

Organizational Health Literacy as a supportive tool for the effective implementation of the 2013/59/ EURATOM Directive in Italy

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Abstract

Introduction. Since 2013, European countries have transposed the 2013/59/EURATOM Directive that lays down basic safety standards for protection against dangers arising from exposure to ionising radiation. In the years between the issuance of the European Directive and its formal transposition, Italian researchers investigated solutions to renew the technological, educational, and organizational culture in radiology departments.

Scope. This article proposed a reflection on the contribution of Organizational Health Literacy (OHL) to implement Legislative Decree 101/2020 in the practice of Italian radiology departments.

Results. By implementing OHL principles, examinations with exposure to ionizing radiation and related informative processes could be personalized based on patients' knowledge, abilities, and competencies, as well as on the services' provision. These principles can be in fact integrated with the organizational, training, and management requirements set by the Directive.

Conclusions. According with the state-of-the-art, decision-makers and health managers could support the application of OHL principles in Italian radiology departments.

Key words

- 2013/59/EURATOM
- radioprotection
- training
- health literacy
- health organizational

INTRODUCTION

The operative implementation of the regulations reported in the European Directive 2013/59/EURATOM is still ongoing in some European countries. This Directive aimed to lay down basic safety standards for protection against the dangers arising from exposure to ionising radiation. In the medical context, this Directive has led to focus on the technological, organizational, and professional implications since Member States were compliant with national regulations, transposition of the European Directive 2013/59/EURATOM requirements. These requirements control and contain radiation doses while achieving optimal diagnostic quality examinations [1-3] and define the general criteria for radiology diagnostic examinations, recommending the introduction of dedicated technologies for dose monitoring [4, 5]. The interventions pay especially attention on the improvement of

population's knowledge about the risks connected with exposure to ionizing radiation. In fact, radiological risk has been usually underestimated by the population due to the difficulty of understanding the consequence of stochastic risk [6-8].

Due to the wide field of action of the European Directive and the slowness of national legislations, nowadays the practical and operational transposition of the Directive has not yet occurred in radiology departments.

European Directive and, consequently, national transpositions encouraged to start sharing all information related to medical exposure to ionizing radiation with patients because it is mandatory, but is it possible to provide adequate information without European shared guidelines on how to do it in the best way? Which could be the consequences of giving information to European patients by health professionals without specific competencies in patient education? Does

it really ensure to lay down basic safety standards for protection against the dangers arising from exposure to ionising radiation if European health professional working in radiology departments have different training paths? Patients are currently informed, but not educated to understand the full meaning of complex health information such as the dose index in accordance with the principles of radiation protection (justification, optimization, and limitation of dose). Still, health professionals are not trained to educate the patient using a communicative register tailored to their educational levels. Furthermore, there are no guidelines on how to do it. The same European Society of Radiology underlined the importance of upgrading the academic training of health professionals working in radiology departments since that the professionals involved in radiology departments will require these specific competences and skills [9]. Radiologists, to whom the responsibility of ionizing radiation exposure is mainly attributed, as well as radiographers and other health professionals employed in radiology departments, must be adequately trained on communication and education [10, 11]. All radiology workforces are responsible for educating patients and caregivers about the benefits and risks associated with exposure to ionizing radiation. A relevant contribution to the debate is given by OHL studies. The application of OHL principles can offer important support in reorganizing radiology departments to be more patient-oriented, according to the 2013/59/EURATOM Directive. The concept of Health Literate Healthcare Organisations (HLHOs) aims to align health care organization performance with patients' Health Literacy (HL) levels [12]. Nowadays, HL is a multidimensional concept with a public health perspective [13] that describes the degree to which individuals can obtain, process, and understand the basic health information to make appropriate health decisions [14, 15]. HL is progressively being recognised as a characteristic related to families, communities, and organisations providing health services [16]. In HLHOs, it is easier for people to navigate health services and to understand and use health information to take care of their health because of the presence of specific attributes owned by literate healthcare organisations [17]. Until now, little attention has been given in literature review to the effect of environmental support on health professionals and few outcomes related to staff satisfaction/perception of helpfulness have been reported. The most common types of interventions and outcomes reported have been related to the patients [18].

