a single health insurance fund for nearly all residents and is highly centralised.

The fund is administered by the National Institute of Health Insurance Fund Management (NEAK), operated under the Ministry of Human Capacities since 2017. The Ministry has exclusive power to set the strategy, controlling financing, determining the benefits package and issuing and enforcing regulations.

Until the end of 2020, the Ministry of Human Capacities administered the health care system through the National Healthcare Service Centre. The Centre was then absorbed by the newly established National Directorate-General for Hospitals under the Ministry of the Interior.

Following this change, local county hospitals have been responsible for planning and managing inpatient care at the county level, under the supervision of National Directorate-General for Hospitals.¹³

Equipment base

CT scanners per million population (2021): 10.3

MRI units per million population (2021): 5.15

PET scanners per million population (2021): 1.03⁷

Note: CT machines owned by a given institution (e.g., Borsod: 7) compared to the total (of 10) in the region. All centres are public only. Even if the equipment is not located on the same site or campus, these CTs are in the same region and organisationally in the same hospital.

Number of radiologists per million population

72⁸

Rationale for selection / representativeness of participating centres

Selection criteria of institutions to be included in the study were based on a discussion between the Hungarian Society of Radiologists and the National Center for Public Health and Pharmacy, considering the guidance of the EU-JUST-CT methodology. Throughout the selection procedure the following aspects were considered: willingness of the institution to participate; the institution itself and departments at different locations in the county or region should have a significant volume of referrals for at least 75 CT examinations per day, in order to obtain at least 250 referrals of adults in a few days; the given volume of referrals should be more than 50% of all CT referrals of the region; the selected institutions should have at least 50% of all the CT equipment available in the region; the institutions should not be located in the same region in order to be representative of different economic and geographical locations (regions are based on the NUTS-1 classification. 14)

¹⁴ https://en.wikipedia.org/wiki/NUTS_statistical_regions_of_Hungary

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Considering the selection criteria, the University of Pécs, the University of Szeged and the University of Debrecen, besides the Borsod-Abaúj-Zemplén (B-A-Z) County Central Hospital, joined the EU-JUST-CT project. These represent 3 of the 4 university hospitals and a central county hospital of the B-A-Z county. The following table summarises the equipment available in each of the selected institutions and their ratio of equipment in their respective counties:

Table 119 No. of CTs per county - HU

County	Total CTs	Selected	Ratio	Region
Borsod-Abaúj-Zemplén	10	7	70%	Northern Hungary
Hajdú-Bihar (Debrecen)	5	5	100%	Northern Great Plains
Csongrád (Szeged)	6	4	66,7%	Southern Great Plains
Baranya (Pécs)	7	5	71,4%	Southern Transdanubia

The institutions listed thus fulfilled the selection criteria and expressed their willingness to participate in the study.

Efforts regarding implementation of justification

A few radiological service providers made local studies on the contents of the referrals they received. As an example, the University of Debrecen checked referrals and compared them to international guidance documents, discussed the results in-house then used the experience as a feedback for their procedures. Unfortunately, these results were not officially published. Hungary also participated in the HERCA campaign on communication between the patient and the referrer¹⁵. Besides the aforementioned initiatives, no further campaigns were carried out nor are they planned for the near future.

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¹⁵https://www.haea.gov.hu/web/v3/OAHportal.nsf/web?OpenAgent&article=news&uid=62DD21FC3C5891EDC12584BA002 470C8

5.6.7 Slovenia

5.6.7.1 General overview

Table 120 Sample overview - SI

	N	% of total	% of scored
Number of audited referrals (Total)	1024	100%	
Of which removed from analysis (duplicates, invalid data)	9	0.88%	
Of which unscored referrals (no/insufficient clinical data)	266	26.86%	
Of which scored	749	73.14%	
Fully appropriate (score 7-9)	594	58.01%	79.3%
Partially appropriate (score 4-6)	96	9.38%	12.8%
Inappropriate (score: 1-3, 0*)	59	5.76%	7.9%

 $^{^{*}0}$ – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Percentage of scored/unscored referrals - SI

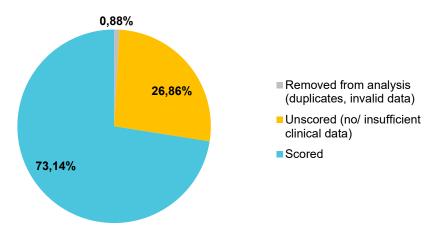


Figure 49 Percentage of scored/unscored referrals – SI

- Data quality in Slovenia is average with about 27% referrals unscored due to insufficient clinical data (in Slovenia it was not possible to differentiate between insufficient data and "clinical reasons not found in the ESR iGuide" due to the deficiency of data as was also remarked by both auditors).
- ⇒ 79.3% of the <u>scored population</u> (594 out of 749) were rated "Fully appropriate" (score 7-9).

⇒ 20.7% of the <u>scored population</u> (155 out of 749) resulted in a score less than 7 and were classified as "Inappropriate" according to a binary variable (7-9 appropriate, <7 inappropriate)

Table 121 Details of referrals removed from analysis - SI

Delete reason	N	%
No referral ID	1	11%
Duplicate entry	8	89%
Total	9	100%

⇒ Most of removed referrals (89%) were due to duplicate entries.

The table below shows the more Appropriate examinations in those cases where CT imaging was marked as inappropriate (score less than 7), according to both auditors, for SI.

Table 122 More Appropriate examinations if CT was inappropriate - SI

More appropriate exam	n (N = 155)	% of total
No other exam was recommended	20	13%
Other exam was recommended	135	87%
MRI	60	39%
Other CT	27	17%
X-ray	21	14%
US	13	8%
Other CT/X-ray	3	2%
US/other CT	3	2%
MRI/X-ray	2	1%
X-ray/US	2	1%
MRI/US	1	1%
MRI/X-ray/US	1	1%

MRI/US/other CT	1	1%
PET-CT/other CT	1	1%

- ⇒ In 13% of referrals scored inappropriate (less than 7), no other study was recommended by either of the auditors. Accordingly, in 87% of the referrals, at least one more appropriate examination was suggested by one or both auditors. In 9% of the referrals more than one test modality was suggested as more appropriate (usually one by one auditor and one by the second auditor).
- ⇒ The most frequent "more appropriate examination" was MRI. In 42% of the referrals scored inappropriate (less than 7), the more appropriate recommendation was MRI or a combination of MRI and other exam modality.
- ⇒ In 22.5% of referrals scored inappropriate (less than 7), the "more appropriate" recommendation was another CT (different from the one referred to) or a combination of CT and other exam modality.
- ⇒ In 19% of referrals scored inappropriate (less than 7), the more appropriate recommendation was X-ray or a combination of X-ray and other exam modality.
- ⇒ In 13% of referrals scored inappropriate (less than 7), the more appropriate recommendation was US or a combination of US and other exam modality.

5.6.7.2 Analysis of CT orders regarding ESR assessment of appropriateness (summary tables)

The following table shows the association between explanatory variables and Appropriateness according to the ESR iGuide (N=749). Pearson Chi-Square Test/Fisher's Exact Test (a binary variable was used, Appropriate meaning score 7-9 and Non-appropriate score less than 7) for SI.¹

Table 123 Association between explanatory variables and Appropriateness – SI

Variable	Appropriate (AR) (N=594)	Non-appropriate (N=155)	P-value*
Institution: Private Public	122/180 (67.8%) 472/569 (82.9%)	180/58 (32.2%) 97/569 (17.05%)	<0.0001*
Patient Status: Inpatient Outpatient Missing=24	130/154 (84.4%) 441/571 (77.2%) 23/24 (95.8%)	24/154 (15.6%) 130/571 (22.8%) 1/24 (4.2%)	0.0531
Gender: Female Male Missing=32	279/363 (76.9%) 287/354 (81.1%) 28/32 (87.5)	84/363 (23.1%) 67/354 (18.9%) 4/32 (12.5%)	0.1665
Patient Age group: Adult Child	561/712 (78.8%) 4/5 (80%) 29/32 (90.6%)	151/712 (21.2%) 1/5 (20%) 3/32 (9.4%)	1.0000

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Missing=32			
Referrer Specialty: Brain related specialties Emergency Medicine Family Medicine Internal Medicine Oncology Radiology Surgical specialties Missing ² =107	45/51 (88.2%) 33/35 (94.3%) 89/129 (69%) 124/146 (84.9%) 55/65 (84.6%) 48/72 (66.7%) 118/144 (81.9%) 82/107 (76.6%)	6/51 (11.8%) 2/35 (5.7%) 40/129 (31%) 22/146 (15.1%) 10/65 (15.4%) 24/72 (33.3%) 26/144 (18.1%) 25/107 (23.4%)	0.0003*
Referrer Specialty (grouped): Family medicine Specialist doctor Missing ² =107	89/129 (69%) 423/513 (82.5%) 82/107 (76.6%)	40/129 (31%) 90/513 (17.5%) 25/107 (23.4%)	0.0007*

^{*}Statistically significant at the level of p ≤ 0.05

The following table shows the numbers of appropriate and inappropriate requests and appropriateness rates (AR) according to the type of CT examination (N=749, Missing=11) for SI.

Table 124 No. of Appropriate and Non-appropriate requests and AR according to type of CT examination – SI

Anatomical area	Appropriate (N=594)	Non- appropriate (N=155)	AR (%)
Abdomen	132	27	83%
Abdomen-Pelvis	23	4	85%
CT guided punction of organ	1	0	100%
CTA, abdomen pelvis and lower extremities	3	0	100%
Chest	116	26	82%
Chest-Abdomen	43	4	91%
Chest-Abdomen-Pelvis	2	0	100%
Chest-Neck	2	0	100%
Coronography	18	2	90%

¹ All statistical tests in this report were performed without the "Missing" category.

² Missing values may be because data is missing or because inconsistencies between both auditors in respect to that variable that could not be resolved by arbitration.

