1. Objective

To prevent unnecessary exposure of a foetus from either a medical exposure or administration of a radioactive material to a pregnant patient.

2. Responsibilities

The Referrer, Practitioner and Operator must co-operate to establish whether or not any individual patient within the age range of 12 to 55 is, or might be, pregnant, when referred for a medical exposure or administration of radioactive material. If the patient is known to be pregnant the Referrer shall include this information in the referral.

Where the justifying Practitioner, or the authorising Operator, sees the patient ahead of justification, they shall re-establish and record pregnancy status. Otherwise justification and authorisation shall be based on the pregnancy status recorded in the referral.

When justifying the procedure, the Practitioner or the authorising Operator shall take account of pregnancy status in deciding whether to authorise or to delay the medical exposure.

The Practitioner shall provide the Operator with sufficient information, either directly or via a local procedure, so that appropriate techniques to minimise the dose to the foetus can be implemented.

The Operator who initiates the exposure shall re-check pregnancy status with the patient and shall record the result of this enquiry in accordance with this Procedure.

The Lead Clinician has responsibility for ensuring that examinations, for which patients need not be asked whether they are pregnant, are recorded in the local procedure.

The Medical Physics Expert for the relevant imaging modality shall, when requested by the Practitioner, assist the Practitioner in risk assessments, dose calculations and appropriate optimisation techniques to minimise the dose to the foetus.

3. Practical Procedure: -

3.1 Referral process

The Referrer must provide the Practitioner, or authorising Operator, with sufficient clinical information to enable them to justify any examination. The Referrer shall therefore:

- Record in the request if the patient is known to be pregnant at the time of the referral.
- Anticipate situations when it would be impossible for the Practitioner or Operator to determine whether the patient is pregnant (e.g. examinations in theatre or intensive care). In these situations the Referrer should ensure that arrangements are in place to obtain this information in advance.
- Record in the request any clinical reason for disregarding the question of pregnancy when they feel this is appropriate for patient management. Examples could include at least one year post menopause, following sterilisation, following hysterectomy, or following a still-birth the previous day.

3.2 Justification process

The Lead Clinician may identify examinations, for which it is unnecessary to enquire whether the patient may be pregnant, because the foetal dose is less than 0.1 mGy and the accompanying risk to the foetus is minimal[1]. For example, this may be considered to apply to x-ray examinations in which the region between the diaphragm and knees is not irradiated directly. Any such exclusion shall be based on documented risk assessments for the foetus and shall be included in the local procedure authorised by the Local Service Lead. An exemption applies for the West of Scotland Breast Screening Service where

pregnancy is not a contradiction and need not be checked. An exemption also applies for Oral Health where pregnancy is not a contradiction if the dose is less than 0.1 mGy and need not be checked.

In Justifying any exposure the Practitioner, or authorised Operator working to a procedure shall:

- Take account of any information supplied by the Referrer.
- Consider whether any other procedure not involving ionising radiation would be more appropriate.
- Pay special attention to the urgency of the exposure in cases when pregnancy cannot be excluded, paying particular attention to relevant published guidance.[2,3]
- Make the decision to justify the exposure if this is appropriate. The decision may be taken in consultation with the Referrer but the decision to justify the exposure remains the Practitioner's responsibility. When a decision is made by the Practitioner to justify an exposure of a patient who is or may be pregnant, then they must document their decision in the patient's records according to the procedure.
- In the event that an exposure is justified where the possibility of pregnancy cannot be excluded, the Practitioner must plan how to minimise the dose to the foetus consistent with the diagnostic purpose of the exposure and pay particular attention to published guidance[2,3,4], making use of the 10-day rule and 28-day rule when appropriate[2,3], and provide appropriate information to the Operator. For Nuclear Medicine procedures the principle[4] is that the foetal exposure should not normally exceed 1 mGy. The MPE will calculate the dose when requested.

3.3 Immediately prior to radiation exposure

Immediately prior to any radiation exposure, the Operator shall determine whether the patient is, or could be, pregnant. This requirement shall not apply where the exposure is excluded in accordance with Section 3.2, or where the Referrer or Practitioner has advised that it is not possible for the patient to be pregnant (e.g. at least one year post menopause, following sterilisation, following hysterectomy, or following a still-birth the previous day).

