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IR(ME)R 2017 Employers Procedures

DCHFT EP5 - ESTABLISHING PREGNANCY STATUS FOR PROCEDURES INVOLVING IONISING RADIATION

Policy Title	IR(ME)R 2017 Employers Procedures - DCHFT EP5 Establishing pregnancy status for procedures involving ionising radiation		
Policy Number	2135	Policy Version Number	2
Applicable to	All Trust staff		
Aim of the Policy	Compliance with the Ionising Radiation (Medical Exposure) Regulations 2017 - procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding prior to an exposure of ionising radiation.		
Next Review Due Date	01 February 2026		
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Policy Sponsor	Dr Rajintha Malavige, Consultant Radiologist		
Expert Group	Trust Medical Exposures Group		
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Primary Specialties	Trustwide; Medica	al Physics	

Document Version Management				
Version	Date	Reviewer	Description of Change(s)	
1	Feb-2024	J Thurston	Changed to reflect move to inclusive process.	

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DCHFT EP5 - Establishing pregnancy status for procedures involving ionising radiation

IRMER17^[1], Schedule 2, Regulation 6, Employer's Procedures, 1.(c):

The Employer's Procedures for exposures must include a procedure for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding^[1].

This Employer's Procedure covers the process for establishing pregnancy status of individuals of childbearing potential prior to procedures involving ionising radiation, and the procedure in accordance with IR(ME)R17 for pregnant patients requiring a radiological procedure, as required under the Ionising Radiation (Medical Exposures) Regulations 2017 (IRMER17).

The Procedure applies to all individuals of childbearing potential, between the ages of 10 and 55 years, who are undergoing a procedure unless the dose to any foetus present is likely to be less than 0.05mSv (a very low dose procedure).

Introduction - Overview

The responsibility for ascertaining the patient's pregnancy status lies with the Operator who makes the exposure.

Initially the patient is asked whether they were born male or female. If male, then the radiological procedure is performed.

If female, the patient is asked whether any previous surgery, treatment or medical condition means that they are no-longer able to become pregnant. If so, then the radiological procedure is performed.

If not, the patient is asked if there is any possibility they could be pregnant. If the answer is no, then the radiological procedure is performed.

If the answer is yes, then further questions or actions are taken.

The response of the patient can either be recorded on a suitable form (signed by the patient and the operator and scanned onto the RIS) or recorded using an electronic system such as a RIS. If a local decision is made to document without a patient signature, then this decision should be recorded and signed off by IRMER Lead Practitioners from each relevant modality.

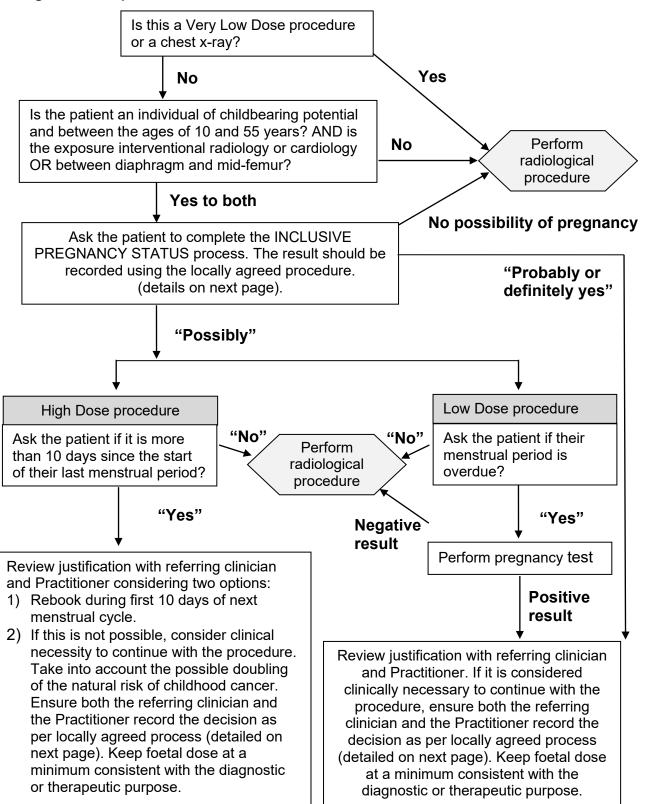
A flowchart and further details for asking the pregnancy question and recording the results are given below.

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When the patient attends the department, the flow-chart below shall be followed taking the subsequent information into account.