Extremities	26	14	65%
Head (/neck)-Chest-Abdomen	21	4	84%
Head and neck	169	59	74%
Head-Abdomen	2	1	67%
Pelvis	3	1	75%
Pelvis-lower extremities	10	0	100%
Spine	14	11	56%

Conclusions: A significant association was found between the degree of appropriateness according to the ESR iGuide and belonging to a public or private institution (p<0.0001), the status of the patient (p=0.053) and the specialty of the referring physician (p=0.0001), with a lower appropriateness rate in the private sector and for ambulatory (outpatient) care compared to public sector and hospitalisation. The appropriateness rate was lower in family/general physicians as compared to specialist doctors (69% vs 82.5%, respectively, p=0.0007).

No association could be found for anatomical area and ESR appropriateness due to the low frequencies of some of the cells (Exact Chi-square did not converge).

5.6.7.3 Institution: Public vs private

The figure below shows the proportion of Appropriate, Partially appropriate and Non-appropriate in the scored population as function of being a private/public institution for SI.

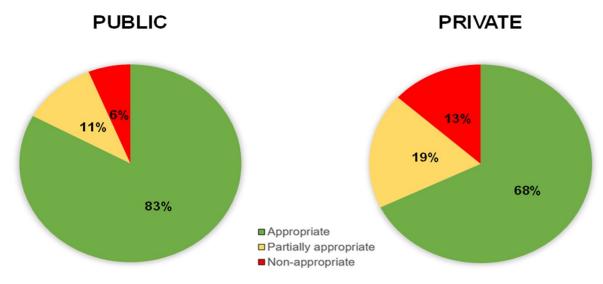


Figure 50 AR as function of private/public institution - SI

The table below shows the association between private/public institution and Appropriateness according to the ESR iGuide (N=749) for SI.

Table 125 Association between private/public institution and Appropriateness – SI

Frequency Expected	Appropriateness			
Row Pct Col Pct	Appr (7-9)	Partially Appr (4-6)	Non-Appr (0*-3)	Total
Private	122 142.75 67.78 20.54	34 23.071 18.89 35.42	24 14.179 13.33 40.68	180
Public	472 451.25 82.95 79.46	62 72.929 10.90 64.58	35 44.821 6.15 59.32	569
Total	594	96	59	749

There were 180
CTs performed in private institutions, 24 of them were Non-appropriate (13.33%).

In total there are 59
Non-appropriate CTs, 24 of them from private institutions (40.68%).

14.179 is the estimated expected value in private institutions under the hypothesis of

Table 126 Pearson Chi-Square Test: private/public -SI

Pearson Chi-Square Test	
Chi-Square	19.7404
DF	2
Asymptotic Pr > ChiSq	<0.0001
Exact Pr ≥ ChiSq	<0.0001

Conclusions: The appropriateness rate was higher when the CT examinations occurred in public institutions as compared to private institutions (83% vs 68%; p<0.0001).

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

5.6.7.4 Patient status: Inpatient vs outpatient

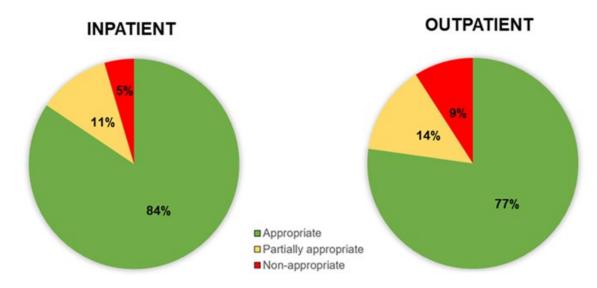


Figure 51 AR as function of inpatient/outpatient status - SI

The table below shows the association between patient status and Appropriateness according to the ESR iGuide (N=749) for SI.

Table 127 Association between patient status and Appropriateness – SI

Appropriateness by patient status				
Frequency Expected Row % Col %	Appropriateness			
	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total
Inpatient	130 121.29 4 84.42 22.77	17 20.179 11.04 17.89	7 12.532 4.55 11.86	154
Outpatient	441 449.71 77.23 77.23	78 74.821 13.66 82.11	53 46.468 9.11 88.14	571
Total	571	95	59	725
Frequency Missing = 24				
AR				

 $^{^{\}star}0$ – This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 128 Pearson Chi-Square Test: patient status - SI

Pearson Chi-Square Test	
Chi-Square	4.5315
DF	2
Asymptotic Pr > ChiSq	0.1038
Exact Pr ≥ ChiSq	0.1082

Conclusions: The appropriateness rate was higher when the CT examinations were performed during hospitalisation as compared to ambulatory care (84% vs 77%; p=0.1038).

5.6.7.5 Patient gender

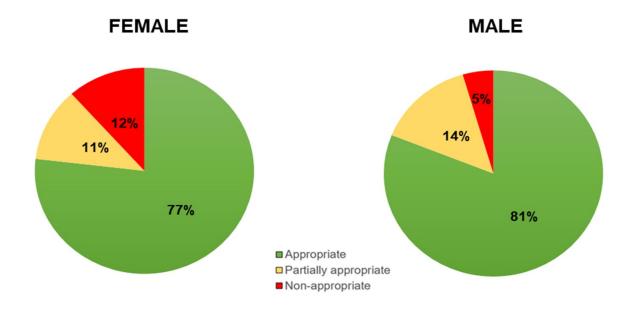


Figure 52 AR as function of gender – SI

The table below shows the association between gender and Appropriateness according to the ESR iGuide (N=749) for SI.

Table 129 Association between gender and Appropriateness – SI

Appropriateness by gender				
Frequency Expected Row % Col %	Appropriateness			
	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total
Female	279 286.55 76.86 49.29	42 47.084 11.57 45.16	42 29.364 11.57 72.41	363
Male	287 279.45 81.07 50.71	51 45.916 14.41 54.84	16 28.636 4.52 27.59	354
Total	566	93	58	717
Frequency Missing = 32				
AR				

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 130 Pearson Chi-Square Test: gender - SI

Pearson Chi-Square Test	
Chi-Square	12.5282
DF	2
Asymptotic Pr > ChiSq	0.0019
Exact Pr ≥ ChiSq	0.0018

Conclusions: The appropriateness rate was higher when the CT examinations concerned male population as compared to female population (81% vs 77%; p=0.0019), although this association was not significant when using a binary variable for appropriateness, suggesting the differences are mainly in the ratio between partially appropriate and non-appropriate.

5.6.7.6 Patient age group: Adult vs paediatric

No further analysis was performed since children (less than 18 years old) were underrepresented. There were only 5 paediatric cases out of the 749 referrals scored.

5.6.7.7 Exam requested (grouped)

Appropriateness rate

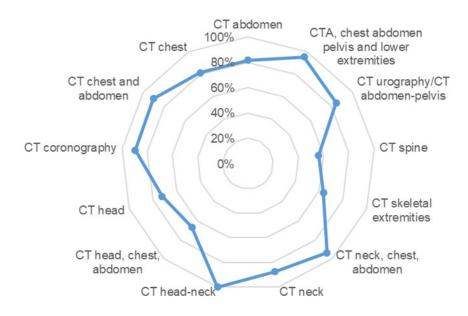


Figure 53 AR as function of exam requested - SI

Note: Exams with less than 5 observations were omitted from the figure.

The table below shows the numbers of Appropriate, Partially appropriate and Non-appropriate requests and appropriateness rates (AR) for CT according to the type of CT examination (N=749, Missing=11) for SI.

Table 131 No. of Appropriate, Partially appropriate and Non-appropriate requests and AR according to type of CT examination – SI

Exam requested	Appr (7-9)	Partially appr (4-6)	Non-appr (0*-3)	AR (%)
CT Abdomen	121	19	8	82%
CT Chest	112	14	12	81%
CT Chest and abdomen	38	3	1	90%
CT Chest, neck	3	0	0	100%
CT Coronography	17	0	2	89%
CT Guided punction of organ	1	0	0	100%
CT Head	150	37	20	72%

CT Head and abdomen	2	1	0	67%
CT Head, chest, abdomen	6	3	0	67%
CT Head-neck	5	0	0	100%
CT Liver	2	0	0	100%
CT Neck	14	1	1	87%
CT Neck, chest, abdomen	15	1	0	94%
CT Pelvis	1	1	0	50%
CT Skeletal extremities	21	5	7	64%
CT Spine	14	5	6	56%
CT Urography/CT Abdomen-pelvis	22	3	1	85%
CT, Chest-abdomen-pelvis	2	0	0	100%
CTA, Chest abdomen pelvis and lower extremities	39	2	0	95%
TOTAL	585	95	58	

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Conclusions: As there are many cells with very low frequency and Chi-square did not converge, no definitive conclusions can be made about the type of CT examination concerning appropriateness.

The appropriateness rate was higher when the CT examinations concerned CTA, chest abdomen pelvis and lower extremities (95%); CT neck, chest, abdomen (94%), CT chest and abdomen (90.5%), CT coronography (89.5%), CT urography/CT abdomen-pelvis (85%) rather than CT head (72.5%), CT skeletal extremities (63.7%) and CT spine (56%).

5.6.7.8 Referrer specialty (detailed)

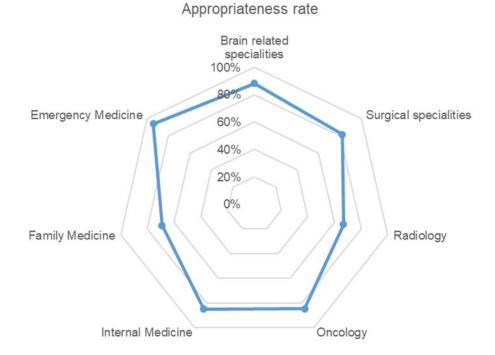


Figure 54 Radar chart: AR as function of referrer specialty – SI

The table below shows the association between Referrer Specialty and CT Appropriateness according to the ESR iGuide (N=749) for SI.

