Section 4 Patient Pregnancy Protocols

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Local documentation to be added to this section:
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Protocols for Comforters and Carers

Key Performance Indicators for this section;
Record kept of pregnancy status of females of childbearing age for all relevant procedures
Evidence of decision to proceed with imaging a pregnant patient
Record of incidents where foetus inadvertently received a radiation dose and appropriate action taken.
Evidence of waiver form and procedure

Relevant National Healthcare Standards;
Standards 2.1, 2.5 (Effective Care and Support)
Standard 3 (Safe Care and Support)
Section 4 Patient Pregnancy Protocols

The service should actively support and promote the safety of pregnant patients as part of a wider culture of quality and safety.

Legislation governing special protection of females of childbearing age

SI 478

Article 20 - Special Protection during Pregnancy and Breastfeeding.

20.1. In the case of a female of childbearing age, the prescriber, the practitioner, the radiographer, or persons referred to in regulations 13 and 16 shall inquire whether she is pregnant or breastfeeding, if relevant, and shall record her answers in writing.

20.2(a) In the case of a female of childbearing age if pregnancy cannot be excluded or where the records fail to indicate whether the patient is pregnant or not, the prescriber, the practitioner, the radiographer and persons referred to in regulations 13 and 16 shall treat the patient as if she were pregnant.

20.2(b) If pregnancy cannot be excluded, depending on the type of medical exposure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure taking into account the exposure both of the expectant mother and the unborn child.

20.3. In the case of a female who is breastfeeding, in nuclear medicine, the prescriber, the practitioner, the radiographer or persons referred to in regulations 13 and 16 shall in recording their justification for continuing with a procedure have specific regard and make written reference to that fact. Special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure, taking into account the exposure for both the mother and for the child.

20.4. Procedures to be conducted on pregnant or breastfeeding females shall be done in accordance with procedures approved by the Medical and Dental Councils.

In addition, Art. 10.3 (Medical Exposures Directive) states:

10.3 Without prejudice to Article 10 (1) and (2), any measure contributing to increasing the awareness of women subject to this Article, such as public notices in appropriate places, could be helpful.

Locations should have pregnancy protocols in place. Pregnancy protocols should be developed locally which incorporate both the legislative requirements of SI 478 and the RPII guidelines on the protection of the unborn child during diagnostic medical exposures.

A recent national audit on pregnancy protocols was issued in 2012. The MERU will issue national recommendations on pregnancy protocols based on the outcome of the audit.
Protection of the unborn child during diagnostic medical exposures

The RPII have produced guidelines on the protection of the unborn child during diagnostic medical exposures, May 2010 (appendix IV). The aim of these guidelines is to provide a concise summary of the actions to be taken when dealing with women of childbearing age.

INTRODUCTION
Under S.I. No. 478 (2002) medical exposures to be carried out on pregnant females shall be done in accordance with procedures approved by the Medical and Dental Councils. The Medical Council has approved the use of a minimally modified version of EC Radiation Protection 1002 as a guidance document when dealing with pregnant/possibly pregnant patients.

The aim of these Guidelines is to provide a concise summary of the actions to be taken when dealing with women of childbearing age in a format that is easily accessible to professionals working in the area. The guidelines are written in accordance with current legislation1,3 and RP100 as approved by the Medical Council. This requires that, for relevant examinations, the pregnancy status of female patients be established and certain processes followed thereafter.

Prepared in collaboration with:
- Medical Council of Ireland
- Faculty of Radiology, Royal College of Surgeons in Ireland
- Irish Institute of Radiography and Radiation Therapy
- Irish Nuclear Medicine Association
- Association of Physical Scientists in Medicine

Guidelines on the protection of the unborn child during diagnostic medical exposures

May 2010
SPECIFIC GUIDELINES

- These guidelines apply to women of childbearing age. An age range of 12 to 55 years is a useful practical guide but should be used with caution.

- The guidelines are recommended for any radiography, fluoroscopy or computed tomography examination involving irradiation between the diaphragm and symphysis pubis and for any radionuclide imaging examination.

- For those examinations listed above, the referring clinician must enquire about the pregnancy status of the patient.

