

 SGSMP
 Schweizerische Gesellschaft für Strahlenbiologie und Med

 SSRPM
 Societé Suisse de Radiobiologie et de Physique Médicale

 Società Svizzera di Padiobiologia et l'Et to Medicale

Schweizerische Gesellschaft für Strahlenbiologie und Medizinische Physik Società Svizzera di Radiobiologia e di Fisica Medica

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Report on the use of patient shielding in radiological procedures

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1. Introduction

1.1 Medical exposure

In the past years, medical imaging has been recognized as an essential tool for diagnostic and treatment procedures. Among all imaging modalities, X-ray based techniques such as CT, fluoroscopy and radiography are of primary importance due to several factors such as low cost of procedures, widespread accessibility, short examination times and broad range of applications. Consequently, the number of X-ray procedures has been constantly increasing. According to the "Exposure of the Swiss population by Medical X-rays" report, in 2013 the number of radiological examinations conducted in Switzerland was estimated to be above 9.9 million[1]. This report indicated that annual effective dose from medical exposure was equal to 1.4 mSv/capita compared to 1.2 mSv/capita in 2008 and 1 mSv/capita in 1998. The marked increase raised concerns over potential risks associated with the exposure to ionizing radiation[2, 3]. Although there is no clear evidence of adverse biological effects at radiation exposure below 100 mSv, the radiation protection community conservatively assumes that any amount of radiation can increase the risk of cancer and hereditary effects[4, 5]. The International Commission on Radiological Protection (ICRP) confirmed a set of radiation protection principles which includes justification, optimization and limitation of exposure[6]. The optimization principle assumes appropriate selection of the protocol (e.g. exposition parameters), and, according to current national[7] and international[4] regulations, the usage of patient- and exam-specific shielding (e.g. leaded garments and blankets).

1.2 Historical perspective

Such patient protection garments were introduced into the clinical routine in the middle of the 1970s[8] with the main aim to reduce the dose to critical organs. Two main factors contributing to the broad usage of patient shielding in clinical practice included the knowledge of the radiosensitivity of various organs as well as dose range and risk estimates prevalent at the time. However, the levels of dose, and thus the estimated risk, have changed over the years thanks to the technical and technological improvement in X-ray based imaging. Additionally, the knowledge of the radiosensitivity of various tissues and organs has evolved with new information and evidence becoming available. For example, the tissue weighting factor for the gonads recommended by the ICRP has been changed from 0.25 to 0.08 over a thirty year period[6, 9]. These facts require continuous revision of the established practice in-line with current knowledge and advice.

1.3 Motivation

Although patient shielding has been an integral part of medical X-ray imaging for almost half a century, multiple researchers and institutions worldwide have increasingly criticized it in recent years[10, 11]. Several countries and medical physics societies have already decided to abandon the use of patient shielding in radiology[12, 13]. This, in turn, raised the question concerning the efficiency of patient shielding in radiological examinations conducted in Switzerland.

In Switzerland, the use of the patient shielding in radiological examinations is defined in the article 24 of the Ordinance[7]. It is stated that the authorisation holder must provide adequate protection (for staff, patient and third parties), but it is up to the healthcare institution to judiciously regulate its use. To guide the healthcare facilities in the implementation of the regulation, a specific guideline "directive R09-02" was issued in 2013 (revised in 2018) by the Federal Office of Public Health (FOPH)[14] in its role of supervisory authority in the field of radiation protection.

In their role as radiation protection experts of medical facilities, the Medical Imaging Physics group within the Swiss Society for Radiobiology and Medical Physics (SSRMP) set up a task group in 2019 to carefully review the role of patient shielding in radiology and consider related benefits and drawbacks. The group aims at updating the content of the "directive R09-02" based on new scientific evidence and publishing a report to be used by the radiation protection experts.

