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EHRA CONSENSUS DOCUMENT

Occupational radiation exposure in the electrophysiology laboratory with a focus on personnel with reproductive potential and during pregnancy: A European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS)

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Introduction

The number of invasive electrophysiology procedures in the last 25 years has significantly increased worldwide and is expected to further increase in the future. The majority of these procedures is guided by fluoroscopy and in spite of recent developments is still associated with moderate occupational radiation exposure.

The percentage of female medical school students and graduates has significantly increased in the last 10 years currently reaching close to 50% both in the European Union (EU) and USA. According to a US survey conducted in 2006 by the American College of Cardiology Women in Cardiology Council, the percentage of female cardiologists has increased in the last 10 years to 18% but still remains low compared to other specialities in internal medicine.[1] The percentage of female trainees in cardiac electrophysiology is only 11%.[1] Although 30% of the female cardiologists performed procedures with radiation risk while pregnant, the survey suggested that occupational exposure is a concern to both men and women. Female cardiologists made more changes in their training and careers to reduce or avoid radiation exposure because of concerns related to risk to a developing foetus. Concerns related to occupational radiation exposure before and during pregnancy is one of the reasons for continuing female underrepresentation in interventional cardiology and electrophysiology. In another previous survey among physicians dealing with pregnant patients, important overestimation of the teratogenic risk associated with radiation exposure during pregnancy has been reported.[2] Electrophysiology and training in electrophysiology may be associated with significant occupational radiation exposure. A lack of accurate knowledge and misinformation regarding the risk of occupational radiation exposure before conception and during pregnancy can cause unfounded fear leading to anxiety and altered career and family choices. Negligence and non-compliance with current radioprotection practices may be on the other side hazardous for the personnel of the electrophysiology laboratory and the unborn child.

Recently, several guidelines have been issued by the International Commission on Radiological Protection (ICRP) on radiological protection in medicine and specifically in cardiology.[3,4] These guidelines have also addressed occupational exposure during pregnancy and proposed new recommendations. Several organizations in subspecialties translated the ICRP guidelines and issued similar recommendations.[5–8] The EHRA has issued in 2014 a practical guide on ways to reduce radiation dose for patients and staff during electrophysiological procedures.[9] The purpose of the current document as an adjunct to the EHRA practical guide is to describe the current knowledge on the risks and to inform about current international recommendations and legislations on occupational exposure in the electrophysiology laboratory to personnel with childbearing potential and during pregnancy.

Evidence review

Members of the Task Force were asked to perform a detailed literature review, weigh the strength of evidence for or against a particular procedure, and include estimates of expected health outcomes where data exist. In controversial areas, or with regard to issues without evidence other than usual clinical practice, a consensus was achieved by agreement of the expert panel after thorough deliberations.

This document was prepared by the Task Force with representation from EHRA and HRS. The document was peer-reviewed by official external reviewers representing EHRA and HRS.

Consensus statements are evidence based, and derived primarily from published data. In contrast to guidelines, we have opted for an easier and user-friendly system of ranking using 'coloured hearts' that should allow physicians to easily assess current status of evidence and consequent guidance (*Table 1*). This EHRA grading of consensus statements does not have separate definitions of level of evidence. This categorization used for consensus statements (used in consensus documents) must not be considered as being directly similar to that used for official society guideline recommendations, which apply a classification (Class I–III) and level of evidence (A, B, and C) to recommendations used in official guidelines.

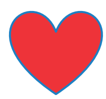
Thus, a green heart indicates a 'should do this' consensus statement or indicated procedure, that is based on at least one randomized trial, or is supported by strong observational evidence that it is beneficial and effective. A yellow heart indicates that general agreement and/or scientific evidence favouring a 'may do this' statement or the usefulness/efficacy of a procedure. A 'yellow heart' symbol may be supported by randomized trials based on small number of subjects or not widely applicable. Strategies for which there has been scientific evidence that they are potentially harmful and should not be used ('do not do this') are indicated by a red heart.

Finally, this is a consensus document that includes evidence and expert opinions from several countries. The approaches discussed may, therefore, include regulations that do not have the approval of governmental regulatory agencies in all countries.

Relationships with industry and other conflicts

It is EHRA/ESC policy to sponsor position papers and guidelines without commercial support, and all members volunteered their time. Thus, all members of the writing group as well as reviewers have disclosed any potential conflict of interest in detail, at the end of this document.

Table 1 EHRA-grading of consensus statements

Definitions where related to a procedure	Consensus statement instruction	Symbol
Scientific evidence that a procedure is beneficial and effective. Requires at least one randomized trial, or is supported by strong observational evidence and authors' consensus (as indicated by an asterisk*)	Recommended/ indicated	
General agreement and/or scientific evidence favour the usefulness/efficacy of a procedure. May be supported by randomized trials based on small number of subjects or not widely applicable	May be used or recommended	
Scientific evidence or general agreement not to use or recommend a procedure	Should NOT be used or recommended	

* Statement is supported by strong observational evidence and authors' consensus.

Basic concepts and nomenclature in radioprotection

Definitions of radiation exposure

Radiation exposure can be expressed as 'absorbed dose' or 'kerma' that represents the energy of absorbed radiation by an organ or tissue per unit of mass, typically measured in milli-gray (mGy).[10] In biology, the term 'equivalent dose' is used, which takes into account the radiation weighting factor relevant for the biological effect of the absorbed radiation. It is expressed in millisievert (mSv). For X-rays, mGy and mSv are numerically equivalent (*Table 2*). In medicine, it is important to estimate the potential biological effect, i.e. radiological risk for an individual (patient or personnel). However, such estimations are difficult. The equivalent doses for all exposed organs and tissues are combined, taking into account their respective radiosensitivities, to obtain a global quantity called 'effective dose' (ED) (which is also expressed in mSv). E.g. the higher biological radiosensitivity of breast tissue explains why women have a higher estimated ED for the same level of exposure. For children, radiation risk is higher due to the sensitivities of their tissues and the longer time-horizon for potential deleterious effects. Moreover, several genetic, environmental and dietary variables can affect the variability of risk observed to any given level of radiation, although these are not taken into account when estimating the radiation risk.