This paper aimed to suggest a reflection about the contribution of HL intervention toolkits for health care organizations [14, 19], especially radiology departments, for implementing the Directive 2013/59/EURATOM in European countries. In line with the principles of the HLHOs, in fact, radiology activities should be personalized to the health needs and knowledges of patient, who should have an active role not only in decision-making but also in the managerial and organizational processes of radiology departments to improve the quality of radiology services.

METHODOLOGY

The methodology of the country case study was considered the most suitable for pursuing the goal of this research [20, 21]. Italy was chosen as relevant country case study because of the mismatching between the formal transposition of the European Directive 2013/59/EURATOM by mean of the Italian law 101/2020 and the practise into the Italian radiology departments.

The case analysis was conducted in three phases [22]:

- *Within case analysis.* Data about the Italian pathway toward the implementation of European Directive 2013/59/EURATOM were acquired through narrative literature review to collect Italian reflections and suggestions on the implementation of the European Directive regulations. The literature review was conducted querying biomedical databases (PubMed, Web of Science, and Scopus) to select the most relevant studies on the topic, or rather the operative applications of regulation reported within the European Directive 2013/59/EURATOM in the Italian radiology department and by Italian scientific society in the field of radiology. The research group decided to include researched since 2013. In fact, the scientific community started to pay attention to the implementation of the Directive regulations before the formal transposition of the Directive at national level with the Italian Legislative Decree 101/2020. There was still no structured and coordinated implementation of the European Directive at national level in Italian radiology departments. This challenge is still ongoing for the different implementation at regional level due to the regional health governance in Italy.
- *Data acquisition.* Literature review showed that Italian professionals working in radiology departments discussed and acted to directly implement Directive's recommendations since its enactment. This paragraph focused especially on the actions applied by Italian radiological workforce to prepare the reference cultural and organizational context offering an overview on the state-of-art about the pathway just done for the Directive implementation in the practise and all the ongoing commitments related to the legislation to be kept. Attention was paid by Italian professionals working in radiology departments to higher social impact sectors, especially in paediatric radiology, computed tomography, nuclear medicine and radiology screening programs. Here the strategic role of the sensibilisation and the education both of health professionals and patients emerged to ensure the appropriateness of requests and the joint decision making.
- *Data discussion.* Depending on the state-of-art about the implementation of European Directive 2013/59/EURATOM recommendations in Italian radiology departments, the initiatives of sensibilization and education promoted in radiology departments were essentially and indirectly related with the improvement of HL level of all the stakeholder involved in the radiological examinations. The research group composed by expert in the field of HL, radiology, and health management focused on the required integrations among all these three perspectives. So, the achievement of better health outcomes in radiology

departments is deeply influenced by the technological progression/innovation and the timely adaptation of organization model, and the improvement of HL levels of every possible stakeholder involved in the diagnostic process. It establishes the pre-conditions to effectively apply the HL intervention toolkits for making the healthcare organizations more literate and, consequently, for sustaining the operative implementation the Italian law 101/2020.

RESULTS

The Italian pathway toward the implementation of European Directive 2013/59/EURATOM started by Italian scholars investigating the degree of knowledge of the risks related to exposure to ionizing radiations by the population to plan and implement actions to engage patients in improving their understanding of radiology departments. Bastiani, *et al* [23] showed that most users were not fully aware of the dangers linked to exposure to ionizing radiations, mostly in the medical context. In particular, the differences between the various radiology methods (traditional radiology vs computer tomography, CT) and the type of ionizing radiation sources (external vs internal) were unclear. These uninformed patients usually did not know where to find more information or who to contact to have clarifications. Initiatives for improving their understanding of the risks associated with exposure to ionizing radiations by radiology professionals were essential. On the other side, well-informed users, who ask for additional information to learn more about the possible health-related consequences in relation to the performed radiology examination (protocol used, professionals involved, dose delivered, and report), must be managed. The engagement of these patients and caregivers must be enhanced over time in relation to the introduction of innovations, more stringent rules about dose containment, and improvement of practice [24].

