MATTERS FOR CONSIDERATION IN THE MANAGEMENT OF POTENTIAL SKIN BURNS FOLLOWING HIGH DOSE INTERVENTIONAL PROCEDURES

FOREWORD

This document was produced by the Voluntary Healthcare Agencies Risk Management Forum Radiation Safety Advisory Group in 2018 under the auspices of Dr Geraldine O'Reilly. The policy has also been approved by the Irish Society of Interventional Radiology. The Faculty of Radiologists Radiation Protection committee is also happy to endorse this policy as a national standard in the management of potential skin burns. The intended audience are all radiologists and cardiologists involved in the delivery of high dose interventional radiology procedures.

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1. Introduction

Interventional radiology uses ionizing radiation to guide 'minimally invasive surgery'. The growing use and increasing complexity of these procedures have been accompanied by concerns resulting from the increasing radiation exposure to both patients and health care personnel. The rise in reported serious skin injuries and the expected increase in late effects such as lens injuries and cataracts, and possibly cancer, make clear the need for information on radiation risks and on strategies to control radiation exposures to patients and health care providers. Although it is recognized that skin injuries are relatively rare and uncommon[13], it is an important feature of good radiation protection practice that patient doses are routinely monitored and appropriate follow up initiated where required. Direct measurement of skin dose is difficult to achieve on a routine basis but DAP levels may be used as a useful indicator of overall risk. Other metrics that can be used are Peak Skin Dose (PSD), Reference Point Air Kerma and Fluoroscopy Time. Of these, DAP is the parameter that should be available on all systems and so can be used as an indicator locally.

This document is intended for Radiologists and Medical Specialists who undertake interventional radiology procedures, for example: Cardiologists, Neurologists, Interventional Radiologists, Endo-vascular Surgeons. It examines the associated radiation risk and proposes a mechanism for follow up post procedure in the event of a high skin dose being received. It is based on guidelines from the Society of Interventional Radiology[1], the CRCPD[11,12], earlier guidance from the National Cancer Institute[2] and data from European studies[7, 9].

1.1 Determinants of Radiation Dose in Interventional Radiology

The radiation beam in interventional radiology procedures is typically directed at a relatively small patch of skin for a substantial length of time. This area of skin receives the highest radiation dose of any portion of the patient's body. The dose to this skin area may be high enough to cause a sunburn-like injury, hair loss, or in rare cases, skin necrosis[3]. Threshold doses for potential radiation effects with related time of onset are presented below[3]. The highest doses have been reported most frequently as a result of PTCA, radiofrequency cardiac ablation procedures, transjugular intrahepatic portosystemic shunts (TIPS) procedures and embolization procedures in the brain[4].

Effects	Threshold Dose (Gy)	Time of Onset
SKIN		
Early transient erythema	2	2-24 hours
Main erythema reaction	6	~1.5 weeks
Temporary epilation	3	~3 weeks
Permanent epilation	7	~3 weeks
Dermal necrosis	>12	>52 weeks
EYE		
Lens opacity (detectable)	0.5Gy	>5 years

As retrospective estimates of skin dose are complex for interventional procedures, a number of authors recommend using a metric such as Dose Area Product (DAP) as a practical method of setting trigger levels for follow up, and a DAP value of 500Gycm^2 has been suggested as a trigger level[1]. The figure of 500Gycm^2 assumes a field size of 100cm^2 at the patient's skin and should be adjusted for other field sizes. Other metrics, such as Peak Skin Dose can be used, if available, as a trigger for follow up and some examples are shown in the table below. Selection of the appropriate metric will depend on availability but the ideal metric will be one that is most reflective of risk of injury **and** is readily available during the procedure.

Parameter/Dose Metric	Threshold for Follow Up
Peak Skin Dose (PSD)	3000mGy
Kerma to Air at a reference point (Kar)	5000mGy
Kerma Area Product (Pka)	500 Gy cm^2
Fluoroscopy time	60 mins

1.2 Radiation Risks from Interventional Radiology

The benefits of a properly performed interventional radiology procedure that has been appropriately justified should always outweigh the radiation risk to the individual. However unnecessary exposure can produce avoidable risk for both patient and operator. Use of good technique, deploying appropriate optimisation measures can significantly reduce overall radiation exposure and minimise the risk of tissue effects.