Calculating and reporting radiation exposure for patients

The most accurate estimation of ED received by patients is to calculate organ equivalent doses with Monte Carlo simulations, taking into account patient parameters (like age and gender) and exposure and geometrical parameters (like angles and other physical imaging values, ideally separately for each of the imaging sequences). From these organ dose values, a global ED is estimated. There are several computer programs for such calculations.[11] It is recommended to use organ doses for research and scientific reports but the approach is not suited for routine practice.

In routine practice, ED of the patient can most simply be approximated with a conversion factor from exposure values that are provided by the imaging equipment. All modern X-ray systems have to report a standard quantity that is 'kerma area product' (KAP), also called 'dose area product' (DAP). Kerma area product/

Table 2 Radiation quantities

Radiation quantity	Most used unit	Comment
Absorbed dose	mGy	A physical quantity reporting the energy of ionizing radiation absorbed per unit mass by matter or tissue
Equivalent dose	mSv	The absorbed dose in a tissue or organ multiplied by a weighting factor as an indication for its potential biological impact.This factor is 1 for X-rays
Effective dose	mSv	The tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body. It allows rough estimation of global biological risk to a standard person (patient or medical worker)
KAP or DAP	$Gy \cdot cm^2$	Measured or calculated by the X-ray system: the integral of air kerma across the entire X-ray beam emitted from the X-ray tube (allows a crude estimate of ED by conversion factors)
Cumulative air kerma	mGy	The air kerma accumulated at the patient entrance reference point. Measured or calculated by the X-ray system, can be used as a rough estimate of the cumulative skin dose
Personal dose equivalent (*Hp*)	mSv	Measured by occupational dosimeters, allowing (within specific preconditions) estimations of organ doses (e.g. hand or eye) and ED of workers

Adapted with permission from Heidbuchel *et al.*, *EP Europace* 2014.[9]
DAP, dose area product; ED, effective dose; KAP, kerma area product.

Dose area product is typically expressed in Gy·cm^2, mGy·cm^2, or μGy·m^2. Dose area product values integrate many more imaging factors than just fluoroscopy time. It also takes into account the degree of collimation, pulse frequency (and hence, number of frames), and dose per pulse. Fluoroscopy time should *not* be an acceptable measure of radiation exposure. The most used factor to convert DAP or KAP values into estimated ED for adults is 0.20, i.e. ED (mSv) = 0.20 × DAP (Gy·cm^2).[12] Thus, a value of 10 Gy·cm^2 (which is 10 000 mGy.m^2) for a cardiac procedure represents about 2 mSv in ED to the adult standard patient. Although conversion factors ideally require specific values for each catheterization laboratory (based on Monte Carlo calculations), the calculated ED remains an estimate with an intrinsic inaccuracy of ±50%. Moreover, comparisons of ED become even more inaccurate when there are significant dissimilarities between the age and sex distributions of the patients or populations being compared.[13] Nevertheless, for sake of applicability in daily care, EHRA in a previous document has recommended to routinely use the internationally accepted conversion factor of 0.2 mSv/(Gy·cm^2).[9] For women and children, the conversion factor is higher since they have a higher risk of cancer development by radiation. For women, the relative risk is roughly 1.38 compared to men.[9,14,15] Therefore, for an adult woman one should use the conversion factor 0.28 (0.2 × 1.38). Some authors have suggested specific conversion factors for children with proposed values being 3.7 ± 0.2 in neonates, 1.9 ± 0.2 for a 1 year old, and 1 ± 0.1, 0.6 ± 0.1 and 0.4 ± 0.1 for 5-, 10-, and 15-year-old boys (and further multiplication by 1.38 in case of girls).[16] Radiation exposure estimated as ED (based on DAP values) is a pragmatic approach to roughly compare the relative radiation risks to patients. It may be a more natural way for physicians to compare the biological risks to patients than DAP values itself, and much more correct than fluoroscopy duration.

Another obligatory value reported by the imaging equipment is 'cumulative air kerma' at the patient entrance reference point. When the field of irradiation is the same throughout the procedure, this roughly represents the cumulative skin dose to the patient, which is expressed in mGy or Gy.[17] In the US reporting, the Cumulative Air Kerma (in mGy or Gy) value of the electrophysiological procedures is preferred as compared to the EU where the KAP/DAP values are used.

Risks of radiation exposure for patients and personnel

Biological effects of ionizing radiation can be classified as stochastic (carcinogenic and genetic effects) and deterministic (also called tissue reactions). The most widely accepted model for stochastic effects is the 'linear non threshold' model, i.e. any small amount of radiation involves an increase in cancer risk without any threshold, and the probability increases linearly with increasing radiation dose.[13,14] This may even hold for cataract,[18] although this is usually considered as a deterministic effect. For deterministic effects (e.g. skin injuries, cataracts, etc.), there is a threshold of dose (below this threshold, the effect is not produced) and the severity increases with the dose. The threshold for skin injuries is considered at 2–3 Gy, but for radiation induced opacities in the eye lens, the ICRP has proposed 500 mGy as threshold.[13] ICRP provided a dose threshold of 500 mGy for non-cancer effects of ionizing radiation to the heart.[13]

Responsible use of radiation

Appropriate imaging is crucial in performing complex EP procedures effectively and safely. The risk of radiation exposure always needs to be balanced vs. the benefits of the imaging itself, based on three principles: justification (i.e. is the use of radiation appropriate), optimization (i.e. reducing dose for the needed diagnostic information), and physician responsibility for occupational dose limitation (i.e. through training and quality control).[9,19]