Table 132 Association between referrer specialty and Appropriateness – SI

Appropriateness by referrer specialty						
Frequency Expected		Approp	riateness			
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total		
Brain related specialties	45 40.51 88.24 7.67	3 6.4181 5.88 3.23	3 4.0717 5.88 5.08	51		
Emergency Medicine	33 27.801 94.29 5.62	1 4.4046 2.86 1.08	1 2.7943 2.86 1.69	35		
Family Medicine	89 102.47 68.99 15.16	18 16.234 13.95 19.35	22 10.299 17.05 37.29	129		
Internal Medicine	124 115.97	16 18.373	6 11.656	146		

	84.93 21.12	10.96 17.20	4.11 10.17	
Oncology	55 51.631 84.62 9.37	8 8.18 12.31 8.60	2 5.1894 3.08 3.39	65
Radiology	48 57.191 66.67 8.18	14 9.0609 19.44 15.05	10 5.7483 13.89 16.95	72
Unknown	75 77.049 77.32 12.78	15 12.207 15.46 16.13	7 7.7442 7.22 11.86	97
Surgical specialties	118 114.38 81.94 20.10	18 18.122 12.50 19.35	8 11.497 5.56 13.56	144
Total	587	93	59	739

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 133 Chi-Square: referrer specialty - SI

Statistic	DF	Value	Prob
Chi-Square	14	37.6611	0.0006
Likelihood Ratio Chi-Square	14	36.8497	0.0008

Conclusions: In general appropriateness rates were higher for requests referred by medical specialists (emergency medicine 94%, brain related specialties 88%, internal medicine 85%, oncology 85%, and surgical specialties 82%) than by general practitioners (AR=69%), p=0.0006. Surprisingly, radiology specialists showed a relatively low appropriateness rate (67%).

5.6.7.9 Referrer specialty (GP vs medical specialist)

The figure below shows the proportion of Appropriate, Partially Appropriate and Non-appropriate in the scored population as function of Referrer Specialty (Family doctor/General practitioner vs. Specialist doctor) for SI.

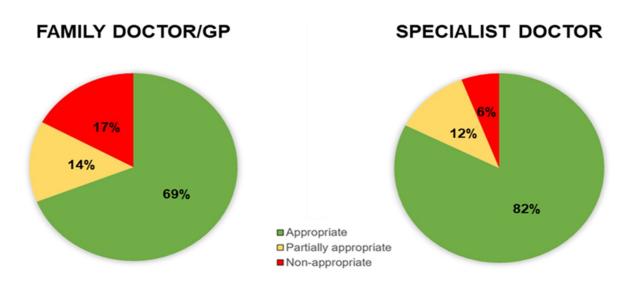


Figure 55 AR as function of referrer specialty - SI

The table below shows the association between referrer specialty (Family doctor/General practitioner vs. Specialist doctor) and Appropriateness according to the ESR iGuide (N=749) for SI.

Table 134 Association between referrer specialty (GP vs specialist) and Appropriateness – SI

Appropriateness by referrer specialty (GP vs specialist)					
Frequency Expected		Арргорі	riateness		
Row % Col %	Appr (7-9)	Partially Appr (4-6)	Non-appr (0*-3)	Total	
Female	89 102.88 4 68.99 17.38	18 15.673 13.95 23.08	22 10.449 17.05 42.31	129	
Male	423 409.12 •82.46 82.62	60 62.327 11.70 76.92	30 41.551 5.85 57.69	513	
Total	512	78	52	642	
	Freq	uency Missing = 107			
AR					

^{*0 –} This score represents cases for which no match was found in the ESR iGuide but the examination was considered inappropriate by the auditor.

Table 135 Pearson Chi-Square Test: referrer specialty - SI

Pearson Chi-Square Test	
Chi-Square	18.7574
DF	2
Asymptotic Pr > ChiSq	<0.0001
Exact Pr ≥ ChiSq	0.0001

Conclusions: The appropriateness rate was higher for requests referred by medical specialists than by general practitioners (82% vs 69%, p<0.0001).

5.6.7.10 Demographics and health system - Slovenia

Population

2,095,861 (mid-year estimate 2020)16

Healthcare system

Slovenia has a compulsory social health insurance system with a single public insurer, which provides near universal coverage and a broad benefits package. The system is largely financed through social health insurance contributions. Voluntary health insurance plays an important role in covering co-payments.

Hospital care is centralised. The state owns almost all hospital capacity, the largest share of outpatient specialist care and the entire tertiary care sector. Inpatient hospital care is provided by 30 – mostly public – hospitals. Primary care is decentralised.

Health expenditure per capita has risen marginally over the last few years but remains well below the average EU rate. Out-of-pocket spending is among the lowest in the EU, however, mainly thanks to voluntary health insurance covering co-payments.¹⁶

Regarding the general availability of the radiological examinations, many private facilities provide examinations that are covered by private insurance companies.

Equipment base

CT scanners per million population (2022): 18.51 MRI units per million population (2021): 13.28 PET scanners per million population (2022): 1.42⁷

Number of radiologists per million population

119⁸

¹⁶ State of Health in the EU, Slovenia, Country Health Profile 2021. https://health.ec.europa.eu/system/files/2021-12/2021 chp sl english.pdf (accessed on 10 July 2023)

Rationale for selection / representativeness of participating centres

As Slovenia is a small country with approximately 2 mio. Inhabitants and only 22 institutions that are performing Computed Tomography, it was decided to include all centres in Slovenia. This approach provided the most reliable overview of the current situation in the country.

Efforts regarding implementation of justification

While some limited audits related to paediatric CT were carried out in the largest clinical centre in Slovenia a few years ago, no systematic audits on justification of radiological procedures have been performed until this project. It is planned to use the findings of the EU-JUST-CT project as a basis for a formal audit on CT justification after the final results are received. A campaign on justification of radiological examinations was prepared in the scope of HERCA's European communication campaign "Getting the right image for my patient" at the start of 2020 but it has been overshadowed by the outbreak of the COVID pandemic.

5.8. Summary/conclusions

5.8.1 Explanatory elements for the low number of paediatric CTs

Very low numbers of paediatric CT examinations were observed in all countries, in the range of 5-27 per country (5 Denmark, 5 Slovenia, 6 Greece, 7 Estonia, 8 Hungary, 14 Finland, 27 Belgium). Belgium had the highest number of children examined (27) and a slightly lower appropriateness rate for children as compared to adults. The high number of paediatric CTs might be due to the fact that some of the Belgian hospitals selected have a separate radiology unit dedicated to children. In other countries numbers of examined children were too low to perform a reasonable analysis. We believe that the real situation was captured, reflecting the fact that paediatric radiologists in Europe are increasingly aware that the preferred modalities for paediatric imaging examinations are ultrasound and MRI rather than X-ray imaging. This observation of declining numbers of paediatric CT examinations in Europe was discussed at a meeting of the ESR EuroSafe Imaging Paediatric Imaging Working Group held during the European Congress of Radiology (ECR) 2023, and it was one of the conclusions of the WG meeting.

5.8.2 Difference in justification rate between general practitioners (GPs) and (other) specialist doctors

Appropriateness rates were statistically significantly lower for general practitioners (GPs) compared to (other) specialist doctors in Belgium, Denmark (where general practitioner is a medical specialty) and Slovenia. In Greece GPs also had lower appropriateness rates than specialists, but there were only 20 referrals from GPs, so statistical significance was not reached. Data about specialist types were not available for Finland, and in Estonia no GPs referred patients, so no analysis was possible for Finland and Estonia. The only perceived outlier was Hungary, where two out of the four auditors classified those physicians who had a working license as GPs/family doctors, but at the time of the referral acted as doctors on behalf of the emergency department. The lowest appropriateness rates in Hungary were observed with brain-related specialists. Differences in justification

rates between GPs and specialist doctors reflect the situation that specialist doctors in Europe have more expertise in their specialty fields to refer patients for the specific imaging modalities as compared to general practitioners, who need to deal with a wide spectrum of diseases and clinical situations. In addition, GPs might have less clinical background information than (other) specialist doctors, who refer the patient at a later stage. This appears logical and was observed also in previous audit projects.

5.8.3 Difference in appropriateness rate between body regions

Differences in appropriateness rates between body regions were observed and in six countries (all except Finland) spine had quite low appropriateness rates, followed by extremities (Belgium, Slovenia, Greece) and pelvis (Denmark, Greece, Estonia). In Finland the lowest appropriateness rate was observed in polytrauma whole body CT. The results are comparable to the audit study in Luxembourg [4], where the appropriateness rate for the spinal area was very low with only 28% for the lumbar spine as well as for extremities with an appropriateness rate of only 50% for lower extremities.

5.8.4 Understanding the differences between public/private facilities

In most countries the balance between public and private institutions was considerably on the side of public institutions, with the exception of Greece. In Hungary all audited facilities were public. In Belgium public and formally private hospitals have the same model of administrative and financial management and the same justification rules and patterns, but better appropriateness rates were observed in the public system in Belgium, like in the other countries. Finland and Denmark have only very small proportions of private centres, which performed a very low number of examinations, so the differences have not reached statistical significance. In Slovenia, Belgium, Greece and Estonia a statistically significant difference was demonstrated in the appropriateness score between public and private centres, and the appropriateness rates were significantly higher for examinations performed in public institutions.

5.8.5 Understanding the overall correlation between justification efforts and audit results

The results obtained point to the conclusion that overall, a correlation exists between justification efforts in specific countries and the audit results.

Considerable justification efforts have so far been performed in Belgium, Denmark and Finland.

In Belgium a national audit on the use of CT and MRI equipment took place in 2020. This audit did not focus on justification as such but provided a valuable overview of the situation in the country. For instance, some currently unexplained regional differences were observed, upon which further studies or actions can be initiated. A large effort to raise awareness among radiologists, medical specialists, general practitioners and the public has been made by the Belgian Medical Imaging Platform (BELMIP). Specific magazines on medical imaging for certain indications, such as lower back pain but also peripheral trauma in children, have been published and spread among all Belgian medical doctors. Public awareness campaigns with slogans such as "X-rays are no holidays pictures" are carried out.

In Denmark justification of radiological examinations is always addressed during inspections by the Radiation Protection Authority, in terms of reviews of procedures for justification. A separate series of inspections with this focus was also carried out as part of the HERCA Inspection Campaign in late 2016. Denmark also participated in the HERCA communication campaign "Getting the right image for my patient" in 2019.

Finland is one of the first countries to carry out clinical audits on the justification of CT examinations. Finland was able to show through clinical auditing that justification of CT examinations can be improved by education, the use of referral guidelines and increased MRI capacities.