In the last few years, algorithms for the modulation of the dose in relation to the patient's mass, dose control software, and artificial intelligence systems became increasingly widespread to progressively reduce the delivered dose for adequate radiology diagnostic imaging and to control the cumulative dose over time [25]. The revision and updating of practice in radiology departments were direct consequences of these adaptations. The continuous training of health professionals working and of colleagues of other medical branches, who have been using these technologies as diagnostic tools, was mandatory.

The European Directive required enhancing communication and comparison between radiology specialists and colleagues of other medical branches to evaluate together the appropriateness of a radiological examination according to radioprotection principles and clinical queries. Radiology professionals have had and are having the role of promoters, teachers, and controllers of good practice in radiology departments. Therefore, they are responsible for the discussion of justification criteria in relation to new available technologies and practices in the medical community [26].

At the same time, the progressive evolution of the radiology sector must be shared with patients using adequate

communication because they are the main actor of the radiology pathway, signing the informed consent [27].

The challenge of dual training of health professionals working in radiology departments, therefore, was and still is in technical and educational areas. Health professionals must be able to adapt their practice, taking full advantage of new available technologies and their communication register according to knowledge, competence, abilities, and skills of each stakeholder.

The possible different configurations of these two variables significantly influenced and are influencing the balancing between risk factors and achievable benefits and, consequently, the justification or not of a radiological examination.

For these reasons, studies have paid attention to the health outcomes obtained by stronger adherence to protocols and more effective information, especially in the following radiology sectors, with higher social impact:

- paediatric radiology: babies, children, and young adults have an increased risk of adverse effects as they are more sensitive to ionizing radiations and have longer life expectancy. These factors have led to the adoption of strict protocols for dose containment [28]. In addition, parents or legal guardians must assume responsibility for minors' exposure to ionizing radiation [29];
- computed tomography, that is the radiological diagnostic examination which delivers the highest level of dose [30];
- nuclear medicine, which presents challenges due to the complex nature of inside-out ionizing radiations and the emergence of hybrid imaging procedures [31];
- radiology screening programs, such as mammography and low-dose lung CT, which enrolls asymptomatic individuals [32, 33].

Paediatric radiology

Over the years, more stringent operating procedures have been implemented in paediatric radiology. The continuous updating of international guidelines in paediatric radiology reform practices at the national level [34, 35] to limit as much as possible the medical exposure to ionizing radiations in the prenatal and postnatal period. The paediatric population has a higher sensitivity to ionizing radiation exposure and a longer life expectancy than the adult population. Nowadays dose containment of exposure to ionizing radiations for new-borns, infants, children, and young adults has been enforced by the widespread availability of dose control technologies [36, 37] and increased focus on the choice of the most appropriate imaging techniques, such as echography, conventional radiology, magnetic resonance imaging, computer tomography, or nuclear medicine [28]. Dose containment in paediatric radiology also depends on the full awareness of the risks associated with exposure to ionizing radiations by both guardians of minors [28 19] and doctors of other medical branches [38]. Numerous campaigns have been conducted towards guardians of minors. Their better understanding of the risks associated with ionizing

radiations effectively have contributed to ensuring respect for radioprotection principles. They must sign the consent for the execution of radiology examination of a paediatric patient only if they are able to critically judge risks and benefits after specific education [39]. For these reasons, research groups have worked hard to increase the HL levels of guardians of minors to reduce the influence of social, educational, and economic variables in the decisional process leading to the signature of the informed consent for the medical exposure to ionizing radiations of paediatric patients [40, 41].