1.4 Aim and scope

The aim of this document is to provide guidance on further use of patient shielding during radiological procedures. Due to the vast number of X-ray based procedures, it is cumbersome to individually consider each type of examination, therefore this report describes generalised reasons for why protection may or may not be applicable in the specific imaging modalities, such as computed tomography, conventional radiography, fluoroscopy and mammography. The use of radiation protection garments for the patients during dental examinations will be discussed in a separate working group.

This document is intended to cover radiation protection applied directly to patients undergoing diagnostic and interventional X-ray procedures. It does not include shielding built into the imaging equipment or in the room design and excludes the radiation protection garments for personnel or third parties.

2. Methods

2.1 Literature review

In order to evaluate pros and cons related to patient protection used in radiological examinations, a systematic literature review was performed. The literature review was focused on peer-reviewed scientific articles that were published during the past 10 years and addressed the benefits and drawbacks of patient shielding for both pediatric and adult subjects. Reports from medical physics societies were also included in our review.

2.2 Classification of patient shielding

The type and manner of use of patients' protection garments depends on the imaging modality and organs at risk. Therefore, this review classifies the patient shielding according to:

- a. Imaging modality (i.e. CT, fluoroscopy and radiography, mammography)
- b. Body region exposed to primary beam (for example head, thorax, abdomen, etc.)
- c. Type of radiation protection garment used to protect organ at risk (i.e. eye lenses, breast, etc.) and
- d. Type of radiation protection garment according to its location (i.e. in- or out-of-plane)

First, the organ at risk can be exposed by the primary beam. In this case, in order to reduce the dose to particularly radiosensitive organs among other techniques of dose reduction, selective organ shielding might be applied. These garments are usually made of bismuth-impregnated latex[15, 16], which offers a modest level of X-ray attenuation, while still allowing X-ray penetration for image formation. Such patient shielding is called *in-plane*.

The other main source of exposure is scattered radiation. Scatter in the tube and housing is a well-known source of secondary radiation generated when primary beam passes through the construction elements of the tube, tube housing and collimator. This scatter will give rise to very low levels of additional dose for the patient. Additionally, the patients themselves are a source of secondary radiation exposure. According to Iball et al.[17], this internal scatter comprises up to 70% of the radiation dose, while only 30% of the dose is determined by the external scatter. The patient shielding aiming to reduce the dose from scattered radiation are made of highly attenuating (high-Z) materials such as lead, and are used to cover/wrap the body parts outside of the examined region. This type of protection is referred to as *out-of-plane* shielding.

3. Results

3.1 Radiation dose

Detailed information for each type of patient protection garment is summarized in Table 1 together with literature references. Our findings were tabulated and the dose reduction for each protective garment was reported in terms of absolute organ dose values.

The maximum reported dose reduction was found to be 8.5 mGy for eyes in conventional head CT. While other values were in a range of sub-mGy. Multiple authors have reported that more prominent dose savings can be achieved by optimizing image acquisition technique [18-21]. On the other hand, the use of patient shielding has a number of drawbacks.

• In-plane

The main drawback of shielding placed inside the imaging field of view (FOV) is that it can significantly obscure anatomy and compromise the diagnostic information[18-20, 22]. In the worst case, the procedure may need to be repeated leading to substantial increase in radiation dose. In addition, *in-plane* shielding can negatively affect automatic exposure control (AEC) in modern X-ray systems, thereby significantly increasing the X-ray output and hence patient dose[19].

• *Out-of-plane*

Patient shielding with high-Z materials does not protect from internal scattering, which is the main source of the radiation dose to internal organs located outside the FOV[23, 24]. For external scatter, the effectiveness of the shielding notably depends on its position relative to the beam edge. Ideally, for examinations such as CT and interventional fluoroscopy the contact-shielding should be placed exactly on the beam edge, which is practically not possible. If the shielding is positioned more than 5 cm away from the beam edge, the dose reduction is negligible[11, 23]. On the other hand, if high-Z shielding enters the imaging FOV, besides compromising image quality, the X-ray system will drastically increase the output, resulting in higher radiation dose to the patient. This is particularly critical for multirow detector helical CT due to overranging and overbeaming effects. According to the recent research, these effects may increase the exposure length by up to 83.1 mm for modern CT system with a beam width of 80 mm in the z-direction[25]. Thus, even when positioned outside of the selected scan range, high-Z material shielding can be exposed by the primary beam, and interfere with the imaging.