Finland, Denmark and Belgium show the best results within the project, with the highest scores of appropriate and the lowest scores of inappropriate exams as well as very low numbers of examinations that could not be scored due to lacking or insufficient data in the referral. One of the reasons for these high appropriateness levels might be the fact that in Denmark and Finland previous images or clinical information/history are sought in all cases and in Belgium in 82% of cases.

In Hungary, a few radiological service providers performed local studies on the contents of the referrals they received, but the results were not officially published. Hungary also participated in the HERCA campaign on communication between the patient and the referrer. Since no further campaigns were carried out nor are planned for the near future, it is to be hoped that the EU-JUST-CT project will incentivise Hungarian authorities to increase efforts regarding the implementation of justification.

With clinical audit having become a requirement, Estonia plans to establish a body conduct external audits as well as a national procedure for clinical audits. Estonia was part of the HERCA communication campaign "Getting the right image for my patient" in 2019.

While some limited audits related to paediatric CT were carried out in the largest clinical centre in Slovenia a few years ago, no systematic audits of justification of radiological procedures have been performed so far. It is planned to use the findings of the EU-JUST-CT project as a basis for a formal audit on CT justification. A campaign on justification of radiological examinations was prepared in the scope of HERCA's European communication campaign "Getting the right image for my patient" at the beginning of 2020 but was overshadowed by the outbreak of the COVID-19 pandemic.

In Greece there is no national committee performing audits of the justification of radiological examinations. However, the Greek NCA is not aware whether internal audits are performed at a hospital/local level. Greece participated in HERCA's European communication campaign "Getting the right image for my patient" in 2019. It is also worth noting that Greece has the highest number of CT scanners per population.

It remains to be hoped that the results of the EU-JUST-CT project will encourage authorities in Greece and Slovenia, and probably also in Hungary and Estonia, to increase efforts regarding the implementation of justification, especially to reduce the rate of referrals with no or insufficient data.

5.8.6 Lessons learned/recommendations for countries wishing to carry out audits

- Quality of the auditors
- Quality of referrals

For countries wishing to carry out audits it is crucial to select auditors who are willing to dedicate sufficient time and energy to perform high-quality audits. Although the auditors within the present project were reimbursed for their work, several auditors dropped out and had to be replaced. Reimbursement was the same for all countries. Some auditors felt that the task of performing the audits was overwhelming as it had to be performed after hours with considerably less payment compared to what they would earn by reporting exams. The issue of providing financial support for auditors has been well covered in the QuADRANT project.¹⁷

Some auditors claimed that they were not able to perform the requested tasks because of their complexity. Overall, the auditors performed well, although the arbitration process revealed that in some instances one of the two auditors performed less well than expected. This may be due to lack of time, which is in general an issue for auditors, as was also shown by the QuADRANT project.

The quality of referrals was very diverse according to the findings of the project's arbitration team. Referrals were excellent in Finland, with abundant clinical data available (although unfortunately no data were provided about the specialty of referrers or whether patients were inpatients or outpatients), of a relatively high quality in Denmark and Belgium, and of a reasonable quality in Estonia, to mention some examples of good practice.

Ensuring a high quality of the referrals is therefore a clear recommendation to member countries.

5.8.7 Impact of MRI availability

According to the survey of centres/institutions that were planned to be audited before the collection of referrals started, MRI is available in 74% of facilities (52 out of 70). It is available in all facilities in Belgium, Denmark, Finland and Hungary, in 75% of facilities in Slovenia, in 58% in Greece and in 53% of facilities in Estonia. Three countries that had the best results had MRIs available in all institutions, so one may conclude that the availability of MRI does make a difference. This might especially be the case in Finland considering its high rate of MRI scanners available per population, which exceeded the rate of CT scanners. However, even if MRIs are not available in an imaging facility, they are nowadays available nearby. Hence, the lack of MRI in a particular imaging facility most likely does not considerably limit access to MRI for patients. In most countries, the most appropriate examination in cases where CT was inappropriate was MRI, so access to MRI is important.

5.8.8. Most appropriate examination if CT was inappropriate (if data available)

In five countries (Belgium, Denmark, Estonia, Slovenia, Hungary) MRI was the most appropriate examination if CT was inappropriate, with percentages ranging from 18% to 39% (39%, 18%, 32%, 39%, 32%). In Greece the most appropriate alternative examination was X-ray (33%) and in Finland other CTs (26%), followed by MRI (21%). MRI is thus the most appropriate examination in the majority of cases, followed by X-ray, other CTs, and ultrasound. The fact that MRI is the most appropriate alternative examination in most cases is similar to the situation observed in the audit study in Luxembourg.

¹⁷ http://www.eurosafeimaging.org/clinical-audit/quadrant

5.8.9 Correlation between quality assurance and quality of results

Based on the survey responses received from centres to be audited before the project started, the countries with the highest percentages of departments applying quality assurance with written procedures describing the justification process in the imaging centre are Denmark, Belgium and Finland. For these countries, the level of appropriateness of CT examinations is very high, which means that a correlation exists between the availability of written procedures for justification and appropriateness.

5.8.10 Correlation between referral guideline availability and quality of results

The survey of departments to be audited revealed that referral guidelines are available in all responding facilities in Denmark and Finland and in over 70% of the facilities in Belgium, while they are not or only partly available in Hungary and available in 25%-47% of the facilities in Greece, Slovenia and Estonia. Even if guidelines are available at the facility, they are implemented completely in the clinical decision support system available to the referrer in only 26.7% (12 out of 45) of cases and partially implemented in 13.4% (6 cases). Clinical decision support is thus at least partially available in only 40% of the facilities that have referral guidelines available. Although Finland, Denmark and Belgium have the best results, the answers demonstrate that guidelines are not used extensively, especially not in the form of clinical decision support available to referrers.

5.8.11 Difference in appropriateness rates between inpatient and outpatient settings

For all countries, the appropriateness rate for CT was better for inpatient/emergency than for ambulatory (outpatient) care. This appears logical, as emergency care physicians are particularly well trained and experienced in this regard and therefore have a thorough understanding of the clinical yield of CT examinations. Also, inpatients, who are hospitalised in different wards, are directed to CT examinations based on their clinical status evaluated by usually subspecialised expert physicians in the hospital. As for ambulatory care patients, the likelihood that they are referred to inappropriate CT examinations is higher if the referral is made by physicians who are not specialised or subspecialised.

5.8.12 COVID-19 situation at the time of referral collection and related impact

The present project was performed during the time of the COVID-19 pandemic. The proportion of patients with COVID-19 who were referred for CT examinations varies widely between countries and was by far the highest in Hungary. COVID-19 was not included as an indication in the ESR iGuide imaging referral guidelines. The large majority of these cases was arbitrated as appropriate, based on clinical practice and knowledge accumulated during the pandemic. This may have somewhat skewed the situation compared to non-pandemic circumstances and increased the appropriateness rates in countries with high proportions of SARS-CoV-2 positive referrals or COVID-19 follow-up examinations. Among the audited referrals, there were 146 COVID-19 patients in

Hungary, 75 in Greece, 16 in Slovenia, 11 in Belgium, 11 in Estonia, 8 in Denmark, and 7 in Finland.

5.8.13 Key findings

Key findings

- Awareness of legal aspects of radiation protection and justification still needs to be increased among Member States.
- The appropriateness rates of the scored referrals in the seven pilot countries/regions varied between 57.9% and 85.9%, showing a large disparity between countries and the need for further action to improve justification of CT examinations.
- The proportion of examinations whose appropriateness could not be assessed because of no or insufficient clinical data also varied considerably between countries (from 0.3% to 27%).
- Appropriateness rates were lower for general practitioners compared to (other) specialist doctors.
- Differences in appropriateness rates between body regions were observed and in six countries spine had quite low appropriateness rates, followed by extremities and pelvis. The results are comparable to those of the audit study in Luxembourg.
- Differences in appropriateness rates were observed between public and private institutions with better appropriateness rates in public institutions.
- MRI was the most appropriate examination in many cases where the CT examination was inappropriate.
- The appropriateness rate for CT was better for inpatient/emergency patients than for outpatients.
- The results obtained point to the conclusion that overall, a correlation exists between justification efforts in specific countries and the audit results. Considerable justification efforts have so far been performed in Belgium, Denmark and Finland.
- The availability and use of imaging referral guidelines is crucial in the process of justification of CT examinations.
- Access to patient history and record is an integral part of the justification process.
- EU member states need to work on improving the quality of referrals for CT examinations in order to enable justification to take place.
- Education and training on justification and clinical audit are essential to improve the implementation of the process of justification.

5.8.14 Suggestions to improve the justification of CT examinations

Suggestions to improve the justification of CT examinations

- Ensure the availability and use of imaging referral guidelines as part of clinical decision support systems so that referrers are required to consult referral guidelines before submitting a referral
- Ensure access to patient history and record
- Improve the quality of referrals for CT examinations in order to enable justification to take place
- Provide education and training on justification and clinical audit
- Perform regular audits of CT justification
- Provide for inspection of justification and clinical audit of justification
- Ensure earlier involvement of the medical practitioner in the process of justification of CT examinations

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Annex 2: Final Audit Methodology and Tools

European co-ordinated action on improving justification of computed tomography

Audit Methodology and Tools

April 2023

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1. Introduction

The Tender entitled 'European coordinated action on improving justification of computed tomography' (acronym: EU-JUST-CT) started on 7 April 2021 and will last until March 2024. The project aims to improve justification of computed tomography in Europe through coordinated action.

The specific objectives of this project are to:

- a) Collect up-to-date information about justification of CT examinations in Europe.
- b) Develop a common methodology for auditing justification of CT examinations.
- c) Carry out co-ordinated pilot audits of justification of CT examinations.
- d) Discuss the status of justification of CT examinations with the Member States and identify opportunities for further action.

The EU-JUST-CT Project team has developed a common methodology and tools for carrying out the co-ordinated national/regional audits of justification of diagnostic CT examinations (adult and paediatric). Referrals for CT examinations for radiotherapy treatment planning, SPECT-CT, PET-CT, CBCT, as well as referrals for interventional procedures carried out with CT imaging, are excluded from these audits.