Monitoring radiation exposure

An individual monitoring program of radiation exposure is intended to provide information about the optimization of protection and to demonstrate that the worker's exposure has not exceeded any dose limit or the level anticipated for the given activities. The ICRP recommends the use of two personal dosimeters for occupational dosimetry in cardiac catheterization laboratories: one worn on the trunk of the body inside the apron (usually at waist level) and the other worn outside the apron at the level of the collar or left shoulder. At least one dosimeter (the collar dosimeter) should always be used.[3 4] Each dosimeter has a pre-determined location to be worn. The dosimeter under the apron provides an estimate of the dose to the organs of the shielded region, including the reproductive organs. The dosimeter worn outside the apron supplies an estimate of the dose to the organs of the head and neck, including the thyroid and the lens of the eyes (if unshielded), but greatly overestimates the doses to organs of the trunk. The advice of a medical physicist should be sought to interpret monitoring results. The ED can be estimated from the dosimeter values for H_w (under the apron at the waist, although this position is not critical) and H_n (above the apron at the neck) from the equation: ED = 0.5 H_w + 0.025 H_n.[3,4] Requirements and recommendations for the number and placement of dosimeters vary from country to country. During pregnancy, the individual dosimeters should be evaluated monthly and the workers should be provided with their monthly dose record. For pregnant workers who have declared their pregnancy, conceptus dose can be estimated using the dosimeter worn under the apron on the front of the torso between shoulder and waist level.[3] Sometimes, for the same purpose, an additional dosimeter is placed on the mother's abdomen, again under her radiation protective clothing. Regulatory requirements to declare pregnancy differ among countries, with a few countries allowing a pregnancy to be not declared. In an international survey of 380 members of the Society for Cardiovascular Angiography and Interventions' Women in Innovations group 8% of the female responders did not declare pregnancy to their institutions.[6] In some cases, prohibition from further working near radiation by declaration of pregnancy played a role. Not declaring pregnancy should be discouraged as it may preclude proper monitoring of radiation exposure during the pregnancy. It could also have negative legal consequences for the employee in case of liability issues. An employee may have the option to request and wear an abdominal/waist badge regardless of whether a pregnancy declaration has been made. The foetus is most sensitive to

Table 3 Typical patient' and physician's radiation doses in electrophysiology

Type of study	Effective dose to patient in mSv median and range per procedure[9]	Effective dose to operator in µSv mean and mean range per procedure[a] [23]
Diagnostic electrophysiological study	3.2	UR[b]
	1.3–23.9	
Ablation procedure	15.2	2.7
	1.6–59.6	0.24–9.6
Atrial fibrillation	16.6	3.3
	6.6–59.6	UR[b]
AT/AVNRT/AVRT	4.4	2.6
	1.6–25	0.2–9
Ventricular tachycardia	12.5	UR[b]
	3–≥45	
VVI/DDD PM or ICD implant	4	4.8
	1.4–17	0.29–17.4
CRT implant	22	UR[b]
	2.2–95	
Coronary angiography	7	4.4
	2.0–16	0.02–38
Percutaneous coronary intervention	15	4.9
	7–57	0.17–31

[a]The reported mean doses and mean dose ranges are mean estimates from a small number of studies including low number of procedures performed before 2008 and should be interpreted with caution. Operator doses varied by two to three orders of magnitude for the same type of procedure.
[b]Under-reported: occupational exposure is reported in an insufficient number of procedures to produce representative numbers for operator effective doses.
AT/AVNRT/AVRT, atrial tachycardia, atrioventricular nodal re-entry tachycardia, atrioventricular re-entry tachycardia; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; PM, pacemaker; UR under-reported.

radiation effects between 8 and 15 weeks of pregnancy. This period is often before the pregnant worker announces her pregnancy to supervisors or co-workers, and therefore she may wish to request a foetal badge before actually declaring pregnancy. A worker who is considering pregnancy may also request an abdominal/waist badge. Reading from this badge can help to establish the likely conceptus dose that would be received with a normal work schedule. Based on the information adjustment of work schedule preconception or during pregnancy may be planned.[7]

The irregular or incorrect use of personal dosimeters is still a problem in many catheterization laboratories and leads to inaccurate occupational exposure estimation. Examples are not wearing the dosimeter during the procedures, leaving the dosimeter in the fluoroscopy room or on the apron being worn by other colleagues or swapping the dosimeters by wearing the inside dosimeter on the outside of the apron. In addition to monitoring personal exposure, dosimeter use helps to increase awareness about radiological protection.[4] Compliance with radiation badge policies during pregnancy is essential and should be enforced.

Magnitude of radiation exposure in electrophysiology

Depending on the nature of the procedure, the radiation dose to the patient and the operator will vary considerably, mainly being influenced by the imaging time and the image quality needed to perform the procedure safely and efficiently. From historical data, typical values for the patient vary from 3.2 mSv for a simple diagnostic electrophysiological study to higher values in more complex ablation procedures, such as in atrial fibrillation, for which the reported median dose was 16.6 mSv (*Table 3*).[9,20] Cardiac resynchronization device implantation is associated with the highest radiation exposure with patient's mean ED reaching 22 mSv per procedure.[9] Estimating the radiation dose to the physician in general is much more difficult due to the many variables involved from energy source to physician. There is an impact of the hardware (detector size, image quality settings), procedure-specific factors (tube angulations, collimation, patient BMI), laboratory setup (use of protective lead lining, position of operator), and operator factors (use of personal protection).[21] As a general rule of thumb, about 10–20% of photons entering the patient are scattered. Adequate lead lining above and below the patient table is capable of blocking upwards of 80% of this scatter.[22] A rough worst-case estimate of total physician dose in this setting would be 5% of total estimated patient dose.

There are very few and small studies reporting occupational exposure dose measurements in the electrophysiology laboratory. In the reported studies, the average operator dose was quantitatively related to the average patient dose, but there was much greater variation in operator doses.[21,23] In a previous comprehensive summary of a small number of studies involving low number of patients operator doses varied by two to three orders of magnitude (100–1000 times) for the same type of procedures.

