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Minimizing Radiation Exposure in Imaging Studies: The European Experience

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Abstract In the European Community, a 1997/43 Euratom directive establishes that indication and execution of diagnostic procedures should follow three basic principles: the justification principle (article 3: "if an exposure cannot be justified, it should be prohibited"), the optimization principle (article 4: "according to the ALARA principle, all doses should be kept As Low As Reasonably Achievable"), and the responsibility principle (article 5: "both the referring physician ordering the test—the prescriber—and the practitioner are responsible for the justification of the test exposing the patient to ionizing radiation"). Any responsible prescription should follow these principles, also reinforced by the recommendations of the Medical Imaging guidelines of the European Commission (first released in 2001) and by the 2014 position paper on use of medical radiation issued by the European Society of Cardiology, stating that X-rays and gamma-rays are proven (class I) carcinogens and cardiologists should make every effort to perform the right imaging exam, with the right dose, to the right patient; an informed physician (or radiologist, or cardiologist) "cannot be afraid of the essential and often life-saving use of medical radiation, but must be very afraid of radiation unawareness."

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Introduction

Europe has been the cradle of medical radiation innovation, since the discovery of X-rays by the German physicist Wilhelm Roentgen in 1895. Artificial radioactivity and early radiotherapy applications were pioneered by Polish-French Marie Curie and her husband Pierre Curie in the following years. The German doctor Werner Forssmann first proposed invasive fluoroscopy in 1929, performing a cardiac catheterization on himself (what we would call today an imaging "selfie"). Interventional cardiology and angioplasty were pioneered by German cardiologist Andreas Gruntzig in 1977 in Zurich, Switzerland. The first tomography was proposed in the 1930s by Italian radiologist Alessandro Vallebona, and the first commercially viable CT scanner was developed by British electrical engineer Sir Godfrey Hounsfield in 1967. From a societal perspective, an even more important contribution was the attempt by the European community as a whole to establish some principles and rules for the optimal use of ionizing radiation in diagnosis and therapy. The rationale behind these attempts to regulate imaging by law derive from the concept that imaging can have a profound effect on the use of public resources and levels of public safety, with implications far too important to be left entirely deregulated in the hands of imaging specialists. We now know that the inappropriate and un-optimized use of imaging can be a significant cause of cancer and wastes significant resources, undermining the sustainability of health systems based on universal access paid for with public money [1]. This concept left a mark on the European Union legal

framework, imaging guidelines, research strategies, and everyday practice, although full implementation of the principles in real imaging life lags far behind, since evidence-based guidelines are generated, disseminated, and modulated by complex professional and commercial vested interests [2].

The European Legal Framework for Medical Radiation Exposure

In the European Community, a 97/43 Euratom directive establishes that indication and execution of diagnostic procedures should follow three basic principles: the justification principle (article 3: "*if an exposure cannot be justified, it should be prohibited*"), the optimization principle (article 4: "*according to the ALARA principle, all doses due to medical exposures must be kept As Low As Reasonably Achievable*"), and the responsibility principle (article 5: "*both the referring physician ordering the test* [*the prescriber*] *and the nuclear medicine physician* [*the practitioner*] *are responsible for the justification of the test exposing the patient to ionizing radiation*") [3••]. Any responsible prescription of an imaging test today should follow these principles. Unfortunately, only a minority of cardiologists and radiologists in Europe are aware of these stringent legal frameworks, and most prescribers and practitioners believe that every examination can be prescribed and/or executed on the basis of the (legally absent) "freedom of prescription" [4]. In reality, unnecessary or excess patient injury has been defined as a bodily injury liable to prosecution [5] as stated for the first time—in application of the existing Euratom law—by a decision of the Federal Supreme Court of Germany in 1998 [6].

