Abstract

Development and implementation of new dose management strategies in compliance with Italian regulation D.Lgs. 101/2020 in the West Turin area

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Purpose: D.Lgs. 101/2020[1], entered into force on 27th August 2020, is the Italian regulation which adapts national legislation to the provisions of Directive 2013/59/Euratom[2]. Among the key innovations of D.Lgs. 101/2020 in the field of medical exposures there are the inclusion of information relating to exposure in the medical report of radiological examinations and the mandatory record on a digital support of the data for the assessment of doses to the population. It introduces also annual dosimetric assessment for patients undergoing high-dose interventional procedures and the definition of follow-up criteria to identify deterministic skin lesions. This thesis work addresses these issues and implements the corresponding legal requirements within the "A.O. Ordine Mauriziano" hub hospital of Turin and the local health departments included in the vast area of West Turin, that are “ASL Città di Torino” and “ASL TO3”.

Methods and materials: The starting point was the updating of the dose management software “Gray Detector” (EL.CO. srl)[3], currently installed in the area West Turin, counting 47 radiological equipment connected via dicom Radiation Dose Structured Report (RDSR) query&retrieve and 25 to be connected soon via Modality Performed Procedure Step (MPPS) messages. A first part of the thesis work involved verifying the integrity and reliability of the data transmitted and stored on Gray Detector for each connected equipment.

Solutions were then developed for the inclusion of information relating to exposure in the medical report, for each of the radiological modalities (CT, computed tomography; XA and DR, interventional and traditional radiology; MG, mammography; MN, nuclear medicine): according to Italian legislation, the information to include in the medical report is made up of “dose classes” (from I to IV), defined on effective dose ranges[4]. For MN exams, the information also includes the radiopharmaceutical and the activity administered to the patient. The criteria adopted to assign the dose class were the following:
- Diagnostic CT exams and CT-related exposure in PET-CT and SPECT-CT exams: dose class is assigned on the basis of personalized effective dose estimate by the dedicated CT dosimetry software VirtualDoseCT[5], interfaced with Gray Detector.
- MG exams (namely clinical exams, since screening exams are not provided with a report): dose class I (up to 1 mSv) assigned by default.
- MN, DR and XA interventional radiology exams: dose class assigned for each performance code matching the dose class proposed in the "Guidelines for diagnostic imaging" document, cited in D.Lgs. 101/2020.

To assess the reliability of the criteria adopted, effective dose assessments in DR and XA exams were validated with the PCXMC[6] dosimetry software and for each CT exam code, the effective dose estimates from VirtualDoseCT were checked using the independent software CT-Expo[7]. Furthermore

the interface and the transmission of input and output between Gray Detector and VirtualDoseCT data was fully checked for errors or discrepancies.
As a comprehensive test of the entire process of including the dose class in the medical report as part of daily clinical routine, was tested and end-to-end validated.

Eventually, in order to fulfill the requirements of D.Lgs. 101/2020 about dosimetric evaluations in interventional procedures and follow-up those patients for which skin dose exceed threshold dose for deterministic effects, all the exams for which cumulative air kerma at interventional reference point exceeds 5 Gy[8] are automatically identified and highlighted in Gray Detector.
Moreover, the possibility of interfacing Gray Detector with a tool to obtain skin dose distributions was tested. The tool studied was OpenSKIN[9], an open-source software that provides skin dose maps and Peak Skin Dose (PSD) evaluation starting from exam RDSR for Siemens angiographic equipment.
As a preliminary assessment, 11 dose maps measured on calibrated radiochromic "Gafchromic XR-RV3" films from a previous *in vivo* dosimetric study were compared with the corresponding dose distributions generated by OpenSKIN. Object of comparison were both the map topology due to X-ray beam overlap and the estimated PSD value.

Results: Starting from an experimentation period, Gray Detector has been installed since 2017 at A.O. Order Mauriziano and from 2019 at ASL Città di Torino and ASL TO3, for a total of 47 connected diagnostic modalities and dosimetric data collected for more than 409,000 exams and 200,000 patients.
From the analysis conducted on the interface between Gray Detector and VirtualDoseCT, it emerged the need to insert checks on the data input and output to assess the correct choice of the phantom model on the basis of sex, weight and height values (if available) and the positioning of the scan range on the phantom on the basis of the input data regarding the irradiated body region. More than 40 checks have been identified. Particular attention was paid to upper and lower limbs scans and to CT-angiography and perfusion exams. After applying the above checks and corrections, a preliminary comparison was made between the distributions of dose classes for each type of CT examination, inter and intra local health departments: even if differences in CT equipment technology are possible as well as a slightly different clinical practice, the distributions and the prevailing dose class appear overlapping and coherent.
Since the dose class must be available before the medical specialist signs the medical report, the timing of the entire end-to-end process was check from the moment of execution of CT exam to its reporting. The test was carried out for a brain CT exam performed in emergency and reported with priority: after 45 seconds from the end of the acquisition, the dose class was already available and displayed in the preview of the report.
Currently the dose class is only visible on report draft but soon it will be printed on the final released report. In the event of possible interruption of communication with VirtualDoseCT, it was decided to insert a default class assigned automatically on the basis of the exam catalog code.

From the preliminary analysis about OpenSKIN tool it emerged that the comparison with *in vivo* dosimetry it is not sufficient to validate the whole software: the irradiation geometry between the flat radiochromic film and the OpenSKIN 3D phantom surface is too different as well as the two sensitive areas and spatial resolution. Even if the resulting synthetic map was often qualitatively similar to the film map, the geometric overlap of X-ray entrance beams and the PSD value was quantitatively and significantly different. As a future development, specific and targeted analyses will be carried out with *ad hoc* film exposures, choosing simple irradiation geometries.

Conclusion: The assignment of the dose class for medical radiological exams has presented scientific and technical challenges, although it has been proposed as a provisional solution to rapidly apply the requirements of the European Directive 2013/59/EURATOM.
To achieve the full application of D.Lgs. 101/2020 it will be necessary to continue the work presented in this Specialization Thesis, with the collaboration of all the professional figures related to the world of medical ionizing radiation. Currently, the Italian Association of Medical Physics (AIFM) has established a dedicated task group and has undertaken a collaboration with all involved italian scientific societies to obtain shared and uniform solutions throughout the national territory.

References

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