At the same time, dose containment has been linked with the number of prescriptions of radiological examinations to paediatric patients by practitioners and paediatricians [38, 42]. The joint development of protocols on how to assess the justification of a radiology examination by radiation protection experts and colleagues of other medical branches reduced inappropriate prescriptions, improve the accuracy of evaluation, and make the communication to patients and caregivers of the risk associated with exposure to ionizing radiations more effective [42]. These good practices must then be extended to all patient targets.

Computed tomography

Computed tomography is still the diagnostic radiology technique that delivers the highest dose. Since the advent of this technique, particular attention has been paid to the development of effective communicative strategies to inform patients about the higher risks associated with this kind of radiology examination [30]. According to the findings of Bastiani and colleagues [23], personalized communication has been essential. Patients must be enabled to achieve an adequate comprehension of health processes, in this case, the execution of a computer tomography examination, with their own knowledge and abilities. Effective communication between patients and radiology healthcare professionals encourages asking questions, prevents excessive fear and limited collaboration, reduces the incidence of unnecessary or unjustified radiology examinations, and empowers patients to personally monitor the overall radiation dose they receive. Patients were able to decide autonomously [30].

It was necessary to measure health competences for patients to tailor the communication according to their needs. The measurement of HL levels helped. HL “entails people’s knowledge, motivation, and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention, and health promotion to maintain or improve quality of life during the life course” [43]. Patients should possess competencies and information to comprehend the conveyed information (functional HL), understand how to reprocess information (interactive HL), and use available information for navigating health care services (critical HL). Applying these abilities in radiology departments, patients should be able to understand information provided on the risks related to medical exposure to ionizing radiations (functional HL). With the available information, patients can make an informed

decision about risk-taking and sign informed consent for a radiology examination (interactive HL). Finally, patients should use health and organizational information to develop their own global vision of the services provided (critical HL), which enables them to judge the quality and effectiveness of radiology departments [44].

Nonetheless, solid knowledge of available technologies and continuous updates of their competences are prerequisites for health professionals working in radiology departments to guarantee the best performance according to radioprotection principles, especially for patients with low HL levels [45, 46].

Nuclear medicine

In diagnostic nuclear medicine, patient information and education have already been extensively discussed because the patient is the source of ionizing radiation due to the administration of radioactive material.

Risks associated with exposure to ionizing radiation are not only for the patient, but also for others during the decay and washing phase of the injected radioisotope. Therefore, patients must be well-educated to exhibit the best behaviour to minimize unintended exposure to third parties [23, 47]. All phases of the diagnostic path are characterized by specific risks, which can be predominantly managed through patient education. From the moment of examination booking, patients must be informed and educated so they can understand, arrange, and adopt precautions to limit exposure to ionizing radiation of third parties, both inside and outside nuclear medicine departments. The use of personalized communication by health professionals is crucial to maximize the patient’s understanding. The 2013/59/EURATOM Directive stresses the importance of adequate health professional training to improve the safety of all stakeholders, particularly the health workforce and patients. Particular attention should be paid to additional training on communication for health professionals employed in nuclear medicine departments. They must be directly involved in improving operational professional competences to optimize dose and indirectly in acquiring communication skills to reduce occupational, organizational, and population risks associated with unintended exposure to ionizing radiation through patients. The effective channelling of different and complex health information to patients in nuclear medicine departments has been, is, and will be guaranteed only by the commitment of the nuclear medicine department staff to adapt their communication register to overcome anxiety, fear, and stress due to forced isolation for the containment of unintended exposure or constriction for imaging acquisition [31, 48]. At the end of the examination, the informative and educational role of health professionals was not concluded because it was necessary to verify for the last time the patient’s understanding and voluntary application of the required cautions to minimize unintended exposure. The informative right of the patient obligates the staff of nuclear medicine departments and the patient’s general practitioner to explain the information included in the final report so that the patient has a full understanding of the obtained diagnosis result [49]. Health

professionals must accompany, inform, educate, and support patients throughout their entire engagement with nuclear medicine departments, which finishes only with the delivery of the examination report.