Radiation Exposure of Workers: Europe Versus USA

The current occupational effective dose limit, as recommended by the International Commission on Radiological Protection ICRP in their publication 103 in 2007, is 20 milliSievert (mSv)/year averaged over a 5-year period and is similar in Europe and in the USA [7]. Additional dose restrictions apply to the pregnant worker, despite being with substantial variability in different countries due to the delicate balance between the legal rights of pregnant healthcare workers and of the fetus as a member of the public [8]. In the USA, the NCRP recommends "pregnant workers can continue to work in the catheterization laboratory if they so choose. Fetal exposure, as measured by a waist dosimeter, should be <0.5 rem (5 mSv) for the entire pregnancy" [9]. In Europe, tighter restrictions apply. After a worker has announced her pregnancy, the ICRP recommends that the additional dose to the embryo/fetus does not exceed 1 mSv during the remainder of the pregnancy. The IAEA Basic Safety standards present similar recommendations. On the basis of these recommendations, radiation safety limits for pregnant workers are <1 mSv in the UK, Spain, and most European countries. In Italy, national law (DLgs 26/03/2001, number 151) requires a woman working with radiation to communicate her pregnancy to the hospital director or to the chief of the practice after which the worker is absolutely forbidden to enter the exposed zone throughout the pregnancy [10]. Since intra-uterine exposure to ionizing radiation can be both teratogenic and carcinogenic [11], Europe might be considered a safer place to be during intra-uterine life for a baby with the mother working in interventional radiology.

Radiation Exposure in Medical Imaging: European Commission Guidelines

The proliferation of imaging may represent added value when appropriate, and added cost and risk when inappropriate. Guidelines established by credible societies and professional bodies form a reasonable basis for defining the appropriateness of testing. The first appropriateness guidelines on radiology imaging were released in 1999 by the Royal College of Radiology and soon endorsed in 2001 by the European Union medical imaging guidelines [12••]. The document prepared guidelines on appropriateness of general or specialized imaging testing, and a catalog of doses of common examinations. The ultimate goal of these documents was to define the appropriate test for the appropriate indication in the appropriate patient: a difficult, elusive, and moving target which is, however, one of the new features, and not the least important, of good quality medical care. In the following years, several non-European general radiology and specialty societies developed appropriateness imaging guidelines. Following the definition of the American College of Cardiology Foundation, an appropriate imaging study is one in which the expected incremental information, combined with clinical judgment, exceeds any expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication [13]. Negative consequences include the risks of the procedure itself (i.e., radiation or contrast exposure) and the downstream impact of poor performance such as delay in diagnosis (false negatives) or inappropriate diagnosis (false positives). These guidelines emphasized the importance of potential harm for patients undergoing inappropriate imaging (who undergo the risk of an imaging study without a commensurate benefit), excessive delay in the waiting lists for other

patients needing the exam, and an exorbitant cost for the society, with no improvement and possibly a reduction in care quality.

Research in Low-Dose Radiation Exposure: The European Experiences

As a medical community, we should make every effort to bring the data on health effects of medical radiation from an evidence-poor to an evidence-rich milieu. Further data are needed, especially in the low-dose range (<100 mSv). BEIR VII listed among top-research needs future medical imaging studies, including "*studies of infants who experience diagnostic exposures*" [14••]. Similar studies have been performed on Australian or British cohorts of 120,000 and 680,000 children, respectively, and adolescents undergoing CT studies, and showed that the cumulative dose from 2 to 3 head CT scans almost triples the subsequent risk of brain tumors, and the relative risk of cancer increases by 16 % for each additional CT scan [15••, 16••]. A similar effort should be made by the pediatric cardiology community, and at least one nationwide French study is currently underway to assess the long-term risk of cancer in children with CHD [17]. Pediatric cohorts are also ideally suited to identify the individual factors important in translating population into individual risk and to assess other major non-cancer effects of radiation exposure, including atherosclerosis, brain aging, and reproductive effects. In Europe, another ongoing study concerns the effects of low-dose chronic radiation exposure on interventional cardiologists. The study is called Healthy Cath Lab Study and is endorsed by the Italian Society of Invasive Cardiology and the Institute of Clinical Physiology of the National Research Council. The study population included 500 exposed staff (interventional cardiologists, technicians, and nurses) and an age-matched unexposed control group. A molecular epidemiology approach is adopted to evaluate "early warning signs" of brain and vascular aging [18].

