

EC Tender Contract N° ENER/21/NUCL/SI2.844392

**European co-ordinated action on improving justification of
computed tomography**

EU-JUST-CT

D4.2: Audit Methodology and Tools

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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.

WP4 will develop 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 this audit. The common methodology will take into account the lessons learned from the literature review carried out for WP2 as well as any guidance in the subject area issued by the relevant European regulatory and professional societies and networks.

Furthermore, the methodology will define 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 will foresee 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 will be adapted and adopted taking into account the literature review from WP 2.

Individual justification of CT examinations is a process through which it is ensured that the patient undergoes the appropriate CT 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 or 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 imaging centres to be audited. In the methodology developed for this WP 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 pilot audits a questionnaire will be developed. The questionnaire will cover 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 is to be provided to the imaging departments providing the referrals to be audited with a request that it be completed. The questions to be put in the questionnaire 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 will be used as a standard for the audits. The guidelines will be 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 will be 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-by-step user guide will be provided. ESR iGuide staff will extract data on the audited referrals as entered into the ESR iGuide web portal by auditors for reporting and analysis. Each session entered by auditors in ESR iGuide is automatically assigned a random identifier ('Decision Support Number', DSN).

The roles and responsibilities of the auditors are described below in section c.

4. Stakeholder Involvement. Roles and responsibilities.

4a. National Competent Authorities (NCAs)

The national competent authorities in radiological protection are responsible for organizing the pilot audits in their countries. They will decide on whether the whole country, a region or a sample of hospitals private and public will participate.

They will provide the project managers with this information. They will provide information on the number of imaging departments to be audited as well as the number of CT examinations carried out per imaging department. They will present the project to the participating centers and liaise with the national professional societies as well as the health authorities where necessary. They will guide the participating centers as regards the purpose and scope of the project, the sampling process and related methodology to ensure high quality data are obtained (e.g. via electronic briefing meetings). They will prepare a letter to be addressed to the centers informing them of the project and requesting them to provide the NCA with the referrals for a specific date/dates to be determined by the NCA. The ballpark target is to obtain 1000 consecutive CT referrals per pilot country/region.

The NCAs will then receive the referrals in paper or electronic format. They will verify the quality of the referrals making sure that each referral has the age and sex of the patient which are essential for the audit to be carried out.

NCAs will have to ensure that referrals are anonymised, but traceable to the hospital which provided the referrals but not traceable to the patient. This will be achieved by assigning a unique ID to each referral in a format to be determined by the coordination team in alignment with the NCA (e.g. a 2-letter code for the country, a code for the centre assigned on random basis by the project team; and then a random unique ID number to individualise the referrals assigned by the NCA). At minimum, the project team need to be able to identify which centre a referral originates from.

NCAs will then provide 500 anonymised referrals to each designated by WP3 auditor. There will be four designated auditors per country so the NCAs will have to provide four times 500 referrals.

NCAs are asked to provide copy of all 1000 referrals to the project office in the format they are received from the hospitals (electronic or in paper) for quality checks.

A small budget has been set aside in case that activity cannot be provided within the regular workflow of the NCAs.

4b. Hospitals

The hospitals will receive the letter from the NCAs. They will provide the referrals for the specific date/dates in paper or electronic format to the NCA. The hospital will be responsible for the anonymization of the referrals. This means removing social security number, name, date of birth, address, contact information, and any other personal data of the patient. Age in years and sex parameters must be retained (or, if necessary, added), which are essential for assessing appropriateness and required in the ESR iGuide workflow.

To be eligible for audit, each referral must therefore at minimum contain:

- Age of the patient in years
- Sex of the patient (male/female/other/unknown)

Plus, if available

- Specialty of referrer
- Inpatient/outpatient

4c. Auditors

A pool of auditors will be established with the support of the national radiology societies of the selected pilot countries/regions.

These auditors designated from WP 3 will be provided with the ESR iGuide tool as well as an excel sheet (or other type of tool to be decided by F. Demuth, ESR iGuide expert in the project team). Each auditor will receive appropriate practical training on the use of the ESR iGuide tool and on the completion of the excel sheet. This training will allow each auditor to be able to evaluate the referrals and to be able to conclude on whether the requested CT examination was appropriate or inappropriate according to the ESR iGuide tool. This training will be provided by ESR. Four auditors will be designated for each country. Each auditor will receive approximately 500 referrals to audit. Each referral will be audited by two auditors. For each referral the auditor will be responsible for evaluating the quality of the referral and for providing the data in the section "Data to be collected" of this document. The auditor will enter 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 ESR iGuide does not include recommendations for a specific indication, auditors will be given the possibility to evaluate justification based on their expert opinion. Each session entered by auditors in ESR iGuide is automatically assigned a random identifier ("Decision Support Number", DSN).

The referrals evaluated based on the expert opinion of the auditor will not have such a DSN.

The auditors will have 3 months to carry out the audits. When the audits are finished the auditors will send the data collected to ESR who will provide it to the WP5 leads for analysis.

4d. Data Analysis (WP5)

The data provided by the auditors will be analyzed in order to determine the % of appropriateness according to the following:

- Country/Region
- Hospital/imaging departments
- Adult population

- Pediatric 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 the case where it is found that two auditors have arrived at a different conclusion concerning the appropriateness of the CT examination the opinion of a third expert will be obtained in order to arrive at a consensus. This will be done through virtual meetings between the two auditors and the third expert.

The third expert could be a member of the advisory group if the language of the referral permits this or one of the second group of auditors or a radiologist from the pilot liaison group. It is important to plan extra timing in the audits for this.

The data will be provided to the NCAs together with the survey results.

5. Referral Sampling

The referrals of already performed CT examinations will be sampled for a specific date/dates in early 2022 in public and private facilities. Weekends and public holidays will be excluded as dates for sampling. For private facilities a minimum of 25 referrals will be sampled for statistical reasons. The referrals will cover all clinical indications, adult as well as pediatric populations. It is proposed to obtain around 1000 referrals per country. The sampling of referrals obtained from big and small hospitals will be made in such a way as to ensure good statistical results.

6. Data to be 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 is to be 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 is based on the evaluation of 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.

This is an accepted limitation of this methodology.

8. References

1. PHE. A retrospective review of justification of computed tomography examinations in Northern Ireland. London: Public Health England 2018 Contract No.: CRCE - RAD - 00 4 - 2018.
2. Bouëtté A, Karoussou-Schreiner A, Ducou Le Pointe H, Grieten M, de Kerviler E, Rausin L, et al. National audit on the appropriateness of CT and MRI examinations in Luxembourg. *Insights Imaging*. 2019;10(1):54.

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?
 - Private / Public?
 - University Hospital/ large regional hospital/small local hospital?
 - 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:
 - 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?
 - 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 radiation dose taken into account?
- 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?