Employers Procedure 4

Ramsay IR(ME)R Employers Procedure

Employers Procedure Number: IR-001 / Employers Procedures 4

Employers Procedure Title: Making enquiries of individuals of child-bearing potential, pregnancy and breast feeding.

1. Governing Policy

- IR-001 Employer Procedure and Employers Statement

2. The Procedure

2.1. Breast feeding Pregnancy Status Check

2.1.1. The purpose of this procedure is to establish the likelihood of pregnancy in a female of childbearing age, and additionally, for Nuclear Medicine examinations to determine whether a female is breastfeeding BEFORE they undergo a medical exposure.

2.2. Pregnancy Status Check

2.2.1. The Referrer is responsible for providing sufficient medical data, including pregnancy status of the individual, in order to enable the practitioner to justify the exposure.

2.2.2. It is the responsibility of the IR(ME)R operator who directly exposes the patient, to evaluate if the patient is likely to be of child-bearing potential and will ask the patient if it is possible that they are, or could be, pregnant before the examination commences. Refer to Section 2.3 and 2.4.

2.2.3. When more than one operator is present, it should be clearly established which operator is taking responsibility for making pregnancy enquiries, and that this is duly recorded on the RIS system patient record.

2.2.4. Where there is no possibility of pregnancy (such as total abdominal hysterectomy (TAH), bilateral salpino-oophorectomy, sterilisation etc), the referrer should provide this information explicitly on the referral. If this information has been provided, then the operator does not need to check the patient's status.

2.2.5. In order to avoid inadvertent exposure to an unborn child, all other patient individuals of childbearing potential, aged between 12 and 55 years, undergoing imaging using ionising radiation between the diaphragm and knees, will be asked to confirm their pregnancy status. For the confirmation of status questions, please refer to (Appendix B) Pregnancy flowchart for non-theatre examinations.

2.2.6. The age range for pregnancy status check should accurately reflect the local patient demographic. The Radiology Manager should document within the department local Employers Procedures if the local age range falls outside of this agreed standard. They may choose to consult the local NHS trust obstetric team to source this information.

2.2.7. The response to pregnancy enquires must be documented in the patient's RIS record, as evidence that the appropriate questions have been asked. The operator has the responsibility of scanning any relevant forms relating to pregnancy and breast-feeding in to RIS.

2.2.8. If the individual chooses not to answer questions relating the possibility of pregnancy, this should be documented and the procedure for unknown pregnancy status followed. The operator should inform the practitioner, who may reconsider justification.

2.2.9. Emergency examinations do not preclude the necessity to check for the possibility of pregnancy, unless the individual's care would be put at risk by doing so. If the examination is due to an emergency, and pregnancy cannot be excluded or is confirmed, the welfare of the pregnant person takes priority. The Radiologist and Referrer will make a decision on whether the examination should go ahead or if it can be delayed.

2.3. Unconscious, anaesthetised or sedated patients in emergency situations

2.3.1. It is the responsibility of the Referrer to confirm the patient's pregnancy status prior to the patient being anaesthetised or sedated as per NICE guideline 45, as well as this being part of the WHO checklist. If a situation arises where the pregnancy status of an eligible patient has not been confirmed, please refer to the "Theatre Pregnancy Status Check Flow Chart". (Appendix A).

2.4. Trans male or gender non-conforming individuals

2.4.1. The Gender Recognition Act 2004 prohibits the disclosure, without consent, of protected information about a person who has changed their gender. There may be situations where an IR(ME)R duty holder is unaware of the possibility of pregnancy due to these circumstances. The individual to be exposed then has the sole responsibility of safeguarding the foetus.

2.4.2. To ensure all patients are aware of the risks and benefits prior to medical exposure, Radiation benefit/risk leaflets and pregnancy posters (Appendix C) must be displayed in the Radiology department and mobile scanner environment. Individuals provided with this information will then have the opportunity to ask further questions and to declare any possibility of pregnancy.

2.4.3. Sex Identity Gender Expression (SIGE) forms and SIGE statement (Appendix D) must be available within the radiology department so that all patients have the opportunity to ask questions and declare the possibility of pregnancy.

2.5. Confirmation of Status

2.5.1. The patient will be asked if there is any possibility of pregnancy. If they confirm a definite 'NO', The patient must sign to confirm the correct date of last menstrual period (LMP). The operator must obtain the date of the last menstrual period before the examination can continue. This must be documented on the referral form. The patient must also sign the 'I certify there is no possibility I am pregnant' section on the Radiology referral form OR where MAXIMS referrals are in use, the Pregnancy status declaration form (Appendix E) must be signed and dated to confirm this is correct and indicate permission to proceed.

2.5.2. The pregnancy status box must be checked on RIS and the LMP date field completed on RIS for the procedure by the operator responsible for the radiation exposure

2.5.3. If the patient confirms that they are definitely or probably pregnant, then the operator must consider the anatomical area of the examination. If the examination is in an area between the knees and the diaphragm, the status of the patient's menstrual cycle shall be taken into account and a review of the justification of the exposure shall take place with the IR(ME)R Practitioner, and referring clinician where required, to provide additional clinical information. Consideration should be given to delaying the examination until after delivery (or until pregnancy is ruled out)

2.5.4. If the clinical benefit of the procedure/examination demands the examination is carried out, the justification must be documented in the patient RIS record, and the dose to the uterus kept to a minimum. Consideration should be made as to whether the exposure could be further optimised to reduce dose to the foetus (e.g. minimise scan area to keep doses ALARP) Refer to Employers Procedure 6 Schedule 2(e) Optimisation

2.5.5. In cases where the patient is known to be pregnant and it is decided by the Radiologist and referring Clinician that imaging is still required, the MPE can be contacted to provide an estimated foetal dose and provide advice to the patient or their doctor. A pregnancy disclaimer form (Appendix F) should be completed with the patient detailing the radiation risks.

