

Date: 27th November 2024

Ref: CORP 2024 - 214

Dear xxx

Freedom of Information request: Pregnancy Enquiries Prior to Ionising Radiation Exposure – (CORP 2024 – 214)

Thank you for your request for information which the Trust received on 30th October 2024.

Your Request:

What is your radiology department's standard operating procedure for making pregnancy enquiries prior to ionising radiation exposure? Please attach current SOP/SOPs with relevant physical/digital enquiry form that the department uses to make these enquiries.

Please find the Trust's response below:

The Velindre University NHS Trust's Radiation Services Employers Procedure C – Enquiries to Patients who may be Pregnant, or Breastfeeding is included as Appendix 1.

I trust this answers your request for information, however, should you not be satisfied with the information supplied or the process of supplying it, you have a right to complain and request a review. Please note that you must submit a request for a review within 40 days of the date of this letter.

You should forward your complaint to:

Mr Ian Bevan via FOI.VUNHST@wales.nhs.uk
Head of Information Governance
Velindre University NHS Trust
2, Charnwood Court
Heol Billingsley
Parc Nantgarw
Cardiff / Caerdydd
CF15 7QZ

Should you wish to take your complaint further, if you are still unhappy with the decision after review, you can contact the:

Mae Ymddiriedolaeth GIG Prifysgol Felindre yn hapus i dderbyn gohebiaeth yn y Gymraeg neu'r Saesneg.
Velindre University NHS Trust is happy to receive communication in Welsh or English.



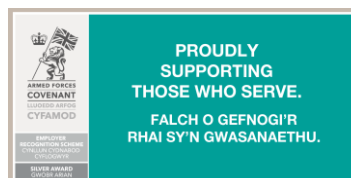
Pencadlys Ymddiriedolaeth GIG Prifysgol Felindre
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Information Commissioner's Office - Wales
2nd Floor
Churchill House
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Telephone: 0330 414 6421
email: wales@ico.org.uk

Yours sincerely

Non Gwilym
Interim Director of Corporate Governance
Velindre University NHS Trust
2 Charnwood Court
Heol Billingsley
Parc Nantgarw
Cardiff
CF15 7QZ

Mae Ymddiriedolaeth GIG Prifysgol Felindre yn hapus i dderbyn gohebiaeth yn y Gymraeg neu'r Saesneg.
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RADIATION SERVICES

Section:	Radiology
Title:	Employers Procedure C – Enquiries to Patients who may be Pregnant or Breastfeeding
Lead Author(s):	Radiology Manager
Owner:	Radiology Manager
Approved by:	Radiology Manager Clinical Director of Radiology

Purpose

To raise awareness of the effects of ionising and non-ionising radiation among individuals capable of childbearing or breastfeeding.

To clarify the responsibility for identifying the individuals this procedure applies to, and who require checking the pregnancy status throughout the examination process.

To minimise the risk of exposing a foetus to ionising and non-ionising radiation, thereby protecting the unborn child.

To define the age range of individuals this procedure applies to.

To ensure the process for documentation of pregnancy status is clear.

To raise patient awareness to inform staff involved in the exposure of a pregnancy / potential pregnancy status.

Scope

This Employer's Procedure applies to all individuals with childbearing capacity between the ages of 12-55 years.

Nuclear Medicine services are not provided within the Radiology Department at Velindre Cancer Centre and therefore the risk to breast-fed infants from the administration of a radioactive material does not need to be considered within this Employer's Procedure.

Paediatric patients are not treated at Velindre Cancer Centre, therefore this patient cohort does not need to be considered within this Employer's Procedure.

References / Related Documents

Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation (HPA, 2009)

ICNIRP Statement on Magnetic Resonance (MR) Procedures: Protection of Patients (ICNIRP, 2004)

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1. Introduction

Ensuring the safety and wellbeing of all patients in Radiology is a priority, particularly those who may be pregnant. Radiological procedures including X-rays, CT scans, MRI scans and other imaging techniques which involve exposure to ionising and non-ionising radiation, may carry specific risks for developing foetuses.

This procedure outlines the steps Radiology staff must take to make appropriate enquiries about potential pregnancy before an imaging procedure. By identifying these individuals, we minimise unnecessary ionising and non-ionising radiation exposure.

2. Ionising Radiation Procedure

2.1. The referrer should check the pregnancy status of the patient and indicate the result on the referral. A further check should also be made by the IR(ME)R Operator when the patient attends for the examination, as their pregnancy status may have changed.