The common methodology takes into account the lessons learned from the literature review carried out in the EU-JUST-CT project, as well as any guidance in the subject area issued by the relevant European regulatory and professional societies and networks. Furthermore, the methodology defines the procedures for sampling, auditing the justification outcomes, and determination of the rates of appropriateness for the different types of CT examinations, against pre-defined audit standards. The methodology foresees mechanisms to identify and analyse the sampling method that should be scientifically sound and reproducible, the differences between adult and paediatric populations, public and private institutions, general practitioners and clinical specialist referrals, etc.

The methodology of the audit process in Northern Ireland 1 and Luxembourg 2 has been adapted and adopted, taking into account the literature review carried out during the EU-JUST-CT project.

Individual justification of CT examinations is a process through which it is ensured that the patient undergoes the appropriate examination in accordance with the clinical indications and the reason for the examination specified on the referral. If the CT examination requested is not appropriate according to the clinical indications and the reason for the examination specified on the referral, then it is considered to be inappropriate.

The process of justification is implemented when the referral is reviewed by a radiological practitioner. The radiological practitioner then decides whether the requested examination on the referral is the appropriate one, whether the requested examination should be changed into a more appropriate examination, or whether the requested examination should be refused. If the clinical indications and the reason for the examination are absent from the referral, then it is impossible for the radiologist to evaluate the appropriateness of the requested CT examination. In this case, the requested CT examination cannot be justified.

The co-ordinated national/regional audits of justification of diagnostic CT examinations aim to evaluate whether this process of justification is implemented in the participating imaging centres. In the methodology developed, two steps have been defined for this evaluation. The first step is a survey to be completed by the participating centres in order to evaluate the implementation of the process of justification in the centres through written

procedures. The second step is to evaluate the appropriateness of the CT examinations already performed on a specific date/dates. The percentage of appropriate CT examinations performed in each centre will be an indicator of the implementation of justification.

2. Survey on the implementation of the process of justification

In order to evaluate the implementation of the process of justification in the imaging departments of the hospitals and private clinics which will participate in the audits, a questionnaire was developed. The questionnaire covers key elements of the referral and justification process including the assignment of responsibilities, the referrals vetting process, existence and use of referral guidelines, communication between the referrer and the radiological practitioner, mechanisms and evidence for resolving conflicting opinions, etc. This questionnaire was sent to the imaging departments providing the referrals to be audited with a request that it be completed. It can be found in Annex 1.

3. Imaging referral guidelines – The ESR iGuide tool

The imaging referral guidelines of the ESR, embedded in the ESR iGuide, are used as a standard for the audits. The guidelines are in the English language. The auditors are expected to have a good level of English.

The guidelines maintained by the ESR are based on the American College of Radiology Appropriateness Criteria and additional ACR Select content. The edition of the guidelines used in the project is the version released by the ESR in April 2021.

ESR guidelines cover all diagnostic imaging modalities including hybrid and nuclear medicine imaging.

Auditors will access the ESR guidelines using the ESR iGuide web portal, and a step-bystep user guide for this was provided via online tutorial. Each session entered by auditors in ESR iGuide is automatically assigned a random identifier ('Decision Support Number', DSN). ESR iGuide staff will extract data on the audited referrals as entered into the ESR iGuide web portal by auditors for reporting and analysis.

The roles and responsibilities of the auditors are described below in section 4.3.

4. Stakeholder Involvement. Roles and responsibilities

4.1 National Competent Authorities (NCAs)

In the EU-JUST-CT project, the national competent authorities (NCAs) in radiological protection were responsible for organizing the pilot audits in their countries. They decided on whether the whole country, a region, or a sample of hospitals (private and public) would participate.

They sought information on the number of imaging departments to be audited, as well as the number of CT examinations carried out per imaging department. They presented the project to the participating centres and liaised with the national professional societies, as

well as the health authorities, where necessary. They guided the participating centres as regards the purpose and scope of the project, the sampling process, and related methodology, to ensure high quality data were obtained (e.g. via electronic briefing meetings). They prepared a letter addressed to the centres informing them of the project and requesting that they provide the NCA with the referrals for a specific date/dates to be determined by the NCA. The ballpark target was to obtain 1000 consecutive CT referrals of already performed examinations per country/region.

The NCAs received the referrals in paper or electronic format. They verified the quality of the referrals, making sure that each referral contained the age and sex of the patient - these are essential for the audit to be carried out.

NCAs had to ensure that referrals were anonymised (i.e. no longer traceable to the patient), but traceable to the hospital which provided the referrals. This was achieved by assigning a unique ID to each referral in a format determined by the NCA (e.g. a 2-letter code for the country/region, a code for the centre assigned on random basis; and then a random unique ID number to individualise the referrals, assigned by the NCA).

NCAs then provided 500 anonymised referrals to each designated auditor. Each referral was assessed by two auditors. As the ballpark target was to assess 1000 consecutive CT referrals per country/region, there were four designated auditors per country/region.

A small budget was set aside in case that activity could not be provided within the regular workflow of the NCAs.

4.2 Hospitals

The hospitals received the above-mentioned letter from the NCAs. They provided the referrals for the specific date/dates in paper or electronic format to the NCA. The hospital was responsible for the anonymization of the referrals. This meant removing social security numbers, names, dates of birth, addresses, contact information, and any other personal data of the patients. Age in years and sex parameters were retained (or, if necessary, added), as these are essential for assessing appropriateness and are required in the ESR iGuide workflow.

To be eligible for audit, each referral must therefore at minimum contain:

- Age of the patients in years
- Sex of the patient (male/female/other/unknown)

Plus, if available

- Specialty of referrer
- Inpatient/outpatient

4.3 Auditors

A pool of auditors was established with the support of the national radiology societies of the country/region.

These auditors were provided with the ESR iGuide tool as well as an audit spreadsheet (Annex 2). Each auditor received appropriate practical training on the use of the ESR iGuide tool and on the completion of the excel sheet. This training allowed each auditor to be able to evaluate the referrals and to be able to conclude whether the requested CT examination was appropriate or inappropriate according to the ESR iGuide tool. A video

recording of the training was made accessible on the EU-JUST-CT website and will remain available for potential future users undertaking their own audit. Four auditors were designated for each country. Each auditor received approximately 500 referrals to audit. Each referral was thus audited by two auditors. For each referral, the auditor was responsible for evaluating the quality of the referral and for providing the data as described in section 6. The auditor entered into the spreadsheet the sex, age in years (which are used as filters for the guidelines), information on the examination that was performed, and the reason for the examination (clinical indication, question to be answered).

If the ESR iGuide did not include recommendations for a specific indication, auditors were given the possibility to evaluate justification based on their expert opinion. This was then entered in the audit spreadsheet. Each session entered by auditors in ESR iGuide was automatically assigned a random identifier ('Decision Support Number', DSN). The referrals evaluated based on the expert opinion of the auditor did not have such a DSN.

The auditors were given 3 months to carry out the audits. When the audits were finished the auditors sent their completed spreadsheets to the NCAs.

4.4 Data Analysis

The data provided by the auditors was analysed in order to determine the percentage of appropriateness according to the following:

- Country/Region
- Hospital/imaging departments
- Adult population
- Paediatric population
- Public sector
- Private sector
- Anatomical region
- Specialty of referrer (if available)
- In patient/outpatient (if available)
- In the case of inappropriate CT imaging, what would have been a more appropriate examination
- According to whether the imaging department has MRI or not

In cases where it was found that two auditors arrived at a different conclusion concerning the appropriateness of the CT examination, the opinion of a third expert was obtained. In cases where only one auditor was found to have audited a given referral, the aforementioned expert acted as the second auditor. Where no consensus was then found, the referral was rejected from the data analysis.

5. Referral Sampling

The referrals of previously performed CT examinations were sampled for a specific date/dates in public and private facilities. Weekends and public holidays were excluded as dates for sampling. For private facilities, a minimum of 25 referrals needed to be sampled for statistical reasons. The referrals covered all clinical indications, for adult as well as

paediatric populations. Referrals from the emergency room were included. The sampling of referrals obtained from big and small hospitals was made in such a way as to ensure good statistical results.

Data collected

In order to evaluate the appropriateness of the CT examination requested on the referral, as well as to obtain all the necessary information for the evaluation of the results by subgroup, for each referral, the following data was obtained:

Identification: Reference number of the referral (Unique ID assigned to the referral)?

Examination: Type of examination?

Patient: Patient gender? Patient age in years? In patient or outpatient?

Referrer: Medical specialty of the referrer?

Clinical elements of Justification: Clinical background (clinical indications, prior examinations etc.)? Question to be answered by the examination?

Recommendation in the clinical guidelines: Is the clinical situation present in the guidelines? Are the clinical elements for justification consistent with the recommendation in the guidelines?

Conclusion of the auditor: Is the CT examination requested appropriate?

If it is mentioned on the referral that a previous imaging examination was done was the CT examination still appropriate?

Complementary question regarding the reason of inappropriateness: Would more clinical elements for justification be necessary? Is there another examination that would be more appropriate? Which type of examination would be more appropriate? Additional remarks?

7. Limitations of the methodology

The methodology developed in this document and used in the EU-JUST-CT project aims to evaluate the appropriateness of a diagnostic CT examination based on the information provided on the referral only. The auditors will not have access to the patient history nor to previous imaging examinations. Some CT examinations that will be evaluated as inappropriate might have been evaluated as appropriate had the auditors had access to the patient history and vice versa. Furthermore, referrals that were rejected were not part of the audit. It is accepted that not knowing the number of rejected referrals could bias auditors; but simultaneously, knowledge of other aspects of the process also risks bias when the goal is to audit the justification of the exams.

This is an accepted limitation of this methodology.