3.2 Non-dose related issues

Besides the radiation-related aspects, several drawbacks applicable to both *in-* and *out-ofplane* shielding should be mentioned here:

- Patient discomfort, related for example to the weight of contact-shielding
- Hygiene issues, especially when protective garments and/or blankets are used in surgical procedures

Additionally, *in-plane* shielding can cause streak and beam hardening artefacts, increase image noise and adversely affect the accuracy of CT numbers resulting in unacceptable image quality.

This document does not consider the psychological aspects of the protective garments. However, it could be noted that such effects can be either positive or negative since the use of radiation protection garments may potentially create a false sense of safety or, oppositely, give the impression that the patient is exposed to great amounts of radiation dose outside the region of interest.

4. Conclusion

Since the dose reduction through patients shielding is negligible and significant dose- and nondose-related drawbacks are clearly present, the use of such protection garments and/or blankets in radiological routine should be discontinued.

Instead, the optimization principle of radiation protection should be fulfilled by appropriate patient positioning and optimizing the acquisition parameters to the actual clinical needs. Additionally, the use of modern dose reduction technologies such as AEC, selective filtration and iterative reconstruction algorithms will result in much more prominent and safe dose savings.

5. Impact on clinical practice

Discontinuing the use of radiation protection shielding for the patients may lead to misunderstandings among both the healthcare providers that are used to utilizing patient shielding and the patient, especially those who undergo repetitive examinations and are used to receiving such radiation protection garments. It is, therefore, important to invest in the following aspects:

• Information

Practitioners and operators should be suitably informed about the scientific evidence and understand the complex influence of shielding on patient safety and diagnostic capacity of the imaging.

• *Continuing education*

Particular attention should be given to continuing education. The practitioners and operators must stay up to date with the current techniques and technologies in medical imaging. These knowledge and skills should be used for comprehensive and individualised dose reduction strategy, ensuring that patient doses are kept as low as reasonably achivable (ALARA).

• Communication

Last, but not least, caregivers should be appropriately trained to be able to provide adequate information around the use of patient shielding. If, for example, the individual is particularly anxious or requires additional reassurance, operators should take time to explain the function of shielding as a part of a multifactorial dose reduction strategy and bring the argument supported by research and latest knowledge. The operator should focus on achieving a suitable diagnostic image, where benefit outweighs risk.

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Modality	Type of Examination	Type of protective garment	Addressed in FOPH Directive R-09-02	Absolute dose reduction due to the usage of protective garments	Non-dose related drawbacks described in the studies	Conclusive statement from the Task group	Supporting literature
СТ	Head	Thyroid protection (out-of-plane)	yes	Absolute dose reduction of about 0.09 mGy	Possible artefacts if head and neck CT is performed, unhygienic	The dose reduction is negligible and does not outweigh the associated potential risks	Abuzaid et al. 2017[26]
		Surround-apron (out-of-plane)	yes	Absolute dose reduction between 0.11 mGy and 0.19 mGy	Possible artefacts, uncomfortable for patients, unhygienic	The dose reduction is negligible and does not outweigh the associated potential risks	Liebmann et al. 2014[27]
		Eyes protection (in-plane)	no	Wang et al. reported the maximum absolute dose reduction of 8.5 mGy for eyes in conventional head CT. Organ- based tube current modulation provides similar dose reduction to the eye, while allowing superior image quality to that with bismuth shielding	Orbit shields can cause significant artefacts	Relatively low dose reduction while increasing image noise and introducing superficial orbital artefacts	Raissaki et al. 2010[28], Wang et al. 2012[18], Hakim et al. 2018[22]
	Chest	Surround-apron (out-plane)	yes	Broad range of values depending on the investigated protocols and organ at risk. Surface dose reduction was reported to be between 0.003 mGy and 0.013 mGy, when the lead apron was placed at distances of 10 cm and 1 cm from the field of scan, respectively. Iball et al. reported organ dose reduction up to 0.068 mGy. (Moreover, the authors did not take z-overscanning or mA modulation into account)	Possible artefacts if misplaced, uncomfortable for patients, unhygienic	The dose reduction is negligible and does not outweigh the associated potential risks	Yu et al. 2019 [11], Weber et al. 2015[24], Iball et al. 2011[17]