2.2. Where there is medically no possibility of pregnancy, the referrer should document this information on the request form.

2.3. For all patients with childbearing capacity aged between 12 and 55 years scheduled for any procedure involving any ionising radiation between the knees and diaphragm, the IR(ME)R Operator must ask the patient '**Are you, or might you be, pregnant?**'. Depending on the answer to this question, patients will be assigned to one of the following groups;

2.3.1. No possibility of pregnancy.

2.3.2. Patient definitely or probably pregnant.

2.3.3. Pregnancy cannot be excluded: low dose procedure.

2.3.4. Pregnancy cannot be excluded: high dose procedure.

2.4. The following steps should be taken for each of these groups to prevent unnecessary exposure of a foetus.

2.5. No possibility of pregnancy

2.5.1. If the patient responds with a definite '**No**', the IR(ME)R Operator must document the response, sign the radiology request form and then ask the patient to sign the request form. The examination may then proceed.

2.6. Patient definitely or probably pregnant

2.6.1. If the patient responds that they are definitely or probably pregnant, the IR(ME)R Operator must document the response.

2.6.2. The patient must be referred back to the Referrer / IR(ME)R Practitioner to either justify the examination or defer until after delivery (or until pregnancy has been ruled out). Consideration should be given to requesting other examinations that use less or no radiation and deferring the examination if it is not urgent.

2.6.3. If justified, the foetal dose should be kept to a minimum.

2.6.4. The IR(ME)R Operator / Practitioner must document the decision to proceed.

2.6.5. Details of the scan / exposure should be recorded and an effective dose request made to Medical Physics Expert (MPE), Radiation Protection Service, Cardiff.

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2.6.6. The results will be recorded on the RIS and a copy sent to the referrer for placement within the patients records.

2.7. Pregnancy cannot be excluded: low dose procedure

2.7.1. If a patient is unsure of the possibility of pregnancy, they should be asked '**Is your period overdue?**'.

2.7.2. If the menstrual period is overdue, treat as probably pregnant and follow the procedure as if the patient is definitely or probably pregnant.

2.7.3. If the menstrual period is not overdue and the imaging procedure involves standard radiography and fluoroscopy procedures, the IR(ME)R Operator must document the response, sign the request form and then ask the patient to sign the request form. The examination may then proceed.

2.8. Pregnancy cannot be excluded: high dose procedure

2.8.1. If the menstrual period is not overdue and the imaging procedure involves a CT Abdomen, CT Pelvis study, the examination may proceed if it is within 10 days of the onset of the last menstrual period.

2.8.2. If more than 10 days following the last period, reschedule the examination to the first 10 days of the next cycle.

2.9. If the exposure is justified, the foetal dose should be kept to a minimum by use of dose optimisation. Lead (or lead equivalent) shielding is not used for dose limiting purposes. The IR(ME)R Operator / Practitioner should document the decision process for justification on the request form and on the RIS.

3. MRI procedure

3.1. The referrer should check the pregnancy status of the patient and indicate the result on the referral. A further check should also be made by the MR Authorised Person when the patient attends for the examination, as their pregnancy status may have changed.

3.2. Where there is medically no possibility of pregnancy, the referrer should document this information on the request form.

3.3. For all patients with childbearing capacity aged between 12 and 55 years scheduled for any MRI procedure, the MR Authorised Person must ask the patient on completion of the MR Safety Questionnaire '**Are you, or might you be, pregnant?**'. Depending on the answer to this question, patients will be assigned to one of the following groups;

3.3.1. No possibility of pregnancy.

3.3.2. Patient definitely or probably pregnant.

3.3.3. Pregnancy cannot be excluded.

3.4. The following steps should be taken for each of these groups to prevent unnecessary exposure of a foetus.

3.5. No possibility of pregnancy

3.5.1. If the patient responds with a definite '**No**', the MR Authorised Person must ensure the response is documented on the MRI safety questionnaire and request form, sign the MRI safety questionnaire and then ask the patient to sign the MRI safety questionnaire. The examination may then proceed.

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3.6. Patient definitely or probably pregnant

- 3.6.1.** If the patient responds that they are definitely or probably pregnant, the MR Authorised Person must document the response.
- 3.6.2.** The patient must be referred back to the Referrer to be discussed with the patient, MR Supervisor and Radiologist and the decision documented in the patient notes.
- 3.6.3.** There is at present insufficient knowledge to establish unequivocal guidance for the use of MRI procedures on pregnant patients. In these circumstances, it is advised that MR procedures may be used for pregnant patients only after critical risk / benefit analysis, especially during the first trimester to investigate important clinical problems or to manage potential complications for the patient or foetus.
- 3.6.4.** The MHRA recommends that pregnant patients are scanned in NORMAL MODE. If there is a need to scan in CONTROLLED MODE the risk / benefit of the scan should be discussed with the patient, Referrer, Radiologist and MR Safety Expert and the outcome documented in the patient's notes.
- 3.6.5.** If the decision is made to proceed, scan adjustments should be made to minimise the potential risk to the foetus from radio frequency (RF) and noise exposure.