8. References

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Annexes

Annex 1. Survey questions for the implementation of the process of justification in the imaging facility providing the referrals

- Name of the imaging facility?
 - o Private / Public?
 - o University Hospital/ large regional hospital/small local hospital?
 - o Number of diagnostic CT examinations performed per year?

a. Availability of procedures and documentation for ongoing justification process

- Are there written procedures describing the justification process available in the imaging facility's Quality Assurance system?
- Are the following issues addressed and described in the procedures:
 - o Minimum requirements for the content of referral?
 - Evaluation of justification and appropriateness of referral?
 - Seek previous images or clinical information/history?
 - Contact between referrer and radiological practitioner when more information is required?
 - Identification of pregnant patients when relevant?
 - o Information of risks and benefits to the patient?
- Are these procedures known by the referrers, radiological practitioners, radiographers and other relevant health professionals?
- Have self-assessments/peer reviews/audits shown evidence or indications that these procedures are implemented in daily work?
- Are these procedures frequently revised and updated?
- Are the procedures in compliance with national regulations?
- General comments and additional information can be given here:

b. Assignment of responsibility among health professionals involved in the justification process

- Are the responsibilities and tasks for the referring physician clearly assigned and documented?
- Are the responsibilities and tasks for the radiological practitioner responsible for diagnostic CT examinations clearly assigned and documented?
- Are the responsibilities and tasks for the radiographer clearly assigned and documented?
- Are the responsibilities and tasks for the receptionist clearly assigned and documented?

- Are the allocated tasks and responsibilities known by the relevant health professionals?
- Is the delegation of tasks documented?
- Are assigned tasks in compliance with national regulations?

c. Evaluation of referral by radiological practitioner

- Is the appropriateness of referred examination evaluated before it is performed?
- Is the referrer contacted in case of insufficient referral to get additional information?
- If the examination is unjustified, is the examination rejected?
- Is the examination authorized before it is performed?
- General comments and additional information can be given here:

d. Referral guidelines

Are referral guidelines available at the facility?

If yes:

- Are they national, regional, local or other?
- Is the level of radiation dose for the recommended examination indicated in the referral guidelines? Are they in compliance with national regulations?
- Are they available to the referrers?
- Are the referrers aware of the guidelines?
- Is there evidence that the guidelines are in routine use by the referrer?
- Are the guidelines in routine use by the practitioner?
- Are the referral guidelines implemented in the Clinical Decision Support system available to the referrer?

e. Continuous education and training of health professionals

 Is education and training in justification of relevant health professionals documented?

f. Availability of MRI imaging

Is MRI available in your department?

Questions are to be answered by a yes, no or partly.

g. Number of diagnostic CT examinations carried out without a referral

 How many diagnostic CT examinations are carried out in your department, if at all, without a referral (for example in emergency situations) per year?

Annex 2. The Audit Spreadsheet

This can be downloaded here: http://www.eurosafeimaging.org/2022_eu-just_audit-form

PART 2: Guidance Document to Assist Radiology Departments in Improving Justification

European co-ordinated action on improving justification of computed tomography

Guidance to Assist Radiology Departments in Improving Justification

February 2024

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Disclaimer

The information and views set out in this report are those of the authors and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein.

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List of Abbreviations

Al Artificial Intelligence

CDS Clinical Decision SupportCT Computed Tomography

HERCA Heads of European Radiological protection Competent Authorities

IHA Individual Health AssessmentNCA National Competent Authority

WGMA Working Group on Medical Applications

WP Work Package

1. Introduction

1.1 Introduction and Background

Justification is the first and arguably most important fundamental principle of radiation protection that applies to the exposure of patients to ionising radiation in medicine (the second being optimisation). Individual justification of diagnostic medical exposures, the third of three levels of justification [1], is a process by which it is ensured that the patient receives the appropriate diagnostic imaging procedure, or in some cases no imaging, in accordance with the clinical indications and the question asked on the referral. In addition, appropriate justification for the patient requires that the benefits outweigh the associated detriments of exposure to ionising radiation, taking into account alternative techniques and that the proposed procedure is consistent with patient safety and ethical approaches in medicine. In the broader sense, it has a major impact on resource availability and allocation.

The use of computed tomography (CT) continues to grow. The estimated growth rate over the last 20 years has been 10% per annum due to increased availability, clinical applicability and the expectation that CT is a mainstream imaging modality. Although significant reductions in dose per examination have been achieved, doses for individuals have risen as it is now used repeatedly in some care pathways and patient populations. Some data suggest it contributes approximately 70% of total patient dose from diagnostic applications in some European countries [2]. Where adults undergo repeated scans and particularly where imaging involves children, the stochastic risks may be significant [3].

While appropriate CT imaging can add considerable value to an individual's healthcare, there remains concern that many examinations are not appropriate and add little or no clinical value. Early estimates from the UK [4] suggested that 20% of all imaging procedures may be clinically unhelpful. Other estimates suggest this figure may be as high as 50%, depending on the healthcare system, referral practices and availability of current imaging guidelines [5,6]. These estimates include unnecessary CT.

The need to address justification has been a key aspect of several European Directives [7, 8], International Standards [9], national and international initiatives [10,11] and numerous publications, including HERCA and ESR statements and publications [12,13].

1.2 Scope, Purpose and Target Audience

This document primarily addresses justification of individual imaging procedures using CT for adult and paediatric patients. These procedures can be individual diagnostic exposures or exposures within a pre-determined and agreed care pathway for treatment assessment and follow-up of an individual patient. In general imaging departments, CT exposures are predominantly used in adult patients. Presentations by paediatric patients are smaller in number in general departments, rather than where specialist paediatric services are provided.

The use of CT in any exposure of asymptomatic individuals, whether as part of screening programmes or as part of individual health assessment (IHA), will involve different justification processes and provide additional challenges. The potential benefits and risks may need to be assessed differently as probability of a condition replaces symptoms and referral practices and mechanisms for the integration of results into health records and subsequent care may differ. Similarly, the use of CT as part of research will involve additional considerations and processes to ensure that ethical values and legal

requirements are fully considered. Elements of this guidance may be applicable to these and to CT guided interventional exposures.

This document is intended to highlight key issues associated with justification of CT imaging and to provide guidance on how justification for individual patients can be improved. It does not address justification of types or classes of practice.

While acknowledging that appropriate justification is a key issue for hospital management, this guidance is primarily for those managing or working within imaging departments, although it is expected that elements of the guidance will be useful for those making referrals for CT, whether from primary or secondary care.

2. European Basic Safety Standards Directive and National Regulations etc – legal requirements

Within Europe, most regulation of practices using ionising radiation is based on the 2013 Euratom Basic Safety Standards Directive (BSSD) [8]. This directive includes requirements for medical exposures and builds on and replaces a previous Euratom Directive [7]. The BSSD is goal setting and addressed to Member States. It allows for some flexibility for medical exposures, in doing so recognising the differences of national healthcare provision systems and culture. It is implemented through national legislation, regulations, orders etc. Practical guidance on how to implement the requirements can be provided by the European Commission, national Competent Authorities and national and international professional organisations.

2.1 BSSD Requirements

Justification of individual medical exposures is addressed in detail in Article 55 – the first article within the medical exposures chapter – and Articles 57 and 62.

Article 55 requires that medical exposures show sufficient net benefit, taking into consideration potential diagnostic (and therapeutic) benefits to the individual and society while considering other available techniques using less or no exposure to ionising radiation. A key requirement is that exposures are justified in advance which presents a challenge for busy imaging departments. This needs to be addressed through local procedures specifying roles and responsibilities. Additionally, previous relevant diagnostic information should be available so that unnecessary exposures can be avoided. Specific requirements are given for the imaging of asymptomatic individuals, whether as part of screening programmes or IHA.

Article 57 states that the referrer and the practitioner are involved in the justification process, as specified by the Member State.

Article 62 requires special attention is given to the justification in pregnancy, taking into account both the expectant individual and the unborn child.

2.2 BSSD Definitions

Chapter 2 Article 4 provides three key definitions relevant to justification, summarised as follows:

"Clinical responsibility" for individual medical exposures is the responsibility of a practitioner and includes justification.

"Practitioner" is defined as a medical doctor, dentist or other health professional who is entitled to take clinical responsibility for a medical exposure.

"Referrer" is a medical doctor, dentist or other health professional who is entitled to refer individuals for medical radiological procedures to a practitioner.

The range of healthcare professionals that are entitled to act as practitioners and referrers varies, is dependent on national legislation and may be determined by the State or by individual employers. The activities of healthcare professionals as practitioners and referrers will require appropriate competence and local agreement. Further detail is provided in section 2.4.

2.3 The Justification Process

Article 57 of the BSSD places a requirement for the referrer and the practitioner to be involved in the justification process rather than justification, which is only one element of the justification process. The justification process includes initial presentation and assessment of the patient, consideration of imaging to demonstrate the condition under investigation, appropriate justification of imaging and authorisation of that imaging. Justification alone, an intellectual process based on knowledge and experience, is only one function of many within this process. In most cases, the process is carried out by more than one person, including the referring clinician and the practitioner. This can be made clear in legislation, while local policies and procedures are pre-requisites for the process to work in practice. Further information is provided by HERCA in its position paper on individual justification [12]. Assigning roles, tasks and especially responsibilities for individuals involved in the process aids transparency and can help to identify the training needed for individuals involved in the process. Processes can be flexible, in that responsibilities for aspects of the process may be transferred from one person to another to ensure the appropriate competence is available. For example, decisions on appropriateness of a CT procedure can be discussed between radiology professionals before responsibility for a final justification is carried out by a clearly identifiable practitioner. Such a practitioner may have specific expertise relevant to the referral.

2.4 Terminology, roles, entitlement and empowerment and responsibilities

The BSSD provides key definitions for the referrer, the practitioner and clinical responsibility. It does so within the legal context of the Directive, which is goal setting. Directives are drafted to allow some flexibility for implementation at a national level and are not prescriptive regarding how the goals defined in the Directive are to be achieved by the member states. National legislation and regulations may be prescriptive or may allow flexibility regarding which healthcare professionals are entitled to be referrers and practitioners and for which examinations.

These defined individuals undertake activities that can be considered as separate elements of the justification process but in some circumstances one individual might take on the role of both referrer and practitioner. It may also be helpful to consider the supporting activities of other staff, e.g., administrative staff, secretaries etc which relate to the justification process. These are important but such non-clinical staff cannot have

legally defined roles, and responsibility for the justification process remains with the referrer and the practitioner.

For referrers and practitioners, the tasks and associated responsibilities should be based on education and training, both clinical and in radiation protection. However professional background alone is not sufficient and up to date competence is required. This is particularly true in CT where technological advances are rapid, and it is difficult for non-specialists to ensure their knowledge remains current. This may be evidenced by continuing medical education or professional development.