Screening programs

At the international level, campaigns for secondary prevention aim to improve patient education on screening programs, personalizing communication according to everyone's abilities. This is particularly important when radiological examinations such as mammography for the preventive diagnosis of breast cancer [32] and low dose computed tomography for lung cancer screening [33] are involved. For each phase of the screening process, a specific communicative strategy has been defined to improve the quality of imaging and minimize ionising radiation exposure by fully collaborating with the patient. This has been including a warm welcome to help overcome anxiety and stress, clear and resolute communication during the examination, and a thorough and polite explanation of the report reception, possible additional examinations of the second level, and an invitation to the next control. The goal is not only to obtain a good quality examination but also to ensure that the patient will return for the next screening [50, 51].

From a literature review, it emerged that health professionals involved in breast cancer screening received *ad hoc* training in communication and patient information as part of their technical learning process [52]. The acquisition of communicative skills through experience has been not enough because consistent information from different health professionals at different appointments is crucial in screening programs. Only through joint informative, communicative, and educational strategies with the patient can this be achieved. The European Society of Breast Cancer Specialists has established standards for the training of specialized health professionals involved in breast cancer, including specific modules on communication to prepare all health

professionals working in screening programs to inform patients and colleagues about adopted protocols [53].

Guidelines for lung cancer screening with low dose computed tomography focused mainly on organizational requirements and modalities for nodule characterization by radiologists. Informative aspects, such as specific indications on service adaptation or personnel training, were absent [54]. The practice of detailed explanation of protocols used for breast cancer screening must be extended to all radiological examinations, starting with screening, for good results regarding health outcomes and patient satisfaction.

These results evidenced how an integration among the different approaches developed and adopted within various radiological fields of action is necessary. In fact, the attention paid in patients and caregivers' orientation of the paediatric radiology service, the effective communication to patients and caregivers by health professionals before the provision of CT examinations for the acquisition of real consensus, the educative commitment of nuclear medicine's health professionals and the specific training session for the same health professionals in screening programs must be part of the core skill-mix of each health professional working in every kind of radiology departments. This represents a significant starting point for decision-makers in the healthcare sector who are seeking appropriate tools to plan, implement, and promote interventions aimed at improving the safety and quality of healthcare services. Specifically, this pertains to Italian radiology departments undergoing HL promotion interventions (Figure 1).

DISCUSSION. OHL AS A TOOL TO IMPLEMENT THE 2013/59/EURATOM DIRECTIVE IN ITALIAN RADIOLOGY DEPARTMENTS

Until now, research on communication in Italian radiology departments primarily focused on patient engagement through spot initiatives. However, these initiatives did not propose effective and lasting solutions