Radiation Risks to Patients

The short term risk to patients is radiation induced skin damage which can result from acute radiation doses of > 2Gy. Although it is difficult to relate skin doses to DAP readings, a figure of 500Gycm^{2}[a] is used as a trigger level for follow up for interventional procedures (assuming a field size of 100cm^2). If PSD is available, a figure of 3000mGy is suggested as a trigger value.

The existence or extent of the skin injury may not be known for weeks after the procedure. Repeated procedures increase the risk of skin injury because previous radiation exposure sensitises the skin. Long term effects include the increased risk of cancer.

Candidates for the follow up of possible radiation effects are patients undergoing either complex or multiple IR procedures.

Follow up should be determined by the dose received as indicated by the DAP value(s) or other dose indicators.

1.3 Physician-patient communication before and after interventional fluoroscopy

Operators should always ask the patient about any previous history of interventional fluoroscopy before undertaking another procedure. It is important to communicate the details of the procedure, patient dose, and immediate and potential long-term health effects to patients and their primary care providers. Information relating to radiation risks should be given in the context of all associated risks and must be balanced against the considerable benefits of a properly justified procedure.

2. Recommended Protocol

2.1 Before Procedure : –

1) For elective procedures, patients should be counselled on radiation-related risks, as appropriate, along with the other risks and benefits associated with the procedure. If patients are likely to have multiple interventional radiology procedures in a short period of time, they should be informed if there is a possibility that significant radiation exposures may accompany these procedures and may cause potential short-term and long-term radiation-related health effects. In the case of emergency procedures, it may not be possible to provide comprehensive information to the patient in advance.
2) Details about previous interventional procedures should be collected when deterministic effects are anticipated or observed.

[a] Values of DAP given for alerts and subsequent follow up, assume a field size of 100cm^2. For other field sizes , the values should be adjusted accordingly.

3) Details of relevant pathological processes (previous diseases specially those affecting skin radiosensitivity such as connective diseases, diabetes, xeroderma pigmentosum, porphyria etc) should be considered when deterministic effects are anticipated or observed.
4) The following details should be recorded:
    b) Patient identification – Name, MRN, DOB
    c) Age and sex
    d) Weight and height
    e) Name of the procedure to be done

2.2 During Procedure:-

Radiation dose is monitored throughout the procedure. This responsibility may be delegated to a radiographer, nurse or other person, depending on local policy. The operator should be notified when the DAP reaches 300Gycm^2 and thereafter at increments of 100Gycm^2. For units that can provide Peak Skin Dose (PSD), the relevant notification points are at 2000mGy and then every 500mGy after that. For units that only record fluoroscopy time, notification should take place at 30 mins of fluoroscopy time and thereafter every 15 mins.

Radiation Monitoring Dose Notification Thresholds		
Parameter	**First Notification**	**Subsequent Notifications**
Peak Skin Dose (PSD)	2,000mGy	500mGy
Reference Point Air Kerma	3,000mGy	1,000mGy
DAP	300Gycm^2	100Gycm^2
Fluoroscopy Time	30min	15min

2.3 After Procedure: –
The following details should be noted when the procedure is completed:
a) Name of the Medical Specialist who carried out the procedure
b) X-ray system used
c) Fluoroscopy time, number and type of images, DAP reading and PSD , if available.
d) For DAP readings in excess of 500Gycm^2, raw data should be stored if possible. If other metrics are used, then the relevant trigger values should be used.

After a procedure, the measured or estimated radiation dose should be reviewed (Miller 2004). For practical purposes a PSD of 3,000mGy or a DAP value of 500Gycm^2 are recommended as trigger levels. For patients exceeding this value, details of the anatomical region exposed should be recorded. If DAP is the metric in use, then the data should be reviewed by the physicist/RPA to establish if the peak skin dose threshold has been exceeded, as it is possible that the use of multiple c arm positions will reduce the peak skin dose.
When it is established that a threshold has been exceeded, then the steps, outlined below, should be taken to ensure adequate patient follow-up.