The tasks and responsibilities of individuals must be agreed by the healthcare organisation in which medical radiological imaging takes place. Local management should provide the framework within which the justification process is carried out. It should agree and specify the scope of practice of referrers and practitioners. This protects referrers, practitioners, other healthcare professionals and the institution by ensuring no-one acts outside their expected roles and that those acting within these roles can be suitably supported by management. For example, it is usually inappropriate for a cardiologist to be entitled or to carry out justification of non-cardiac CT procedures even if they have sufficient general medical training and radiation protection knowledge from their own practice.

2.4.1 The referrer

The role of the referrer is to initiate the justification process by requesting imaging to address a clinical problem or potential clinical problem. Before doing so, the referrer should assess the patient and collect clinical information to inform justification of appropriate imaging. It is the responsibility of the referrer to provide the practitioner with a referral that is complete. The referral must contain all the information necessary such as clinical indications, clinical question asked and previous examinations, to allow the practitioner to justify the imaging examination.

The role of referrer can be undertaken by a range of appropriately qualified staff, depending on the clinical situation and modality to be used. In most European countries, all doctors are permitted to refer patients for CT imaging. In some healthcare systems however, referrals for CT are carried out only by hospital doctors, whether specialists or in training. In exceptional circumstances, other non-medically qualified clinicians act as referrer as part of agreed protocols, but these are usually applicable only in well-defined circumstances. This contrasts with referrals for radiography and ultrasound which are often provided by family doctors and other healthcare professionals.

2.4.2 The practitioner

The role of the practitioner is to consider relevant patient information, including previous imaging, and to justify the imaging procedure. For most cases in imaging departments, the practitioner is a radiologist. The radiologist is best placed to ensure that medical exposures, including CT, are appropriate, taking into account the clinical question to be answered and all the imaging modalities available.

In some cases, specialists other than radiologists may act as practitioners for a limited range of procedures, carried out within the radiology department or in separate facilities. Examples include some cardiologists and dental surgeons who are trained in the use of CT within their own specialty.

In some healthcare systems, other non-medically qualified healthcare staff may justify a limited range of CT procedures, according to defined protocols. These include specialist radiographers and nurses and physician assistants who have received additional training. This is not currently common practice across Europe.

2.4.3 The patient

Patients have no specified role or responsibility relating to justification or the justification process within the BSSD. Nevertheless, patients are central to their own healthcare and no procedures should take place without their agreement. For justification, the patient has a general duty on initial presentation to provide the referrer with accurate information about their condition, including pregnancy status. As patients' involvement with their healthcare evolves, they may also exert their rights to question the justification of CT procedures. This is already seen in paediatric CT imaging where concern is expressed about radiation dose for children. Proper information should, of course, be provided about the benefits and risks of the CT examination and the potential impact on future care.

3. Education and Training

Education and training, including continuing medical education and professional development, provide the basis for knowledge and competence for all healthcare professionals. They ensure that specialist staff keep up to date with advances in their fields.

All doctors should have adequate competence in patient assessment, and this should be sufficient to carry out many of the referrer's duties. However, family doctors and many hospital doctors are unlikely to have up to date knowledge on radiation protection and CT imaging and this may affect their ability to request specific CT procedures. This in turn may limit the advice and support they can give to their patients regarding any future imaging pathway. This is not normally the case for specialists, who should be aware of imaging options and capabilities within their field of practice.

For healthcare professionals involved in the justification of CT imaging, training and education should include knowledge of the appropriateness of other imaging modalities, specific radiation protection training and an understanding of their roles and responsibilities under the legal framework associated with the use of ionising radiation in medicine.

4. How the Justification Process is Carried Out in Practice

The justification process should be described in local policies and procedures. It may be helpful to consider this as part of the framework which describes the processes involved in requesting, justification and written authorisation of individual exposures. Policies and procedures should include requirements for: supporting clinical information so that justification can be carried out appropriately; the suggested imaging procedure requested; the procedure agreed on and justified; and verification of the identities of the referrer and practitioner. They should also include agreed actions when these requirements are not satisfied.

The BSSD requires justification in advance of the medical exposure taking place. Ideally, this should be prior to the patient's appointment being made to ensure that the patient's expectations and the procedure undertaken are consistent. In addition, the justification should include the specific anatomical regions to be imaged, whether contrast is required

etc. However, the facility should exist to modify this during the patient's appointment and prior to the exposure if new information comes to light, but only if agreed by a practitioner.

For CT imaging, most processes will follow one of three scenarios:

Scenario 1 – the referring clinician (the referrer) initiates a request, preferably consistent with available imaging referral guidelines or national guidelines for IHA and in line with their scope of practice. Supporting written information should be supplied and the referrer identifiable as part of the request. The radiologist (the practitioner) considers the information supplied, checks that the request is consistent with the hospital approved scope of practice of the referrer and justifies an appropriate CT procedure, in accordance or not with the imaging procedure suggested by the referrer. Where the CT procedure initially requested is not agreed, this should be communicated and discussed with the referrer. The practitioner who justifies the CT procedure should be identifiable and this should be documented. This is probably the most common scenario for CT imaging. Reporting the CT images is a separate activity and is not part of the justification process. This is normally carried out by a radiologist, but this does not have to be the radiologist who justified the scan.

Scenario 2 – the consideration of the CT request is delegated to another healthcare professional (e.g., specialist radiographer) who undertakes the delegated task of assessing or vetting the request and authorising the procedure to take place. This is done in accordance with justification criteria provided by the practitioner (a radiologist). These criteria should at least be consistent with well-developed imaging referral guidelines but may be more detailed to address specific justification requirements. The healthcare professional is identifiable, but a radiologist retains responsibility for justification. The justifying radiologist is the person who takes responsibility for the justification criteria. In this scenario, the healthcare professional assesses or vets rather than justifies the exposure. If the healthcare professional is unsure or the request is outside agreed justification criteria, the referral is passed to a radiologist who then provides the justification. In such cases, the radiologist undertaking the justification is the practitioner, not the radiologist who provided the justification criteria. This radiologist should be identifiable.

Scenario 3 – the referrer is a specialist with agreed authority to both request and justify procedures (e.g., cardiologist or dental surgeon) within a limited scope of practice. Here, one individual carries out both roles of referrer and practitioner, but these activities should still be considered as separate and be documented to the same standard as described for scenario 1.

Other variations may exist but are not common practice. In particular, it is currently unusual for justification of CT imaging to be the responsibility of healthcare professionals other than radiologists and medical specialists, but this may change as imaging protocols and artificial intelligence (AI) play a greater role in CT imaging.

NB The scenarios posed in this document are examples of the justification process. These may not be applicable in all Member States. In all cases, responsibilities, roles and the entitlement to act as a duty holder must align with national legislative requirements.

5. Practical Tools to Facilitate and Undertake the Justification Process

5.1 Imaging referral guidelines

These have been available in some parts of Europe for over 30 years. These, and subsequent guidelines [14,15] were originally intended to help the referrer make the best use of the imaging department and in 2000 the European Commission produced similar guidelines [16]. Both their value as an aid to improving the justification process and the importance of availability have been investigated [17,18]. Nevertheless, availability does not always equate to appropriate use [19,20].

The use of CT in individual health assessment (IHA) [21] is a relatively recent practice and is justified for only a small number of circumstances. Guidelines may not be well established in all Member States. These guidelines will be based on probability rather than symptoms of a condition.

Following guidelines may increase the number of CT procedures undertaken for some conditions. This is not necessarily a negative consequence as the aim should be to ensure appropriate examinations, including appropriate imaging with CT, rather than to reduce the total number of procedures undertaken.

Imaging referral guidelines have greater influence if they are available, easily accessible to referrers, up to date and reflect current practice. Integration into normal working practices increases their routine use and removes the need for repeating initiatives to promote their use.

The guidelines also need to be considered as valuable by referring physicians and health policy makers. Their generation needs to be based on published evidence and follow rigorous approaches and to include the views of multiple specialties if inconsistencies between them and physician generated protocols are to be avoided.

5.2 Clinical Decision Support (CDS) systems

These integrate imaging referral guidelines into electronic requesting systems and provide feedback to referrers. Their major advantage is they address many of the problems that may occur with stand-alone guidelines i.e., lack of availability, ease of use etc. CDS systems are more common in some parts of the USA than in Europe but early evidence from Croatia [22] is encouraging and the EU-JUST-CT project should provide further evidence relating to justification of CT.

Introduction of CDS systems requires investment as well as political will, on-going support at national and local level, integration into healthcare pathways and education and training on their use.

In the future, benefits of CDS systems may be further enhanced if Artificial Intelligence (AI) is a fundamental basis for the architecture of these systems. Al offers the possibility of greater patient focused care by considering justification of exposures in multiple and differing potential pathways for the patient, informed by the patient's pathway and evolving clinical history and depending on whether the use of CT is intended for initial assessment, staging, treatment planning, treatment assessment or follow-up. Al based CDS systems have the potential to significantly change the justification of CT procedures and to influence greatly the role of the clinical radiologist. Nevertheless, under current legal approaches, AI cannot be considered a duty holder in justification and should be considered as a tool to support the referrer and practitioner, who remain responsible for the process.

6. Practical Tools to Assess the Justification Process

Clinical audit is a requirement of the BSSD and justification of CT exposures is a prime subject for this. Guidance on clinical audit has been produced by the European Commission [23,24,25] and HERCA [26,27]. Member States and professional bodies have audited the appropriateness of CT examinations using retrospective data collection and analysis. This is time consuming and labour intensive. The ESR has produced a practical audit tool – Esperanto, now in its 3rd edition [28] – which includes audit of CT use.

The introduction of CDS systems offers the capability to undertake real-time review of cases, referral patterns and subsequent justification and this has the potential to reduce the effort required to undertake audit and to increase the frequency at which it is done.

7. Challenges for Imaging Departments

Justification of CT imaging is more likely to be appropriate when referring physicians are engaged with local available imaging services. Policies, procedures, and processes for CT imaging need to be developed, understood and agreed with appropriate stakeholders (clinicians and appropriate administrative staff) and up to date imaging referral guidelines or CDS systems should be available. Radiological imaging departments should ensure good communication with referrers, whether based in the community or hospitals and radiologists should be available to discuss requests, particularly if these are not consistent with imaging guidelines.