Reality Check: Practice in Medical Imaging

Different ways to approach the radiation issue by the specialty community and different regulatory frameworks can lead, theoretically, to different practice patterns, with greater radiological awareness leading to higher prescription appropriateness and dose optimization in Europe. Unfortunately, as a rule, the levels of basic radiological knowledge and attention paid to dose optimization and prescription appropriateness are suboptimal both in Europe and in the USA. The great number (>30 %) of inappropriate examinations [19, 20], the frequent unawareness of dose and risks by the referring physician and the practitioner [4, 21], and the provision of limited radiation safety information to the patient [22] may raise ethical and legal issues [23], amplified in research-oriented applications, especially in children. This ethically and legally uncomfortable situation also offers a unique opportunity for knowledge-based intervention [24]. Simple information provided on mobile support at the point of prescription on the radiologic dose and direct cost of imaging tests immediately shifts the prescription patterns toward radiation-free and less costly techniques [25].

Conclusions

The radiation issue is no longer a hidden variable unknown or ignored by doctors and patients but a key factor in determining the rating of our division, the risk–benefit assessment of competing diagnostic and therapeutic options, the direction of future research, and the commercial success of new radiation-sparing technologies. Raised only 10 years ago as an issue of concern and debate [26, 27], the radiation issue is today considered a priority for the most important European medical scientific societies. The mainstream knowledge is represented in the takeaway message of the recent European Society of Cardiology position paper on medical radiation: "*X-rays and γ-rays used in radiology and nuclear medicine are proven* (*class I*) *carcinogens and cardiologists should make every effort to give the right imaging exam, with the right dose, to the right patient. The priority given to radioprotection in every cardiology department is an effective strategy for primary prevention of cancer, a strong indicator of the quality of the cardiology division, and the most effective shielding to enhance the safety of patients, doctors and staff. A smart cardiologist cannot be afraid of the essential and often live-saving use of medical radiation, but must be very afraid of radiation unawareness*" [28••]. According to the European Society of Radiology, the expected scenario in the next few years will allow better protection of patients (and staff) through appropriateness, optimization actions through technological improvements, dose recording and dose management through Dose Reference Levels, and dedicated radiation protection training with certification (also for cardiologists) [29]. The quest for justification and optimization is especially relevant in Europe, since cost inflation for inappropriate and risky examinations undermines health systems based on solidarity. However, as attempts to wind back medical excess intensify and gain

Table 1 Radiation in medicine: our responsibility to change

	What we have	What we need
Patient		
Dominant culture	More (exams) is better	Less (dose) is better
Keep record	Number of test	Dose of each test
Radiation history	Absent	Present
Radiological informed consent	Absent	Informative
Received dose in report	Missing	Mandatory
Dose coding	Fluoroscopy time	Effective dose
Organ dose	Ignored	Considered
Doctor		
Technology upgrading	More short-term cost	Less long-term risk
Lowering dose	A curiosity for physicist	Preventing cancer
The cancer risk	Theoretical	Proven
What can protection do	Reduce work comfort	Allow living longer
Dose reading	Off-line, months after	On-line, real time
Scientist		
Radiological risk estimation	Population-based	Personalized
Epidemiological data on staff	Nuclear power plant workers	Interventionist
Epidemiological data on pts	Adults	Children
Focus on risks	Only cancer risks	Non-cancer risks

Adapted from Ref. [33]

ground, vested interests "*will no doubt fight back hard to defend their turf and their markets*" [30]. However, it is reassuring that the mainstream culture has now accepted—both in Europe and USA—the need to include radiation history as a key component of the cancer risk profile of the patient [31, 32].

In few fields of medicine, one can obtain such an improvement in the quality of care with so little increase in awareness. You add awareness to the health care system, and you obtain safety [33]. You inject responsibility, and you gain primary prevention of cancer. It is time to abandon old, time-honored practices of radiological unawareness that we learned from our teachers and enter a new era of radiological responsibility, full of opportunities for patients, doctors, and scientists (Table 1). X-rays, CT, invasive fluoroscopy, and nuclear medicine are essential tools for physicians—but they must be used prudently and optimally. European legislation promotes a responsible attitude toward radiological prescription, but we cannot reinforce prudence, responsibility, and common sense by law alone.

Compliance with Ethics Guidelines

Conflict of Interest Dr. Eugenio Picano and Dr. Clara Carpeggiani each declare no potential conflicts of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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