CT Che	Chest	Fetal protection for pregnant (out-of-plane)	no	Fetal dose reduction ranged between 24 and 195 μGy, depending on gestational age, position of the fetus, maternal shape and CT protocol.	Possible artefacts, uncomfortable for patients especially in the later stages of pregnancy, possible problems with vena cava and blood circulation due to the heavy aprons, unhygienic	The use of contact- shielding is not justified. Other possible approaches such as scan length reduction and low-dose protocol are more efficient.	Ryckx et al 2018[29]
		Breast shields (in-plane)	no	Broad range of values for absolute dose reduction depending on the investigated protocols and methods used for dose assessment, i.e. Wang et al. reported the dose reduction to the breast of about 3 mGy), while study performed by Fricke et al. reported dose reduction of 0.004 mGy.	Possible artefacts, CT number inaccuracy, increased image noise, unhygienic	The appropriate tube current modulation leads to the same dose reduction as bismuth shielding for both pediatric and adult but does not affect image noise and CT number accuracy.	Colletti et al. 2012[19], Fricke et al. 2003[30], Wang et al. 2011[20], Lambert et al. 2016[21]
	Abdomen/ Pelvis	Gonads protection (in- and out-of- plane)	yes	Absolute dose reduction 0.2- 0.3 mGy. Shielding reduces the dose from primary X-rays, but the majority of the gonadal dose is from internal scatter radiation. Additionally, there is a gap between the shield on the surface of the body and the gonads, so the efficiency of this garment is very low.	Streak artefacts when used in-plane, unhygienic, can cause patients pain (male gonads capsule)	In the primary field gonads shields lead to extremely poor image quality due to severe streak artefacts. For out-of-plane shielding the dose reduction is negligible and does not outweigh the associated potential risks.	Dauer et al. 2007[31], Strauss et al. 2017[10]

СТ	Abdomen/ Pelvis	Fetal protection for pregnant women (in plane)	yes	Fetal dose reduction between 24 and 195 μ Gy depending on gestational age, position of the fetus, maternal shape and CT protocol. The in-plane shielding might increase the dose when the tube current modulation is employed.	Significantly compromise image quality, uncomfortable for patients especially in the later stages of pregnancy, possible problems with vena cava and blood circulation due to the heavy aprons, unhygienic	Dose to the fetus does not exceed 20 mSv (below 100 mSv). In-plane shielding impairs the diagnostic quality.	Ryckx et al.2018[29], Marsh et al. 2018[8], Iball et al. 2011[17]
Mamma	Mammography	Gonads protection (out-of-plane)	yes	Dose is negligible due to the remoteness from the investigated region. Moreover, according to ICRP 103, the risk is much lower than it was assumed in the past (tissue weighting factor 0.08 instead of 0.2)	Uncomfortable for patients, unhygienic	The dose reduction is negligible and does not outweigh the associated potential risks.	Jeukens et al. 2020[32], AAPM Position Statement 2019 [13]
Mamma- examination	Mammography	Thyroid protection (out-of-plane)	no	Thyroid dose reduction between 16 μGy and 187 μGy (p<0.001), but age group is not at risk	If thyroid shielding enters the FoV it can cause artefacts that obscure breast tissue, requiring a retake of the mammogram, uncomfortable for emotional situation	The dose reduction is negligible and does not outweigh the associated potential risks.	Pyka et al. 2018, Sechopoulos et al. 2012 [33], ACR statement 2012 [34]
	Thorax	Gonads apron (out-of-plane)	yes	Ovaries/uterus dose reduction is reported to be 0.035 µGy or 4% at 8-cm depth and 15 cm from the field edge, lower dose decrease for spine and other bones expected	Uncomfortable for patients, unhygienic	The dose reduction is negligible and does not outweigh the associated potential risks.	Matyagin et al. 2016[23], AAPM Position Statement 2019 [13]
Conventional X-ray	Extremities/ shoulder	Apron/ Gonads apron (out-of-plane)	yes	Dose is negligible due to remoteness from the investigated region.	Uncomfortable for patients, unhygienic	The dose reduction is negligible and does not outweigh the associated potential risks.	AAPM Position Statement 2019[13]
	Brain	Apron/ Gonads apron (out-of-plane)	yes	Dose is negligible due to remoteness from the investigated region.	Uncomfortable for patients, unhygienic	The dose reduction is negligible and does not outweigh the associated potential risks.	AAPM Position Statement 2019[13]