Modest operator dose reductions over time were observed for ablation procedures due to technological improvements. The right column in *Table 3* summarizes the reported mean EDs and mean ED ranges received by the operators per procedure before 2008 from this summary.[23] In general, implantation of cardiac resynchronization devices is associated with highest operator exposure dose due the proximity of the operator to the radiation source. In a more recent study at the operator's hand, a mean of 1.2 mSv (up to 9. mSv) per procedure exposure was measured with a ring dosimeter.[24] Given the reported great variability in occupational exposure mean doses per procedure (from 0.2 μSv to 59 μSv) and the low number of small studies included, the numbers in *Table 3* are indicative and should be interpreted with great caution. It should be also noted that ED for the operator does not reflect the doses to unprotected parts of the body (as the hands and the eyes) and overestimates the dose to the areas under the apron. The dosimeter under the apron also overestimates actual dose to the embryo because radiation attenuation by the mother's tissue is not considered. In a simulation study a conversion factor between the pregnant worker's air kerma and foetus dose was proposed.[25] The authors of this study calculated a conversion rate of 0.27, 0.23, and 0.17 between air kerma and foetus dose in the first, second, and third trimester, respectively.

Personnel in the electrophysiology laboratory who are positioned in the control room are protected by both shielding and distance from the X-ray beam. Exposure factors for the operators are 1000 times higher than staff working in the control room. The supporting staff working in the operating room (nurse, technicians, and anaesthetist) was also reported to receive significantly (in one study 20 times) less radiation than the primary and assistant operators.[20] All personnel working in the catheterization laboratory should be trained in radioprotection measures and should were personal protection and dosimeters. A simple way to avoid unnecessary exposure is to stay in distance from the radiation source whenever possible.

A more recent study reported physicians' dose during various ablation procedures with the use of a radioprotection cabin.[26] The directly measured radiation level was reduced to normal background levels inside the cabin protected areas. Median dose outside protected areas (cabin or lead) was 57–452 μSv per procedure. Use of a radioprotection cabin is therefore able to eliminate radiation risk completely or almost completely.

The increasing number of AF ablation procedures, together with the fact that transcatheter AF ablation is currently a complex procedure requiring greater fluoroscopy duration and radiation exposure than other catheter ablation procedures, has incentivized operators to develop workflows and adopt technologies aimed at reducing ED during these procedures. Non-fluoroscopic three-dimensional navigation and electroanatomical mapping (EAM) systems have been developed to address this need. Most experience exists with the Ensite-NavX system (St.Jude Medical, USA) and the CARTO system (Biosense Webster, USA). Both systems have been shown to reduce ED significantly during AF ablation.[27–30] In addition, these systems have been used in synergy with other cardiovascular imaging modalities to further reduce ED. Three-dimensional rotational angiography (3DRA) and intracardiac echocardiography (ICE) have been used to acquire detailed 3D anatomical models that can be integrated in EAM systems and allow entire procedure workflows with limited or even zero radiation exposure.[31–33] As opposed to 3DRA, ICE is not associated with radiation exposure to the patient. Several other systems are under active development or in the early stages of commercialization and will undoubtedly also incorporate low- or zero fluoroscopy workflows. Complementing these mapping systems are images from traditional cardiovascular imaging modalities, acquired to assist ablation procedures by providing the operator with a 3D anatomical model. These imaging modalities may reduce total ED both to the patient and the operator in spite of preprocedural additional radiation to the patient.[34,35] Electrocardiogram (ECG)-gated acquisition has enabled significant ED reductions for computed tomography scans (non-gated or prospectively gated ± 4 mSv vs. retrospectively ECG-gated ± 15 mSv).[36] Using low-dose 3DRA protocols, computed tomography-like 3D reconstructions can be obtained at an ED of 1.0–6.6 mSv.[33,37] Magnetic resonance imaging and ICE-guided catheter ablation offer promise for high-resolution catheter imaging with minimal or no radiation, as well as providing opportunities for real-time dynamic imaging.[38]

Occupational exposure during catheter ablation procedures has significantly decreased in the last 5–10 years with the use of modern technologies. However, there are no data reported yet on the current range of occupational exposure and on the magnitude of decrease in the electrophysiology laboratory.

Methods to reduce radiation exposure in the electrophysiology laboratory

Irrespective of the gender of the first hand operator, working in the electrophysiology laboratory carries its professional risk of radiation-induced diseases which is why working in these environments is regulated strictly. A number of equipment-based and personal radiation protection measures are available and can lead to a substantive reduction of the overall radiation exposure during invasive EP procedures. *Table 4* is a summary of these recommendations adapted from the EHRA practical guide.[9] Similar recommendations were issued as the 10 pearls of radioprotection in a poster format available at the International Atomic Energy Agency (IAEA) website.[39]

Specific recommendations for female operators during pregnancy

There a number of reports on pregnant patients undergoing low or zero radiation ablation procedures,[40–46] but dedicated reports on female physicians performing invasive procedures during their own pregnancy are scarce. However, some recommendations are common sense and frequently applied. In general, radiation awareness, appropriate use of monitoring and radioprotection measures should minimize exposure to the operator to lowest possible level during pregnancy. Device implantation procedures expose the operator to much more scattered radiation than invasive EP studies and careful positioning and optional shielding should be achieved during these procedures.[24,47] A two-piece wrap around lead skirt and vest should

Table 4 Recommendations for reduction of fluoroscopy exposure during electrophysiological procedures

