The impact of IR(ME)R 2017 IR(ME)R (NI) 2018 on pregnancy checking procedures

Background
One of the changes, and perhaps challenges, presented to radiographers, doctors and other healthcare professionals acting as operators, practitioners and referrers under IR(ME)R 2017/IR(ME)R (NI) 2018 is identified in Schedule 2 Employer’s Procedures 1(c), which states that written procedures for exposures must include procedures:

“for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding”.

This represents a subtle but important change from the wording in the previous regulations, which required: “procedures for making enquiries of females of childbearing age…”

Why is this?
What does it mean and how does it affect what we do?

The principle behind why we do this has not changed. It is necessary to avoid accidental or unintended exposure of a fetus. However, the application (how we do this) has rightly changed to reflect the diversity of the gender spectrum in the worldwide population.

Comprehensive guidance around pregnancy and breastfeeding will be available in revised editions of A Guide to Understanding the Implications of the Ionising Radiation (Medical Exposure) Regulations in Radiotherapy and A guide to understanding the implications of the Ionising Radiation (Medical Exposure) Regulations in diagnostic and interventional radiology, both of which will now include nuclear medicine. The anticipated publication date for these revisions is late 2019.

In the interim, the SCoR is aware of the need for employers to meet this requirement in a respectful manner that addresses the needs of all individuals and is practicable and consistently employed throughout the radiographic workforce. Employers should take care to ensure that any changes to written procedures do not disadvantage one individual in an attempt to meet the needs of another. This position statement is intended to support equality and good practice and to protect the sensitive and compassionate relationship between radiographers and the individuals under their care during an ionising radiation exposure.

What should be considered when amending written procedures to meet the requirements of Schedule 2 Employer’s Procedures 1(c)?

Ask yourself WHY you are asking the individual whether there is any possibility they may be pregnant.
Are they at risk?
What is this risk?
Are they informed about the procedure and have they been given adequate information about the benefits and risks associated with ionising radiation?
Have they had the opportunity to ask questions?
Do you have all the information you need from the referrer?
What is the referrer’s relationship with the individual? Do they have access to their clinical history?
Has the individual consented to the referrer sharing information relating to, for example, their gender transition?
Have you consulted your local patient representative groups for advice on writing the procedure?

The SCoR believes the practical applications of the regulations are as follows:

Establish the risk to your local population, taking care to consider local demographics and evidence in terms of the age from which the question on the possibility of pregnancy is asked. Do this in collaboration with your medical physics expert (MPE).

Establish the risk in terms of the imaging pathway and whether the 10-day rule or 28-day rule applies. Do this in collaboration with your MPE.

Through your local clinical governance framework and image optimisation teams, and with reference to the above, establish when the question on the possibility of pregnancy should be asked. For example, this could be from the age of 11 to 55 years for diagnostic examinations that include the pelvis and for all high-dose interventional procedures. Please note: these are employer decisions and should be based on local demographics. Ensure this applies equally across the gender spectrum; in other words, if you are going to ask anyone in this demographic whether they may be pregnant, you should ask everyone at risk. Sanders and Pederson offer useful advice about how we can improve communication with the gender-diverse community in diagnostic imaging departments. They propose using a questionnaire known as the SIGE (Sex, Identity, Gender and Expression) form, which may be considered suitable for adoption into UK practice, with care. This should be done in collaboration with image optimisation teams and in consultation with the workforce to ensure that compassionate care is not compromised in an attempt to achieve equality. There is a fine balance to be met between raising awareness and raising alarm.

Ensure your written procedures reflect the requirements of the Equality Act 2010 and the Gender Recognition Act 2004.

If your local written procedure involves checking the possibility of pregnancy with individuals under 13 years of age, ensure there is a written procedure to clearly indicate the responsibilities of duty holders in relation to the Sexual Offences Act 2003 in the case of an affirmative response. Advice should be sought from your local safeguarding lead when developing this procedure.

Ensure adequate information is available to ALL individuals prior to the exposure. This entails employers working with referrers, practitioners and operators to provide consistent and appropriate resources, eg patient information leaflets, posters and booklets that explain the benefits and risks of the procedure.

Ensure individuals have the time, opportunity, privacy and safety to raise the possibility of pregnancy with the referrer, practitioner or operator.

Ensure practitioners and operators are adequately trained to be able to explain the benefit and risk of the exposure. While it is not a requirement of IR(ME)R that referrers are adequately trained, it is considered an important element of patient safety that referrers understand and follow local
referral guidelines, appreciate the harmful biological effects of ionising radiation and how this is related to dose, and receive practical training in the referral process.

In summary: What should we change about our local written procedures?

- For all the regulatory changes in IR(ME)R 2017\textsuperscript{1}/IR(ME)R (NI)\textsuperscript{2} 2018, ensure the new requirements are reflected in the wording of your written procedures.
- Ensure changes reflect the local demographic and the benefit and risk of each examination/procedure to the individual.
- Ensure changes are made through appropriate governance processes and in collaboration with patients and the workforce, including your MPE.
- Seek the advice of local safeguarding lead practitioners when developing written procedures that may be required as an adjunct to your pregnancy checking procedure.
- Ensure adequate training is undertaken by all duty holders.

For further information please refer to the joint professional body publication Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation: Advice from the Health Protection Agency, The Royal College of Radiologists and the College of Radiographers\textsuperscript{9}. 
References