3.7. Pregnancy cannot be excluded

- 3.7.1.** If a patient is unsure of the possibility of pregnancy, they should be asked '**Is your period overdue?**'.
- 3.7.2.** If the menstrual period is overdue, treat as probably pregnant and follow the procedure as if the patient is definitely or probably pregnant.
- 3.7.3.** If the menstrual period is not overdue, the MR Authorised Person must document the response, sign the MRI safety questionnaire and request form and then ask the patient to sign the MRI safety questionnaire. The examination may then proceed in NORMAL MODE and where possible, acoustic reduction techniques applied.

4. Considerations

- 4.1.** The use of blood and urine pregnancy test results as part of the justification process may not be reliable in the case of early pregnancy.
- 4.2.** Radiology staff do not carry out pregnancy testing for patients.
- 4.3.** When ascertaining a patient's pregnancy status, privacy and sensitivity will always be exercised.
- 4.4.** In some instances, patients may discover that they were mistaken and that they were in fact pregnant at the time the procedure was carried out. In all such instances the event should be reported following the Trust Incident Reporting Procedure. The Radiation Protection Adviser / MPE / MRSE must be contacted immediately to estimate the risk to the developing foetus and the Referring Clinician or Radiologist should discuss the implications of the foetal exposure with the patient. In most instances the inadvertent exposure of a developing foetus is unlikely to justify the greater risks of invasive foetal diagnostic procedures (e.g. amniocentesis) or those of a termination of the pregnancy.
- 4.5.** In cases where a foetal exposure takes place when the pregnancy was not known and the radiation exposure exceeds 10mGy, this must be reported to the regulator following CSAUE processes.

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5. Special Circumstances

5.1. Patients who lack capacity, are mentally impaired or confused.

5.1.1. If the patient is unable to accurately give the requested details to the IR(ME)R Operator / MR Authorised Person, the Referring Clinician should be contacted, and they must then ascertain the patient's pregnancy status.

5.2. Patients who have a sensory impairment or are hard of hearing.

5.2.1. If a patient can lip read, they may be able to follow the procedure for checking the patient's pregnancy status.

5.2.2. Patients unable to lip read will require written instructions provided by the IR(ME)R Operator / MR Authorised Person asking them to confirm their pregnancy status.

5.2.3. Alternatively, a sign language interpreter may be offered.

5.2.4. If the patient cannot follow any of the above, follow the procedure for patients who lack capacity, are mentally impaired or confused.

5.3. Patients who cannot communicate verbally.

5.3.1. If the patient cannot communicate verbally, they may be asked by the IR(ME)R Operator / MR Authorised Person to confirm their pregnancy status by written statement.

5.3.2. If the patient cannot follow the above, follow the procedure for patients who lack capacity, are mentally impaired or confused.

5.4. Patients who are unable to speak / communicate in English / Welsh.

5.4.1. If a patient is unable to speak / communicate in English / Welsh, Language Line should be accessed where an interpreter can be selected to support the patient.

5.5. Unconscious, anaesthetised or sedated patients and emergency patients.

5.5.1. It is responsibility of the referrer to confirm pregnancy status prior to the patient being anaesthetised or sedated. Emergency examinations do not preclude the necessity to check for the possibility of pregnancy, unless the individual's care would be put at risk to do so. In this instance, the referrer should assess the risks / benefit of the examination proceeding. This decision should be documented on the request form and on the RIS.

5.6. Trans male or gender nonconforming individuals.

5.6.1. Disclosure of information that a person has changed their gender is protected under the Gender Recognition Act 2014 and cannot be disclosed without permission. The IR(ME)R Referrer, Operator, Practitioner / MR Authorised Person could be unaware of the possibility of pregnancy when the individual is unidentified / undeclared as a trans male. In circumstances where permission for this information to be shared has not been given, the responsibility for safeguarding the foetus lies with the individual. The risk / benefit information given before every procedure should be sufficient that the individual has adequate understanding that allows them to ask further questions if required or declare the pregnancy.

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