Measure	Effect on reduction	Comment
Equipment-based factors		
Lower frame rate for fluoroscopy and cine acquisition	Important reduction of overall (patient and operator) exposure	As low as 2.5 frames per second may be sufficient for fluoroscopy
Use under table lead shielding	7-10 fold reduction of operator dose	May be difficult if cranial/caudal projections are chosen
Use over table lead glass shielding	4-10 fold reduction of operator dose	Easily achieved even in device procedures
Use collimation	2 fold reduction of patient (and operator) exposure	Regularly adjust collimation of the image to the region of interest
Minimise the use of steeply angulated projections	Reduction of patient and operator exposure	In LAO the operator exposure can be up 6 times higher as in RAO projection
Keep the patient as far as possible from X-ray tube	Reduction of patient exposure	Adjust the height of the table
Place image detector as close to patient as possible	Reduction of operator exposure	Detector should be adjusted after changing table height
Use intermittent short radiation (as opposed to continuous) radiation	Reduction of patient and operator exposure	Avoid or minimalize radiation when advancing catheters from the groin or retracting catheters
Avoid cine acquisition by use of "store fluoro" option	Reduction of patient and operator exposure	Fluoroscopy yields lower resolution images compared to cine acquisition, but for documentation of site of ablation or pulmonary vein venography, this cine resolution is usually not necessary.
Avoid magnification	Reduction of patient and operator exposure	If possible collimation is preferred
Keep maximal distance from X ray source and patient as practically achievable	Radiation exposure is inversely proportional to the square of the distance	Doubling distance from the patient reduces scatter exposure by a factor of 4
Personal protection factors		
Wear complete lead apron protection (including thyroid shield)	90-95% dose reduction in operator exposure	Two-piece wraparound apron provides extra protection to the low abdominal region and distributes the aprons weight
Avoid exposing your own hands	Dose reduction to operator's hands	Place metal object on the skin to mark puncture site on fluoroscopy
Additional personal lead aprons (head, leg and arm shields, gloves)	Dose reduction to protected regions	Necessary for specific situations eg. device implantation
Wear lead glasses	Dose reduction in operator eye exposure	Protection to the eye lenses: radiation cataract
Radiation cabin	Zero exposure to operator's body	If available
Special features for catheter ablation procedures		
Use of 3D mapping systems	Reduction to near zero exposure is possible once the mapping/ablation process is started	Very much depending on operator experience and system accuracy
Remote navigation systems	Near zero exposure to operator as he/she is located in control room	If magnetic navigation or remote mechanical navigation systems are available

For further details see the EHRA practical guide on 'practical ways to reduce radiation dose for patients and staff during device implantations and electrophysiological procedures.[9]
LAO, left anterior oblique view; RAO, right anterior oblique view

be used with a minimum of 0.5 mm lead equivalence in the front (where the two sides overlap) and 0.25 mm lead equivalence in the rear. Adding a second apron will have a minimal effect on the conceptus radiation dose (providing only an additional ∼4.75% attenuation).[7] The additional weight due to extra protection has to be traded-off with the additional orthopaedic strain and fatigue for the working mother, with possible exacerbation of musculoskeletal and orthopaedic symptoms very frequent in interventional electrophysiologists and invasive cardiologists even outside pregnancy and when aprons are not worn.[48–50] A radiation protection cabin may be used if available.[26] Whenever possible, further radiation reduction measures such as using 3D mapping systems or remote navigation systems can be employed to reduce the overall exposure. A decrease of the workload specifically for procedures with high radiation exposure should be arranged if possible and achievable and chosen by the pregnant operator.

Importance of training and education on appropriate radiation protection measures during cardiology residency

Radiation protection and comprehensive training in the correct use of all available protection measures should be part of the curriculum of all trainees in specialized EP/device training programs irrespective of their gender.[9] Careful attention should be taken of the correct use of the protection shielding and personal protection by adequate lead apron as well as constant use of the radiation dosimeters at the correct position.[8] The attitude towards recognition of the radiation exposure for both patient and operator/staff needs to be governed by the reasonably achievable (ALARA) principle at all times. Long term radiation exposure as a key health concern for all electrophysiology laboratory personnel needs to be recognized.[51–53]

Effect of radiation exposure on spermatogenesis and fertility in electrophysiologists

Occupational exposure to potentially hazardous factors including radiation can impact both male and female reproductive health. However, due to obvious ethical constraints, only a few experimental data are available and the majority of the findings are based on either animal models or epidemiological studies.

Most of the studies are focused on male reproductive performance as testicular tissue is highly sensitive to ionizing radiation. Early studies conducted on healthy volunteers exposed to different doses of radiation showed clear dose-related effects on sperm production, in terms of both the magnitude and the duration of sperm count suppression.[54] Transient sperm count deterioration was observed between 105 and 330 days after exposure with dose greater than 0.15 Gy. However, no clear effect has been reported after exposure to less than 0.08 Gy. Similarly, the histological samples from two available human studies revealed suppression of prime population of spermatogonia (stem cell populations of the germ cells) to about 20% of control values by 0.2 Gy and less than 1% by 4 Gy occurring between 100 and 250 days after exposure. Comparable results were also observed in animal models. However, it is important to state that sperm counts appear to be less sensitive to low doses and more sensitive to high doses than type A spermatogonia (the differentiating group from the stem cell populations of the germ cells).[55] Based on those studies, a temporal damage resulting in short-term reduction of sperm counts can be expected after absorbing of radiation dose in the range of 0.11–0.15 Gy, while 2–3 Gy may result in long-lasting or permanent sterility.[56] In the occupational exposure dose range, these effects do not occur. A recent study in health workers occupationally exposed to ionizing radiation reported worse semen quality than unexposed controls (as assessed by motility characteristics, viability, and morphological abnormalities), with higher incidence of sperm DNA fragmentation and hyper-methylated spermatozoa, suggesting that occupational radiation exposure may have substantial detrimental effect on sperm functional, genetic and epigenetic integrity in health workers.[57] Based on these reports, an occupational exposure limit of 15 mSv/year has been adopted in several countries, and if this limit is not exceeded,[15] testicular effects of radiation are unlikely. In comparison, an earlier simulation study of ED values, eye lens, skin, and gonadal doses in EP laboratory personnel has shown that a procedure requiring 40 min of fluoroscopy yields a maximum ED of 129 μSv and a maximum gonadal dose of 57 μSv to operators wearing 0.35 mm lead-equivalent apron.[58] This study has shown that operator ED values vary by a factor of 40 due to positioning during fluoroscopy and by a factor of 11 due to radiation protection equipment. Undercouch protective shields reduced gonadal doses up to 98%.[58]

Exposure to noxious factors can potentially alter the sex ratio at birth. However, studies among populations exposed to different types of radiation have yielded conflicting and inconclusive results.[59–62]

As there are no applicable direct measurement methods to estimate the influence of radiation exposure on female reproductive health, evidence for such interactions is more indirect and based mainly on observatory studies in survivors of childhood cancer. Potential effect of radiation on genetic material is currently not known and there is concern that germ cells may carry mutations that could lead to genetic disease in offspring. However, large studies reported a similar range of major and minor congenital abnormalities between the offspring of patients exposed to radiotherapy for childhood cancer and normal populations.[63] Furthermore, there was no increased prevalence of cancer in offspring of childhood cancer survivors in the absence of known cancer predisposition syndromes.