	Cervical/ lumbar spine	Gonads protection (out-of-plane)	yes	Dose is negligible due to remoteness from the investigated region.	Uncomfortable for patients, unhygienic	The dose reduction is negligible and does not outweigh the associated potential risks.	AAPM Position Statement 2019[13]
Conventional X-ray	Abdomen/ Pelvis/ Hip	Gonads protection (out-of-plane)	yes	No dose assessment in terms of absolute dose	Inaccurate positioning, compromising of diagnostic information, extra irradiation, ovaries have variable positions, special gonadal shielding is required, better methods of determining ovaries, education needed	The dose reduction is negligible and does not outweigh the associated potential risks.	Karami et al. 2017[35], Tsai et al. 2014[36], Mraity et al. 2016[37], AAPM Position Statement 2019[13]
	Cardiology	Pelvis shielding (out-of-plane)	no	Without apron 15.4+/-24.1 µSv, with apron 28.9+/-81.1 µSv, thus lead apron might even increase patient dose.	Uncomfortable for patients, unhygienic, obstruction of patient anatomy when entering the imaging FOV	The influence of lead protective garments on patients' dose is either negligible or even controversial (i.e increased radiation dose). The risks outweigh the potential benefits.	Musallam et al. 2015[38], Marcusohn et al. 2018 [39], Boyle et al. 2010[40]
Fluoroscopy	Kyphoplasty/ Vertebroplasty	Pelvis shielding (out-of-plane)	no	No dose assessment (in terms of absolute dose) for the patients, for the operator any reduction provided by the patient shielding was negligible compared with the one provided by the operator's apron	Uncomfortable for patients, unhygienic, possible visual obstruction of the patient's anatomy	The risks outweigh the potential benefits.	Smith et al. 2018[41], Boyle et al. 2010[40]
	Orthopedics (displaced supracondylar humerus fracture)	Thyroid, torso shielding (out-of-plane)	no	Increased dose to patient and personnel when shielding in FoV.	Uncomfortable for patients, unhygienic, obstruction of patient anatomy when entering the imaging FOV	The risks outweigh the potential benefits.	Martus et al. 2016[42], Boyle et al. 2010[40]
	General fluoroscopy	General (out-of-plane)	no	No patient dose estimates, only for operators	Uncomfortable for patients, unhygienic, obstruction of patient anatomy when entering the imaging FOV	The risks outweigh the potential benefits.	Phelps et al. 2016[43], Boyle et al. 2010[40]

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Members of the working group

Natalia SaltybaevaUniversity Hospital Zurich (USZ), ZurichMarta Sans MerceUniversity Hospital of Geneva (HUG), GenevaMichael IthUniversity Hospital of Bern (Inselspital), BernStefano GianoliniHirslanden Private Hospital Group, Glattpark

Elina Samara

Valais Hospital, Sion