Expectations of patients are often set before or during initial consultations with family doctors and as imaging is accepted as an essential part of healthcare there is significant demand for radiological procedures, including CT imaging, to be performed. Referring physicians and radiologists have a clear role in managing these expectations and communicating and advising patients on possible alternative imaging or other diagnostic strategies and healthcare options. While patients have a right to be involved in every step of their own care, they should make decisions having been provided with clear and concise information and given the opportunity to discuss their requirements and concerns. However, where specific imaging is not considered to be justified by those responsible, it should not take place.

Public health initiatives play an important role in setting and managing expectations of the public and subsequently patients. These should be formulated in conjunction with appropriate clinical practitioners including radiologists. Examples of these in Belgium and Luxembourg have highlighted radiation dose issues, that radiological imaging is not without risks, that it should not be demanded and in some cases, it is not helpful. Such initiatives may provide the basis for discussion when a member of the public becomes a patient. At this stage, radiation risk is unlikely to be a factor for many patients. The exception is imaging of children when radiation exposure can be a significant and sometimes overemphasized (by the patient's representative) factor when deciding whether imaging should take place. Information campaigns [29] and international guidance all play a role in ensuring appropriate CT imaging takes place.

CT imaging is used in screening, initial diagnosis, planning of treatment, treatment assessment and patient follow-up. As stated previously, individual CT imaging procedures may be included, and accepted, as part of an agreed protocol or guideline covering a proposed healthcare pathway, and in future, greater emphasis may be placed on justification of imaging over the entire patient pathway and over extended periods of time. By doing so, resources, both equipment and staff, may be used more effectively and

focused on aspects of the service that are likely to produce the greatest impact e.g. justification by radiologists of complex CT imaging rather than routine procedures which are part of agreed evidence based and established clinical pathways. However, while the protocol or guideline itself may be accepted as appropriate in general, there may be circumstances where some of the CT procedures involved are not appropriate for an individual patient, i.e., they add no benefit. It may be necessary for the practitioner to review and revise the justification of such an exposure. In some cases other modalities may provide the clinical information needed either for lower cost or lower or no radiation dose and in addition, revision may result in CT availability being improved for other patients. To undertake such revisions, radiologists should be aware of the context of all individual procedures within a patient's clinical pathway.

The impact of equipment and specialist staff availability, structures and methods of delivery of primary and secondary care within different healthcare systems should not be underestimated. Insufficient access or long waiting times for CT may result in more critical scrutiny of CT requests and better justification. Conversely, insufficient access or long waiting times for MRI may result in inappropriate use of CT to provide patients with crosssectional imaging, particularly in cases of perceived urgent clinical need. There is some evidence that healthcare systems dominated by private practice may have greater rates of inappropriate CT justification than publicly funded systems and reimbursement mechanisms can have significant implications for appropriate justification of CT imaging. In some systems, patient self-referral and physician self-referral are common and may influence the appropriate use of CT imaging [30.31]. Similarly, where over availability of CT services exists, this can increase the use of unnecessary imaging. Service providers may feel a need to accept inappropriate referrals to make their services financially viable and patients may feel empowered to try other CT services if, at an initial consultation, they are advised that the CT imaging they desire is not justified and will not be carried out. It is acknowledged that saying no to a request for CT imaging may not be easy, particularly where imaging has no value. A concerned patient may lose trust and it takes more time to refuse a request than to simply comply and provide the imaging. However, in many cases inappropriate imaging requests for CT can be addressed by proposing more appropriate procedures using other imaging modalities. This is unlikely to result in an overall reduction in imaging but can provide improvement in modality selection while still retaining the patient's confidence and providing the answer to the clinical question posed.

7.1 Specific Challenges in Teleradiology

Teleradiology brings its own challenges for justification of CT imaging, specifically where the referring clinicians, the practitioner, the CT imaging service and image interpretation are operated without an overarching single employer structure and framework.

As teleradiology essentially relates to the transfer of images between a location where the image is produced to another location where the image is interpreted, it should ideally have little impact on the justification process. It may however provide further complexity regarding clinical responsibility, which includes justification and image interpretation. All legal responsibilities and roles of the referrer and the practitioner remain and understanding of these should be acknowledged, agreed and verified between all parties prior to contracts being developed and agreed. The referrer still has responsibility for assessing the patient and providing pertinent information so that a CT imaging procedure can be justified by the practitioner, wherever the procedure takes place. It is important therefore that the radiologists providing justification, overseeing the scanning service and those providing image interpretation are involved in the contracting process and understand their legal responsibilities, tasks and roles.

The practitioner will need to be confident that justified procedures will be carried out to appropriate standards and with appropriate techniques and protocols required for patient safety and high-quality imaging. The practitioner needs to be assured that the equipment used to undertake the scanning and that used to reconstruct data for image interpretation are fully compatible. This is particularly true if the radiologist justifying the scan is also responsible for interpreting the images and providing a medical report. Where different radiologists provide image interpretation and justification, feedback on scan findings and the value of CT imaging for individual patients may improve justification for future examinations of these patients and others.

8. The Regulator and the Imaging Department

In most medical disciplines, it is highly unusual for a doctor's clinical practice to be subject to specific regulation and inspection but the inclusion of medical exposures within the BSSD makes this a requirement for radiology.

In Europe most radiation protection inspectors do not have an appropriate background, sufficient training or sufficient knowledge to be able to comment on the justification of individual exposures. In addition, the depth of inspection regarding justification will depend on national regulations relating to patient anonymity – in many countries an inspector may not have access to patient records.

It is more likely that inspections will focus on processes and compliance with national regulations. The institution should be able to provide local policies and procedures including those relating to the justification process, including of individuals to act as referrers and practitioners, whether their scope of practice is defined, how clinical data relevant to medical exposures is provided and whether justification can be confirmed to have taken place before exposures are carried out. Confirmation of the completion of stages of the justification process and its timing should be included in any activity trail, using unique individual healthcare professional identifiers (signatures, electronic passwords etc) and dating systems in accordance with departmental procedures [12].

Most inspectorates do not publish inspection checklists, although there are exceptions. However, valuable information relating to the expectations of national authorities is often available and can be gleaned from annual reports and from communicating directly with the Competent Authority.

Other sources of information are available. In Luxembourg, the Ministry of Health has published comprehensive guidance on justification of medical imaging [32] and in 2015 the HERCA Working Group on Medical Applications (HERCA WGMA) held an inspector workshop on justification in radiology and organised a European Action Week on the inspection of justification, including CT, involving 148 inspections in 17 countries [33].

The responsibility for compliance with regulations lies with the licensee and healthcare professionals. This should be reviewed on an ongoing basis. Inspection programmes can have an impact on routine day-to-day practice but this will be dependent on the scope and frequency of inspections. In addition, if professionals consider inspection to be an adversarial process, focusing on enforcement rather than compliance, this may result in reluctance to change and improve practice. The main focus of proactive inspections should always be demonstration of compliance with regulations rather than enforcement. It can also provide opportunities to clarify the contents, purpose, application and synergy of regulations, approved codes of practice and national guidance, where provided in conjunction with the regulator, for specific clinical settings. The inspector must remain independent from the institutions under scrutiny and refrain from providing direct practical advice on how to comply with legal requirements. Nevertheless, good practice from

institutions, shared between professionals and within subsequent reports can improve local compliance and an active dialogue between licensees, healthcare professionals and the regulator, along with published results of inspections, can improve CT justification.

9. Conclusions

Appropriate justification of individual CT procedures remains a key aspect of patient safety, patient outcome, and the effective and efficient use of radiological imaging resources.

Dialogue with referring clinicians is essential if conflicts between referrers and radiological imaging departments are to be avoided.

Radiologists should be involved either directly or in setting up and approving policies, processes and procedures where other medical specialists and healthcare professionals provide justification. In all cases, the roles and responsibilities of all those involved in the justification process should be clear and identifiable.

As part of the process, clinical imaging guidelines and CDS systems can provide essential tools and their generation, availability and use should be considered a priority by hospital and healthcare providing organisations.

Assessment of appropriate individual justification can be provided by clinical audit. Inspection is an important process, but its scope, frequency and aim may limit its impact on a daily basis.

These steps are summarised in Appendix 1 – Five practical steps to improving justification in CT imaging.

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11. Appendix 1

11.1 Five practical steps to improving justification in CT imaging

1. Communicate with referrers

Establish links to ensure that referrers are aware of the CT services offered by the radiological imaging department and which CT examinations can be requested by referrers within primary and secondary care

Referrers should be aware of the clinical information required to support a CT referral (patient clinical details, diagnostic question to be answered, impact of imaging on subsequent patient care etc) and the consistency of the referral with agreed imaging guidelines.

2. Define roles, responsibilities and entitlement for referral and justification

Clarify the roles and responsibilities of all referrers, practitioners and those acting in accordance with the directions of practitioners. This should apply to primary and secondary care settings (e.g., family doctors, hospital doctors in training, specialists, other healthcare professionals)

Referrers, practitioners and those acting in accordance with the directions of practitioners should be clear on the scope of their practice, dependent on education, training, operational parameters and entitlement to act as agreed within the imaging department and its parent organisation (health authority, hospital etc)

3. Establish policies and procedures for justification

These should include operational processes for undertaking the justification process and verifying that justification has taken place, in accordance with the roles, responsibilities and entitlements agreed within the parent organisation.

4. Provide imaging referral guidelines or Clinical Decision Support (CDS) systems

Ensure that the latest imaging referral guidelines (in stand-alone analogue or digital formats or within CDS systems) are available to referrers in primary and secondary care settings and provide guidance on how referrals consistent with these are processed.

Further guidance should be provided relating to processes for imaging requests that are not consistent with imaging referral guidelines etc.

5. Audit compliance of referrals with best practice imaging referral guidelines

Periodically audit referrals for CT against CT examinations performed and feedback information to referrers – to improve communication, expectation management, effectiveness, efficiency and appropriateness of the justification of CT examinations

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