Radiation might induce alterations in the hypothalamic–pituitary axis function influencing fertility and outcome of pregnancy. However, in human no data are yet available on the presence and importance of these effects.

Effect of radiation exposure on the foetus

In most cases, the estimation of radiation doses derived from occupational exposures in electrophysiology laboratories to the conceptus is made by a medical physicist or by a radiation protection expert, using the readings of personal dosimeters worn over and under the protective apron. As a conservative approach, the monthly dose registered by the personal dosimeter worn under the lead apron (usually positioned at waist level for pregnant workers) is assumed to be the dose to the conceptus and should be in the range of a few μSv per month if radiation protection tools are properly used.[5,64] These doses depend on the shielding used (protection devices and lead apron), increase with the workload, and vary according to how close the worker is to the patient during the clinical procedures.

Radiation dose for the conceptus may be reported in mSv (equivalent dose) or in mGy (mean absorbed dose). Both quantities and units are used in the literature and are equivalent for X-ray radiation.

Importance of gestational age

Prenatal low doses (as typically received by workers properly protected in EP laboratories) present no measurable increased risk of prenatal death, malformation, or impairment of mental development over the background incidence of these entities. There are radiation-related risks throughout pregnancy, which are related to the stage of

Table 5 Probability of a live birth without malformation or without childhood cancer as a function of radiation dose[7]

Dose to conceptus above natural background radiation (mGy)	No malformations (%)	No childhood cancer (%)	No malformations and no childhood cancer (%)
0	96.00	99.93	95.93
0.5	95.999	99.926	95.928
1.0	95.998	99.921	95.992
5.0	95.99	99.89	95.88
10.0	95.98	99.84	95.83

Table 6 Spontaneous risks facing an embryo at conception in the general population[7]

Risk of spontaneous abortion in known pregnant women	1 in 7
Risk of major congenital malformations	1 in 33
Growth retardation	1 in 33
Risk of childhood leukaemia per year	1 in 25 000 per year

pregnancy and the foetal absorbed dose. ICRP states that radiation risks are most significant during organogenesis and the early foetal period, somewhat less in the second trimester, and least in the third trimester. Throughout most of the pregnancy, the embryo/foetus is assumed to be at about the same risk for potential carcinogenic effects of radiation as are children.[65] See more details in the section on risks at different dose ranges.

Pre-conception irradiation of either parent's gonads has not been shown to result in increased cancer or malformations in children.[65] In 2001, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reported to the General Assembly that 'radiation exposure has never been demonstrated to cause hereditary effects in human populations'.[66]

Risks at different dose ranges

The dominant effect of a moderate irradiation during the pre-implantation is early death of the conceptus. At doses under 100 mGy, such lethal effects will be very infrequent.[67] In the occupational dose range of less 1–5 mSv exposure to the mother, death of the conceptus due to radiation is not described.

The risk of malformation is greatest during the period of major organogenesis with an estimated dose threshold of around 100 mGy. The ICRP judges that risks of malformation after *in-utero* exposure to dose well below 100 mGy are not expected.[15]

The risk of reducing the intelligence quotient (IQ) occurs after high-dose irradiation in the most sensitive period (weeks 8–15 post-conception). Any effects on IQ following *in utero* doses under 100 mGy and in the mother's occupational exposure range (<5 mSv) would be of no practical significance.[15]

Estimating the risk of cancer induction is the most important subject in foetal exposure. The ICRP recognizes that there are particular uncertainties on the risk of radiation-induced solid cancers following *in utero* exposure and considers that it is prudent to assume that life-time cancer risk following *in-utero* exposure will be similar to that following radiation in early childhood, i.e. at most, about three times that of the population as a whole.[15] If we consider the life-time risk of fatal and non-fatal cancer of any type (solid tumours and leukaemia), according to Biological Effects of Ionizing Radiation (BEIR) VII (2006) estimation for age = 0 (newborn) the life-time cancer risk is estimated to be around 1 in 500 for 5 mSv *in utero* exposure, and 1 in 2500 for 1 mSv *in utero* exposure.[14] *Table 5* presents the probability of healthy births as a function of the absorbed dose to the conceptus above average annual natural background radiation globally estimated at 2.4 mSv.[9] *Table 6* shows the spontaneous pregnancy risks in the general population. *Table 7* depicts the calculated life-time cancer risk following in utero exposure.

The risk of conceptus death, malformation or childhood cancer in the occupational exposure range of the mother respecting the 1 and 5 mSv limits during pregnancy is negligible.

Review of current international recommendations on occupational radiation protection of pregnant workers from medical professional organizations

This topic is referred to as 'protection of pregnant worker', but the focus is on the protection of unborn child,[69] a term used to cover the entire time period of development from conception to delivery. The special protection for the unborn child is justified since the foetus is not a patient, will not benefit from medical procedures, is more sensitive to radiation, and has a whole life-time to develop radiation-induced detrimental effects.[68] After a worker has declared her pregnancy, the ICRP recommends that the additional dose to the unborn child does not exceed about 1 mSv during the remainder of the pregnancy.[3] The restriction of a dose of 1 mSv to the embryo/foetus of a pregnant worker after declaration of pregnancy does not mean that it is necessary for a pregnant woman to avoid work with radiation completely, or that she must be prevented from entering or working in designated radiation areas.[3] The ICRP states that if a pregnant woman wishes to continue her work in a fluoroscopy-guided procedures laboratory, this should be allowed with the following conditions: (i) she should do it on a voluntary basis and confirm that she has

Table 7 Life-time risk of developing cancer following *in utero* exposure[14,68]

	Probability of developing cancer in the general population (%LBR)	Life-time attributable risk for exposure (%LAR)	Probability of developing cancer if adding this extra-level of risk (%LBR + %LAR)
No exposure	42	0	42
1 mSv exposure (age 0)	42	1 in 2500	42.04
5 mSv exposure (age 0)	42	1 in 500	42.20

Data refer to exposure at age 0 as the risk for in utero exposure. The calculations are based on references.[14,68]
LAR, lifetime attributable risk: the additional risk of premature incidence or mortality from a cancer attributable to radiation exposure; LBR, lifetime baseline risk: the chance of having a cancer (incidence) and/or dying of cancer (mortality over the course of a life-time).