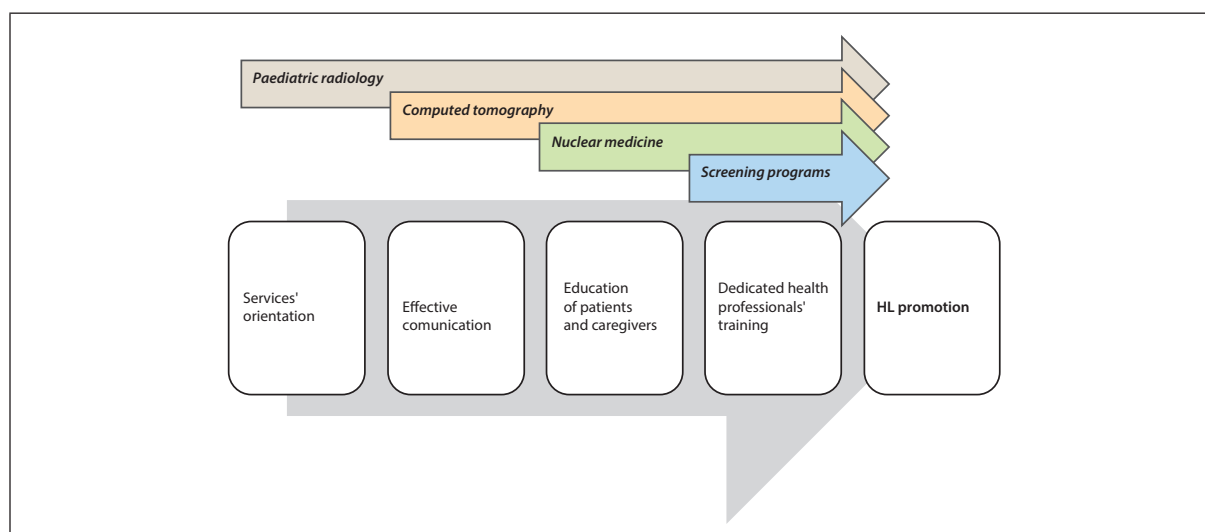


Figure 1
The contribution of different radiological areas to Health Literacy (HL) promotion.

for educating patients over time or meeting the informative and educative needs of health professionals in other medical branches. Radiologists and radiographers were and are still the only ones delegated to explain the justification principle, or the balance between the benefit of diagnosis and the possible risks associated with exposure to ionizing radiations, even though they have not received adequate training [10, 11]. The 2013/59/EURATOM Directive recommended *ad hoc* training for health professionals employed in radiology departments to acquire specific educative competences and adapt their communication strategies to the knowledge and abilities of the different stakeholders in their departments. These commitments must be integrated part of the daily activity of the radiology workforce. Primarily, radiologists and radiographers must acquire these skills as responsible for the application of the justification principle and the acquisition of informed consent. Then, anyone who works in the radiology department, including nurses, administrative staff, and support personnel, may be called upon to fulfil this commitment [26, 45].

The barycentre of radiology departments must return to being the patient, instead of the provision of service, according to the implementation of the 2013/59/EURATOM Directive. The required reorientation and reorganization of radiology departments could be sustained by the application of OHL principles in this specific context. The path for achieving the OHL attributes matched perfectly with the changes required by the implementation of the 2013/59/EURATOM Directive in Italy (Table 1) [17]. The final scope of both the Directive and OHL is the patient as the paradigm for

thinking, renewing, and reorganizing the governance and management of health organizations, specifically radiology departments.

The impact related to the improvement of OHL levels has been studied in different health branches and healthcare settings [12, 55-57]. However, none of them was applied to radiology departments until now. The Italian Society of Medical Radiology only published recommendations for including the dose index level in radiology reports and a manual to assess the quality of radiological examinations and treatments. The mere partial and formal fulfilment of the implementation was done, moving from the evidence by literature review and the requirements of the 2013/59/EURATOM Directive.

In contrast, the implementation of the European Directive in practice could pass through making Italian radiology departments more health literate by following the indications given for the application of the OHL attributes. The application of OHL principles in Italian radiology departments could start with the training of health professionals [18, 19, 58, 59].

The 2013/59/EURATOM Directive required the acquisition of educative competences to tailor communicative information in relation to patients/caregivers' knowledge, or rather according to their HL level, and stresses the optimal use of available technologies for dose monitoring and containment by the radiology workforce (OHL principle 3, 5, 6, 7, 8, 10). These aspects enforced the respect of the principles of justification, optimization, and limitation of the delivered dose and the involvement of patients in the decision-making process related to their health (OHL principles 2 and 9).