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When asking the patient about their pregnancy status, the following should be taken into account:

- > Record of pregnancy status must be appropriately documented (see section below).
- ➤ If given verbally, the question must be posed with care as it may offend or embarrass some individuals. The policy should be explained to the patient to enable them to appreciate the need for accurate information.
- > Should a patient initially refuse to answer the questions, explain the policy to them to enable them to appreciate the need for accurate information. If they still refuse, seek advice from the Practitioner and again record the result appropriately.
- Some patients will not have regular periods and therefore may not fit neatly into the flow-chart. If they are able to state that they are not pregnant, then go ahead with the radiological procedure. If they are not able, then a pregnancy test may be required.
- ➤ If practicable, children under the age of 16 should be asked the question without their parents present. In any case a child's signature (rather than a parent or guardian's) is appropriate to this situation provided that in the opinion of the health professional they understand what is being asked. If the health professional doubts that the child understands the significance of the question, they must then involve the parent/guardian who may sign the disclaimer on the child's behalf. Please note that children under 13 are legally unable to give consent to sexual activity and therefore if possibility of pregnancy is reported, follow the Trust's Safeguarding procedures.
- ➤ If the patient is unable to answer for themselves because of language difficulties, then a translator is required.
- ➤ If the patient is unable to answer and/or sign the disclaimer for themselves because of special needs, then an accompanying parent, legal guardian or someone who has power of attorney for health and welfare, can answer and/or sign on their behalf.
- ➤ For unconscious patients such as trauma cases, possible pregnancy must be assumed and examinations undertaken accordingly with the referring clinician and Practitioner recording their decision as per local practice.

Documentation of Pregnancy status

The process for recording of pregnancy status checks and any signed documentation must be detailed in a local procedure.

If it is considered clinically necessary to continue with the procedure even though a pregnancy test result is positive or (for a high dose procedure) it is more than 10 days since the patient's last menstrual period, ensure:

- the foetal dose is kept at a minimum consistent with the diagnostic purpose.
- both the referring clinician and the Practitioner record the decision by locally agreed process.

Classification of procedures involving ionising radiation

1) Very Low Dose procedures, those where the dose to the foetus is likely to be less than 0.05mGy (for which patients should not be asked about their pregnancy status):

Chest X-ray

DEXA scans (lumbar spine / hip)

X-rays away from the abdomen (e.g. extremities or head)

CT Head / sinuses

CT Neck

2) High Dose procedures, those where the dose to the foetus is likely to be greater than 10mGy (for which more stringent procedures apply):

CT IVU

CT Colonoscopy

CT Lumbar Spine CT Kidneys Ureter Bladder

Any CT that includes the Pelvis (with or without contrast)

All Cardiology Catheter Lab procedures except EPs

All Interventional Radiology procedures

3) Low Dose procedures are all other procedures not detailed under the High or Very Low dose definitions.

Special procedures for exposures performed in theatres

Ultimately the responsibility for determining the patient's pregnancy status lies with the Operator. For most theatre cases, the radiographer acts as the Operator. However, due to the nature of such cases, the radiographer may only arrive whilst or after the patient is being anaesthetised so the opportunity is not there for the radiographer to ask the patient directly.

Pre-Anaesthetics

➤ The surgeon or anaesthetist should check the pregnancy status of the patient and document the response either in the patient notes or theatre checklist.

Post Anaesthetics

- ➤ If pregnancy status has not been documented in the patient notes / theatre checklist, the radiographer should check with the attending anaesthetist whether they have checked the pregnancy status. The radiographer should then document this check as per local procedure.
- If the anaesthetist is unsure of pregnancy status, then they must sign the electronic referral acknowledging that he/she accepts responsibility.
- ➤ If anaesthetist is unwilling to sign, the consultant/surgeon must provide their signature accepting responsibility for the continuation of the procedure despite not knowing the patient pregnancy status.
- If neither the anaesthetist nor surgeon is willing to provide a signature, then the procedure must be delayed until such time as the pregnancy status can be established.

In the case that a foetus is inadvertently exposed

- > Report the incident as soon as possible to the modality lead, the Department Manager or Superintendent and the Practitioner.
- Complete a DATIX entry and Trust radiation incident form (with a copy sent to the Trust Medical Physics Expert - MPE).

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- Medical Physics Expert (MPE) will estimate the dose to the foetus.
- A Radiologist or Clinician should counsel the patient on the event and the associated risk using the information provided by the MPE investigation.
- The MPE will ascertain whether the incident needs to be reported to the CQC as a "significant accidental or unintended exposure" (SAUE).

References

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, March 2009.

The IR(ME)R 2017 Employers Procedures – Establishing Pregnancy Status, will be brought to the attention of all employees working with ionising radiation and will be reviewed biennially by the Medical Exposures Group (MEG).					
Signed: Date:20.02.2024					
Chair of the MEG. Dorset County Hospital NHS Foundation Trust					