Table 8 Protection of the pregnant worker (and unborn child)

	Worker	Pregnant worker
Allowed exposure	<20 mSv/year	<1 mSv in pregnancy (in EU) <5 mSv (in USA)
Awareness	Cancer, cataract risks	Child risks (including cancer)
Lead-equivalent apron	0.25 mm (>90% protection)	0.50 mm (>95% protection)
Dosimeter	Above and/or under apron	Waist level (under apron)
Dose reading	Variable	Monthly

understood the information provided on radiation risks; (ii) a specific dosimeter should be used at the level of the abdomen to monitor the dose to the foetus monthly, and the worker should be informed of the dose values; (iii) a radiological protection program should exist in the hospital or clinic, supervised by a medical physicist or equivalent competent expert; (iv) the worker should know the practical methods to reduce her occupational dose, including the use of existing radiological protection tools; (v) the worker should try to control the workload in fluoroscopy guided procedures during her pregnancy; and (vi) the worker should know the risk of potential exposures and how to reduce their probability. The <1 mSv dose restriction is applied to the period of gestation after pregnancy is declared, and exposures that may have incurred in early pregnancy are not included in the total estimate of foetal dose. The IAEA Basic Safety Standards present similar recommendations.[70]

In general terms, the same key principles of optimization of radioprotection (time, distance, and shielding) suggested for the standard worker[71] may apply to the unborn child protection, but with some more restrictive criteria (*Table 8*). As always, the best protection comes from good radioprotection habits of the catheterization laboratory, routinely implementing a policy of dose optimization and personal shielding.[7] The 1 mSv limit (or 5 mSv limit in the USA) cannot be regarded as a dose credit, but rather as the lower boundary of the unacceptable exposure.[72] The child exposure should always be optimized towards the lowest possible levels, since the best dose for the child is no dose, and the awareness of the mother is the best protection of the unborn child. When local regulations allow, as it happens in the USA, the pregnant worker can continue to work on a voluntary basis. As should be applicable to all radiation operators,[8] the pregnant worker should not only be cautious about radiation exposure but also should be aware of protective and reduction measures.

Review of current legislations for pregnant personnel in Europe and in the USA

As a general rule the condition of pregnancy does not require removing the exposed professional from work, but careful review of working conditions to comply with current regulations is warranted.

At present, the *EU* member states national system for ionizing radiation protection is based on the *Directive 96/29/Euratom*,[73] which in the case of pregnancy requires that as soon as a woman declares pregnancy, the protection of the child to be born shall be comparable with that provided for members of the public; that is, the equivalent dose to the child to be born should be as low as reasonably achievable and not exceed 1 mSv during at least the remainder of the pregnancy.[73] The employer is responsible for training and providing information on the radiation health risks (for the professional and the child to be) and assuring that the working conditions of the pregnant woman meet the safety criteria. On December 2013 a new revised basic safety standards Directive was unanimously adopted by the EU Council (Directive 2013/59/Euratom[74]). This new basic safety standards directive takes into account the recommendations from the ICRP.[13,15] The general instructions in regards to pregnant workers are similar (i.e. once the woman has declared pregnancy, the employer must ensure that the foetus equivalent dose remains ≤1 mSv). The ICRP also requires for a radiation protection expert to give a competent advice on the matters relating to the compliance with applicable legal requirements, in respect of employment conditions for pregnant and breastfeeding workers.[74] EU Member States will have until February 2018 to translate this directive into national legislation (Article 106—Directive 2013/59/Euratom[74])

Table 9 Consensus statements

Consensus statements
Measuring and monitoring radiation exposure
The DAP or KAP or cumulative air kerma (in mGy or Gy) should be reported in all electrophysiological procedures*
For occupational dosimetry, two personal dosimeters should be used all the time correctly: one worn on the trunk of the body inside the apron (at waist level), and the other worn outside the apron at the level of the collar or left shoulder. At least one dosimeter (the collar dosimeter) should always be worn*
Pregnant occupationally exposed personnel should be provided a dosimeter to estimate the conceptus radiation dose. This dosimeter should be evaluated at minimum on a monthly frequency*
Reducing radiation exposure
The use of radiation should be governed by the as ALARA principle*
Occupational and patient exposure should be further decreased by training in radiation protection and the correct use of available protection and dose reduction measures*
Correct use of waist protection should be achieved with a two-piece wrap-around apron with an anterior lead equivalent thickness of 0.50 mm and provides >95% protection*
Regulations for pregnant personnel
In the EU as soon as a woman declares pregnancy, the protection of the child to be born shall be comparable with that provided for members of the public; that is, the equivalent dose to the child to be born should be ALARA and not exceed 1 mSv during at least the remainder of the pregnancy*
In the USA, occupational exposure of the foetus should be limited to a value As ALARA, but not to exceed 5 mSv during the entire pregnancy and 0.5 mSv per month of the pregnancy*
Pregnant medical workers may continue to work in a radiation environment if they wish to provided that there is reasonable assurance that the foetal exposure dose can be kept below 1 mSv in the EU and 5 mSv in the USA during the course of pregnancy and requiring the employer to review the exposure conditions of pregnant women carefully*
Declaration of pregnancy is encouraged as it allows proper monitoring of radiation exposure during the pregnancy*
Occupational radiation protection measures should be consistent with international standards and recommendations in all electrophysiology laboratories and must also comply with national and local regulations*

ALARA, low as reasonably achievable; KAP, kerma area product; DAP, dose area product.
*Statement is supported by strong observational evidence and authors' consensus.

There are other relevant European Directives, in regards to X-ray exposure for pregnant healthcare workers:

- *Directive 92/85/EEC*[75] on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding, which states that pregnant professionals cannot perform activities involving risk of exposure to agents (including ionising radiation) when, according to the conclusions of the risk assessment, it can endanger her or the foetus' safety or health. It is the employer's responsibility to assess the health risks, any possible effect on the pregnancy, and to decide what measures should be taken.
- *Directive 2002/73/EC*[76] of the European Parliament and of the Council on the implementation of the principle of equal treatment for men and women as regards access to employment, vocational training, promotion, and working conditions, which mandates avoiding professional discrimination against women of childbearing age.