2.6. Low dose procedures – where pregnancy cannot be excluded

2.6.1. A low dose procedure is defined as any procedure in which the foetal dose is likely to be below 10mGy. The vast majority of routine diagnostic examinations fall into the category of a low dose procedure

2.6.2. If pregnancy cannot be excluded and the menstrual period is not overdue, according to the twenty-eight (28) day rule, the examination can still proceed.

2.6.3. If the menstrual period is overdue, according to the 28-day rule, then the patient should be treated as probably pregnant (see above)

2.7. High dose procedures – where pregnancy cannot be excluded

2.7.1. A high dose procedure is where the dose to the foetus is likely to be greater than 10mGy. The following examinations are considered to be high dose:

- CT examinations of the abdomen or pelvis. For a list of typical foetal doses for common diagnostic examinations (Health Protection agency et al, 2009) refer to Appendix G.
- All high dose fluoroscopic and interventional procedures where the primary beam directly irradiates the abdomen or pelvis

2.7.2. If the pregnancy cannot be excluded, the patient will be asked if they are within the first ten days of their menstrual cycle. If the patient confirms that they are, the date of the LMP must be recorded as outlined in Section 2.5 and the patient must sign to confirm the date of LMP before the examination can proceed.

2.7.3. The pregnancy status box must be checked on RIS and the LMP date field completed on RIS for the procedure by the operator responsible for the radiation exposure

2.7.4. When there is uncertainty from the patient and the patient is outside of the ten-day rule, the following is advised, in consultation with the Practitioner and possibly the Referrer.

- Delay the examination until the next menstrual period to confirm no pregnancy (if it is safe to delay)

- If clinical benefit of procedure/examination demands it is carried out, document this Justification on RIS and keep dose to the uterus to a minimum consistent with the intended purpose

- If the patient's menstrual cycle is overdue, the patient should be treated as probably pregnant (see above).

2.8. Testing for pregnancy

2.8.1. A pregnancy test should only be carried out on the instruction of the Radiologist, where feasible. A hormone-based blood test should always be used in preference to a urine-based test where the age of gestation is likely to be less than two months.

2.8.2. A Clinitest point of care pregnancy test kit must be used in accordance with CN-040/SOP-003 Pre-operative Pregnancy Testing

2.8.3. Clintest is to be carried out by a competent member of staff following the point of care instructions

2.9. Confirmation of Status for patients under 16 years of age

2.9.1. Identifying pregnancy in young patients can pose specific problems due to the reluctance to disclose sexual activity, especially if accompanied by a parent or carer. The decision on how to discuss this is made based on the patients age, maturity and ability to appreciate the risks that have been explained to them.

2.9.2. There is a legal concept known as the 'Gillick Competence' which holds that, for a person under the age of 16, valid consent can be given (without intervention from a parent or even their knowledge) if, in the opinion of a health professional, they fully understand what is being asked or explained and demonstrate competence to make their own decisions. Asking in the presence of a parent may not obtain an honest answer. It may be appropriate to say something like: ***'I need to ask your child a sensitive question, please would you wait outside the room for a moment?***

2.9.3. In the case of young people, who may not understand, it may be appropriate to first ask: ***'Have you started your periods yet?***' If the answer is negative, there is no need to pursue questioning

2.9.4. There is further guidance on Pre- procedure pregnancy checking for under-16s: guidance for clinicians. Available at https://www.rcpch.ac.uk/pregnancychecks

2.9.5. Pregnancy testing must be a last resort for this patient group and only undertaken with support from an appropriate paediatric nurse or Consultant.

2.9.6. For patients under 16 years old that suspect they may be pregnant, staff should follow safeguarding procedures CN-045 - Safeguarding of Children and Young People.

2.9.7. The patient should be referred back to the Consultant or GP who will make a judgement regarding the patient's on-going care. This should be done in confidence, unless the parent/carer is already aware

2.9.8. Refer to the Ramsay information leaflet available for Teenagers and pregnancy: http://ukintranet/dept/clinicalservices/Clinical%20Generic%20Forms%20and%20Leaflets/Teenage%20Pregnancy%20CL-4252-000-R.pdf

2.10. Pregnancy and Vulnerable Individuals

2.10.1. In the situation where individuals are reluctant to disclose their pregnancy status in the presence of others, such as a concealed pregnancy, a result of abuse, or are unwilling to confirm pregnancy due to cultural or religious beliefs. It may be appropriate to say something like: ***'I need to ask the patient a sensitive question, please would you wait outside the room for a moment?***

2.10.2. For vulnerable individuals suspected of abuse, staff should follow local safeguarding processes. Further guidance on safeguarding procedures is available CN-037 - Safeguarding Adults at Risk of Abuse or Neglect.

3. Approval

Individual Approval			
If you are happy to approve this document, please sign and date it and forward to the chair of the committee/group where it will receive final approval.			
Name	Abiola Adebayo	**Date**	28/07/2021
Signature			
Committee Approval			
If the committee is happy to approve this document, please sign and date it and forward electronic copies to the Integrated Governance Assistant who has responsibility for disseminating and implementing the document and for maintaining the organisation's database of approved policies and procedural documents.			
Name	Viv Heckford	**Date**	25.08.21
Signature			

4. References

- Health protection agency, The Royal College of Radiologists and College of Radiographers (2009) Protection of patients during diagnostic exposures to ionising radiation. Available at: https://www.rcr.ac.uk/system/files/publication/field_publication_files/HPA_preg_2nd.pdf/