- The referring clinician has a responsibility to ensure that the examination is justified and shall provide the practitioner with all relevant information as part of the examination request.

- For high dose examinations, involving greater than 10 mGy to the fetus, the 10 day rule should be applied. In practice this means that abdominal or pelvic CT and some barium studies should be scheduled in the first 10 days of their menstrual cycle. This timing refers to patients with a regular 28 day cycle and should be scaled according to cycle length. For further information on fetal doses, see Table 1.

- For urgent examinations that are justified irrespective of pregnancy status, a clinical waiver section within the request, should be completed by the referring clinician.

- When a female patient of reproductive capacity presents for any of the relevant examinations above, the following process should be applied:

  - The patient should be explicitly asked by the radiologist, the radiographer or the medical specialist (if relevant), whether she is or might be pregnant and her answer should be recorded in writing. The record should be kept according to local protocol. The date of the first day of the last menstrual period (LMP) of the patient should be recorded. This can be useful when retrospective analysis of uterine exposure is required.

  A brief but simple explanation should follow, such as: "I have to ask because radiation in pregnancy may increase the risk of childhood cancer above the natural baseline level" (see Table 1 for the risk levels or refer patient to physicist if patient requires more information).

  - The examination may proceed if the patient states that she is not pregnant.

  - When a patient answers that she:

    - is pregnant, or
    - might be pregnant or
    - cannot exclude the possibility of pregnancy and the menstrual period is overdue the referring clinician should be asked to review the justification for the examination, bearing in mind the possible presence of a fetus.
When there is definite pregnancy, or potential for an unknown pregnancy, the review of justification should consider the following:

- Is there a suitable alternate approach to imaging using non-ionising radiation, e.g. ultrasound or magnetic resonance?

- Is the examination critical to immediate and essential patient management, or could management proceed if the examination is deferred until pregnancy can be completed or definitely excluded?

- Is the likely foetal radiation dose and risk of the examination greater than the benefit of the examination and/or greater than the risk incurred by not doing the examination? Examples of doses accrued from specific examinations are given in Table 1.

- The use of contraception does not rule out pregnancy. Whilst contraceptive use mitigates against the likelihood of pregnancy, the efficacy of the method used is a matter for professional judgment and where there is doubt, these guidelines should be followed.

- Pregnancy tests should not replace proper inquiry. Whilst positive pregnancy tests are useful in directing further justification, negative pregnancy tests undertaken before the period is due should be treated with caution. In particular, a negative urinary pregnancy test, taken at the point of care, should be confirmed with a more sensitive laboratory based test with the required sensitivity in those women where the possibility of pregnancy cannot be ruled out.

- When an examination is justified during pregnancy or when pregnancy cannot be ruled out, all accepted methods of optimising the examination and reducing the dose delivered should be applied.

**ADDITIONAL GUIDANCE**

- Where there is uncertainty about the dose delivered to the uterus as a result of local procedures, equipment or techniques, the advice of the Radiation Protection Adviser (RPA) should be sought.

- A clearly displayed multi-lingual notice briefly explaining the importance of declaring a pregnancy before an X-ray examination is recommended.

- The difficulties associated with requests to X-ray anaesthetised patients should be addressed by a local policy where pregnancy status is established prior to anaesthesia.

- For non-English speaking patients, the hospital interpretation services should be used.

- The difficulties associated with questioning minors about their pregnancy status should be addressed by a local protocol that takes account of associated legal issues.

- Additional information on risk estimates can be found in reference 4.
REFERENCES


2. European Commission, Radiation Protection 100, Guidance for unborn children and infants irradiated due to parental medical exposures 1998, as amended under licence by the Medical Council.


4. Health Protection Agency, 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, Documents of the Health Protection Agency, RCE-9, March 2009.


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Radiological Protection Institute of Ireland
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Local Documentation for Section 4
Patient Pregnancy Protocols

Insert:
Pregnancy protocols for patients
Protocols for the protection of the unborn child during diagnostic medical exposures
Protocols for comforters and carers

NOTE:
If the local documentation is not held in this file please indicate where it is held and ensure that it can be easily accessed upon request and readily available to the relevant personnel.

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