In the *USA*, the National Council on Radiation Protection and Measurements in *Report No. 174* recommends limiting occupational exposure of the foetus to a value ALARA, but not to exceed 5 mSv (500 mrem) during the entire pregnancy and 0.5 mSv per month of the pregnancy. If the gestational exposure is within 0.5 mSv of the limit when the employee declares pregnancy, only an additional 0.5 mSv of exposure is recommended for the remainder of the pregnancy. It is advised that pregnant workers declare their pregnancy, and that they wear an individual dedicated monitoring device worn under the lead apron at the waist for the purposes of monitoring foetal radiation exposure, if they choose to work in an exposed setting.[77] These recommendations are implemented on a state-by-state basis.

In summary, legislations in both Europe and the USA seek to protect women and foetus from damaging exposure while still permitting reasonable risk for those who elect to work in a radiation environment. However, despite the relatively homogeneous directives, there is currently in fact great disparity in the approach when a healthcare worker becomes pregnant and in the expectations and rights of female interventional cardiologists. In the USA through the Pregnancy Discrimination Act of 1978 (which amended title VII of the 1964 Civil Rights Act), American employers are required to treat their female employees equally with respect to 'pregnancy, childbirth or related medical conditions'. Legal precedent from the US Supreme Court was established in 1991 regarding the conflict between legislating foetal protection and protecting maternal rights to non-discrimination, supporting the female employee.[6,78] As a consequence, the majority of US hospitals allow interventional cardiologists to continue to work with radiation exposure during pregnancy by federal and state law. In contrast in Europe, the European directives were incorporated and interpreted in local law using own judgement in each country. In general, the majority of European countries adopted a stricter approach arguing that the 1 mSv dose limit cannot be guaranteed.[72] In many European hospitals, female interventional cardiologists are not allowed to continue their work with radiation exposure as operator by local law and employers' implementation of local law.[6] In conclusion, the different radioprotection policies for pregnant workers reflect different bioethical orientation of the law, which prioritizes the pregnant worker's rights in an anti-discriminatory perspective in the US and mostly the safety rights of the unborn child in the European legislation. Additionally, despite the existence of the basic safety standards directives in the EU and USA, and the translation into legislation, there is no clear guidance on how centres should implement measures to ensure the woman's and foetus' protection against ionizing radiation (number/type/location of dosimeters, etc.).

Summary on safe use of radiation for pregnant electrophysiology personnel and individuals with reproductive potentials

The expert consensus statements of this document are summarized in *Table 9*. Radiation dose to the patient and the operator depends on the nature of the electrophysiological procedure and for the patients varies between 3 and 17 mSv. Estimating the radiation dose to the physician in general is much more difficult and may vary by two to three orders of magnitude for the same type of procedures. The ED to the operator is in the range of 0.2–60 µSv per procedure. Complex ablations (especially in the past) and cardiac resynchronization therapy implants are associated with higher doses. Although health workers occupationally exposed to ionizing radiation have recently been reported to have worse semen quality, radiation exposure has never been demonstrated to cause hereditary effects in human populations. Radiation risks are most significant during organogenesis and the early foetal period, somewhat less in the second trimester, and least in the third trimester. Early death, malformation, and mental retardation of the foetus do not occur in the occupational exposure range. The probability of live birth without malformation or childhood cancer at 1 mGy conceptus dose above the average annual global natural background radiation of 2.4 mSv is 95.99% and at 5 mGy 95.88% as compared to 95.93% in the general population. In the occupational exposure range working around radiation while pregnant is typically safe, provided that proper protocols are adhered to, including routine monitoring of occupational radiation dose to the conceptus. The ICRP recommends that after a worker has declared her pregnancy the additional dose to the unborn child does not exceed about 1 mSv during the remainder of the pregnancy. Occupational radiation exposure during pregnancy is further regulated in Europe by the directives of the EU and country specific and in the USA by federal and state law. In EU member countries local law interprets the European directives and employers are responsible for implementing local law. Currently in many European hospitals continuation of work with radiation exposure is not allowed for pregnant cardiologists. In contrast in the USA cardiologists may continue to work with radiation exposure during pregnancy by both federal and state law in the majority of US hospitals. This consensus document supports the ICRP recommendation stating that pregnant medical workers may work in a radiation environment provided that there is reasonable assurance that the foetal dose can be kept below 1 mSv (5 mSv in the USA) during the course of pregnancy and requiring the employer to review the exposure conditions of pregnant women carefully.[65]

Areas for future research

Female and male interventional electrophysiologists with a substantially higher radiation exposure than diagnostic radiologists should be focus of research. There are little data on fertility and the pregnancy outcome of these specialists including spontaneous abortion, small birth weight, birth defects, and childhood cancer in the offspring's. Data on occupational exposure dose ranges in the area of modern electrophysiology are surprisingly scarce. It is mandatory to focus on waist dosimetry, but it might be also useful to measure extra-waist mother dosimetry in the pregnancy period, since head and neck irradiation may impact pregnancy outcome.[79] Currently, active personal dosimeters capable of real-time measurement of radiation dose in the interventional cardiology field are being developed.[80] The use of these dosimeters during pregnancy with audible alarm above a pre-set dose range would be ideal to avoid incidental overexposure. It would be also important to collect dosimetry and reproductive data on exposed men, since the gonadal irradiation in the vulnerability window 1–10 weeks prior to conception may have impact on fertility and child health.[81] As evidence exists on the detrimental effects of occupational radiation exposure on functional and genetic integrity of germ cells a diagnostic sperm test might be added to occupational health examinations. There is also lack of comprehensive data on reproductive health of couples with integrated assessment of mother-and-father (in the post-conceptional and, in case of fathers, pre-conceptional 3-months period) to gain insight into the determinants of fertility and offspring health.

Supplementary material

Supplementary material is available at *Europace* online.

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