Table 1. Comparison between the Italian transposition of the 2013/59/EURATOM Directive and the 10 Organizational Health Literacy (OHL) attribute

Law 101/2020 TITLE XIII – MEDICAL EXPOSURES (Art. 156-171)	OHL attributes A Health Literate Health Organization
EU Mandate	1. Has leadership that makes HL integral to its mission, structure, and operations.
Art. 157. Application of the principle of justification to medical exposures Art. 158. Application of the principle of optimization to medical exposures	2. Integrates HL into planning, evaluation measures, patient safety, and quality improvement.
Art. 162. Training	3. Prepares the workforce to be health literate and to monitor progress.
Art. 166. Special protection during pregnancy and breastfeeding Art. 168. Population dose assessment and clinical audits	4. Includes populations served in the design, implementation, and evaluation of health information and services.
Art. 159. Liability Art. 161. Procedures Art. 164. Documents	5. Meets the needs of populations with a range of HL skills while avoiding stigmatization. 6. Uses HL strategies in interpersonal communications and confirms understanding at all points of contact. 7. Provides easy access to health information and services, as well as navigation assistance. 8. Designs and distributes print, audio-visual, and social media content that is easy to understand and act on.
Art. 167. Incidental and undue exposure Art. 170. Supervision	9. Addresses HL in high-risk situations, including care transitions and communications about medicines.
Art. 162. Training Art. 161. Procedures	10. Communicates clearly what health plans cover and what individuals will have to pay for services.

In order to make this possible, the high and middle management of Italian radiology departments should work together to establish OHL [60]. Implementation of OHL should be easier and faster with adequate governmental and organizational support. It can be considered a strategic management approach to improving the health outcomes of health organizations, updating, and increasing the roles of both health professionals and patients in terms of controlling and critically evaluating the process of care and making suggestions for improvement (OHL principle 1).

The next step should overcome resistance to change and to rethink the practice of Italian radiology departments. These department should be more open and resilient in adapting to the needs of both patients/caregivers and colleagues, with input from all stakeholders in the decision-making process. In this way, the reform of Italian radiology departments will satisfy the requirements of both the 2013/59/EURATOM Directive and the population (OHL principle 4), becoming a virtuous example of a Health Literate Health Department [61]. Radiology departments should be an example for colleagues in other departments. The increasingly widespread application of the OHL attributes in health organizations should be an internal mechanism of change and evolution, able to positively reform the entire Italian national healthcare system.

The auspicated impact of the OHL principles' introduction in radiology departments will bring to increase the advantages for patients and caregiver in relation with the positive outcome given as in the cardiac rehabilitation (feasible organizational quality improvement interventions that responded to local HL needs, enhancement of social support and individualized care, organizational impact promoting co-design process, motivation and ownership among service's users, staff, and leaders), maternal and child departments (teaching activity) or primary care settings (participative development and evaluation process of a HL self-assessment tool with general practitioners and community care organizations) in which these have already been adopted with knowledge of the facts. In these fields of actions, the additional and significant variables were especially

the will and the mandate by the top management as decision-maker to implement HLHO thought these actions for the achievement of fixed purposes, or rather to more navigable patient-centred health services.

CONCLUSIONS

Since the issuance of the 2013/59/EURATOM Directive, European studies focused on the technological equipment and professional competences required to contain exposure to ionizing radiations. These studies influenced the procurement of new technologies and the review of procedures adopted. However, the improvement of radiation protection knowledge among patients, caregivers, and health professionals, through the enhancement of the informative and educational competence of radiology staff, remains a critical issue. Although their training needs are clear, no solutions have yet been proposed to address this.

Today, there is no longer any time to postpone. Improving the OHL in Italian radiology departments could provide an opportunity to expedite this process. The requirements mandated by the 2013/59/EURATOM Directive and the attributes that a health service or organization should possess to increase its level of OHL are the same. Health policymakers and top management of healthcare organizations should promote this experimentation in radiology as a pilot study for cross-sectional collaboration with the entire healthcare sector. This experience could validate the positive results already obtained in some other medical specialties. If the expected benefits are confirmed, improving OHL should be adopted as a systematic approach to reposition the patient at the centre of the Italian healthcare system. This is likewise the primary objective of Mission 6 – Health of the National Plan of Recovery and Resilience drawn up by the Italian government to address the severe economic crisis resulting from the COVID-19 pandemic.

Conflict of interest statement

Nothing to declare.

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