The Operator shall enquire directly of the patient whether there is any possibility that they may be pregnant.

The Operator shall ask the Patient the following questions:

1. **"Is there any possibility that you may be pregnant?"**
2. **"What is the date of the first day of your last period?"** or **"Is there a chance that your period is late?"**

The result of the pregnancy status enquiry shall be documented by the Operator in the patient's records according to the procedure and where applicable this shall include the reason why pregnancy status was not established.

In the event of a referral for a therapeutic administration of radioactive material, an appropriate pregnancy test should be performed.

The Operator must follow the cascade decision diagram in the figure below, in order to determine whether to proceed with the exposure or whether to defer it. The start points for this decision process are based on whether the dose to the uterus is expected to be less than 15mGy or not, and also whether the patient has declared whether they are definitely pregnant or not.

Note: If there is any uncertainty over pregnancy status for potential exposures between 10 and 15mGy (e.g. high dose CT, PET-CT, Interventional Radiology procedures of the abdomen and pelvis) then a pregnancy test **must** be undertaken.

There should be a locally agreed protocol for checking pregnancy status before elective surgery[5]. The protocol should detail who is responsible for making the check.

A system should be in place to facilitate transgender and non-binary patients who were female at birth, to confidentially inform a member of staff, so that pregnancy can be excluded[6]. Note, the patient's gender history cannot be recorded or shared without their consent[6]. Guidance including suitable inclusive patient questions can be found in EP-Guidance-018.

3.4 Individuals of child-bearing potential aged 12 to 15 years

In Scots Law, all young people who can give valid consent (i.e. with decision making capacity)[7], have a fundamental legal and ethical right to determine what happens to their own bodies. Consequently, the Referrer, Practitioner and Operator should normally make enquiries on pregnancy status for individuals of child-bearing potential[8] between the ages of 12 and 15 years in private, with the parents/guardians not present.

If the individual is declaring their pregnancy for the first time, then the Referrer, Practitioner or Operator to whom the declaration has been made should provide them with written information on how to self-refer for further clinical services as detailed in EP-Guidance-009. The Referrer, Practitioner or Operator to whom the declaration has been made also has a duty to notify the Teenage Pregnancy Service and contact Child Protection Services if necessary for advice, according to the "Clinical Pathway" detailed in EP-Guidance-010.

4. References

1. Unintended and accidental medical radiation exposures in radiology: guidelines on investigation and prevention. CJ Martin, J Vassileva, E Vano, M Mahesh, S Ebdon-Jackson, KH Ng, DP Frush, R Loose, J Damilakis. J Radiol Prot. 37:883-906, 2017, doi: 10.1088/1361-6498/aa881e.
2. RCE-9: Protection of pregnant patients during diagnostic medical exposures to ionising radiation: Advice from the Health Protection Agency, The Royal College of Radiologists and College of Radiographers, Health Protection Agency, Centre for Radiation, Chemical and Environmental Hazards, Didcot, 2009, ISBN 978-0-85951-635-8.
3. Diagnostic medical exposures: Advice on exposure to ionising radiation during pregnancy. C Sharp, JA Shrimpton, RF Bury, National Radiological Protection Board, College of Radiographers and Royal College of Radiologists, Didcot, 1998, ISBN 0-85951-420-X.
4. Notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources. https://www.gov.uk/government/publications/arsac-notes-for-guidance, Administration of Radioactive Substances Advisory Committee (ARSAC), Centre for Radiation, Chemical and Environmental Hazards, Public Health England, Chilton.
5. Preoperative tests (update): Routine preoperative tests for elective surgery. Clinical Guideline NG45. Methods, evidence and recommendations. National Institute for Health and Care Excellence, 2016.
6. IR(ME)R annual report 2019/20: CQC's enforcement of the Ionising Radiation (Medical Exposure) Regulations 2017, The Care Quality Commission, October 2020.
7. Age of Legal Capacity (Scotland) Act, 1991.
8. The impact of IR(ME)R 2017 IR(ME)R (NI) 2018 on pregnancy checking procedures, Society and College of Radiographers, London, 2019.

Cascade Decision Diagram