For all patients where the DAP value exceeded 500Gycm^2 or PSD >3,000mGy:

- The RSO/RPA should be notified that a trigger value has been exceeded and the procedure for follow up is to be initiated
- Follow up should be scheduled within 60 days of the procedure.
- Subsequent follow up, if required, to be determined at that time.
- Send the interventional procedure description, operative notes, doses and information about possible short-term and long-term effects to the patient's primary care provider.
- The patient and primary care physician should be specifically requested to notify the operator if observable skin effects occur.
- Responsibility for the tasks outlined above rests with the Consultant responsible for the interventional procedure but may be delegated to a named individual who takes responsibility for this role. The mechanism for follow up (eg by phone, visit,) should be such that it can be integrated easily into local practice.

Although DAP is the most commonly available dose metric, thresholds for follow up for other dose metrics are summarised below.

Thresholds for Patient Follow Up	
Parameter	**Threshold**
Peak Skin Dose (PSD)	3,000mGy
Reference Point Air Kerma	5,000mGy
DAP	500Gycm^2
Fluoroscopy Time	60min

3. Conclusion

Interventional radiology is an increasingly important and valuable tool for treating disease, but it is not without risk. In this context, optimisation of patient dose is critical. Operators and Physicians need to be aware of the potential for adverse effects and should manage these risks proactively. It is recommended that a follow up procedure, specifically designed to monitor skin damage, be a routine part of clinical care in those instances where high skin doses have occurred. A DAP value of 500Gycm^2 or PSD of 3,000mGy should be used as a trigger level.

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Appendix A Draft Template for Patient Consent for Use of Ionising Radiation

As noted in the protocol, patients should be given information on all radiation risks before the procedure. An example is given below. For elective procedures, this information could be provided in advance and/or integrated into the consent process in accordance with local governance procedures. It should be provided in the context of other associated risks and should be balanced against the considerable benefits of a justified procedure.

Informed Consent for Radiation Risk (to be adapted as required for local use)

You have been scheduled for an interventional procedure. This involves the use of x-rays for imaging during the procedure and documenting the results. Because of the nature of the planned procedure, it is possible that we will have to use significant amounts of radiation. Potential radiation risks to you include:

- A slightly elevated risk for cancer several years later in life. This risk is typically less than ½ percent. This risk is low in comparison to the normal incidence of human cancer, which is 1 in 3 according to the National Cancer Registry Ireland.

- Skin rashes occur infrequently; on very rare occasions they may result in tissue breakdown and possibly severe ulcers. Hair loss may occur which can be temporary or permanent. The likelihood of either of these occurring depends on the difficulty of the procedure and whether you are sensitive to radiation due to previous procedures, disease, or genetic conditions. You or your family (proxy) will be advised if we used amounts of radiation during the case that might result in effects to the skin or hair. If this happens, you will be given written instructions stating that you are requested to have a family member check you for any of the above signs.

Appendix B Draft Template Discharge Instructions after Trigger Level Exceeded

It is recommended that in the event of the trigger value being exceeded, the patient should be given written instructions regarding the follow up procedure. The content of these instructions should be such that the follow up can be integrated in to existing practice and so will vary for different institutions. An example of such instructions can be found below. Further examples can be found in Stecker et al (2009)[1].

Draft Template - Patient Discharge Instructions

The interventional procedure which you have undergone today _____/_____/ 20_____ involved the use of x-rays for imaging and recording the results. The use of radiation for any interventional procedure involves some potential radiation risks to the skin in the short to medium term. These risks include:

- Skin rashes which occur infrequently (on very rare occasions they may result in tissue breakdown and possibly severe ulcers).
- Hair loss which can be temporary or permanent.

The likelihood of either of these occurring depends on the difficulty of the procedure and whether you are sensitive to radiation due to previous procedures, disease history, or genetic conditions.

Because of the necessary radiological component of your procedure you are being advised that radiation side-effects while unlikely are possible. To help us to identify any possible radiation side effects we would ask you to please inspect (or have a family member inspect) your _____ which was the area of your body that was irradiated during the procedure. You should look for signs of redness or rash. This inspection should be carried out two weeks from today on _____/_____/ 20_____ as these effects (when they do occur) do not usually appear until several days after the exposure. If signs of redness or rash are noticed, please contact your GP.

Please call _____ (e.g. Clinical point of contact for relevant speciality) between ___hrs and ____ hrs after you have carried out this inspection.

It is important to contact us whether or not any signs of redness or rash are seen.

_____

Consultant in Charge of the Radiological Procedure