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

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## INTRODUCTION

Under S.I. No. 478 (2002)<sup>1</sup> 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 100<sup>2</sup> 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 legislation<sup>1,3</sup> 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

### 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<sup>4</sup>. 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<sup>4</sup>.
- 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<sup>1,3</sup>. 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<sup>2</sup>?

- Is the examination essential 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 fetal 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<sup>8</sup>.
- 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<sup>2</sup>.

### 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<sup>2,9</sup>.
- 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<sup>10</sup>.
- 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.

Table 1 Typical fetal doses and risks of childhood cancer for some common diagnostic medical exposures<sup>4</sup>. Doses should be assessed locally (where practicable) in case local practice may result in an increase to the fetal dose with respect to the doses shown below.

Examination		Typical fetal dose range (mGy)*	Risk of childhood cancer per examination
X-ray X-ray X-ray X-ray X-ray X-ray CT <sup>51</sup> Cr <sup>81</sup> mKr	Skull Teeth Chest Thoracic spine Breast (mammography) Hand and/or neck GFR measurement Lung ventilation scan	0.001 – 0.01	< 1 in 1,000,000
X-ray CT <sup>99m</sup> Tc	Pulmonary angiogram Lung ventilation scan (Technegas)	0.01 – 0.1	1 in 1,000,000 to 1 in 100,000
X-ray X-ray X-ray X-ray X-ray CT X-ray CT 99mTc 99mTc 99mTc 99mTc	Abdomen Barium meal Pelvis Hip Pelvimetry Chest and liver Lung perfusion san Thyroid scan Lung ventilation scan (DTPA) Renal scan (MAG3, DMSA) White cell scan	0.1 – 1.0	1 in 100,000 to 1 in 10,000
X-ray X-ray X-ray CT X-ray CT 39mTc 99mTc 99mTc 201TI 18F PET	Barium enema Intravenous urography Lumber spine Lumber spine Abdomen Bone scan Cardiac blood pool scan Myocardial scan Cerebral blood flow scan (Exametazine) Renal scan (DTPA) Myocardial scan Tumour scan	1.0 – 10	1 in 10,000 to 1 in 1,000
X-ray CT X-ray CT X-ray CT <sup>99m</sup> Tc <sup>18</sup> F PET/CT	Pelvis Pelvis and abdomen Pelvis, abdomen and chest Myocardial (SPECT rest-exercise protocol) Whole body scan	10 – 50	1 in 1,000 to 1 in 200 Natural childhood cancer risk ~ 1 in 500

\*Fetal doses derived from doses to the uterus seen in recent UK surveys<sup>5,6</sup> and the ARSAC Notes for Guidance<sup>7</sup> so only apply to early stages of pregnancy while the fetus is small.

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#### REFERENCES

- 1. European Communities (Medical Ionising Radiation Protection) Regulations, 2002 (S.I. No. 478 of 2002).
- 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.
- 3. European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations, 2007 (S.I. No. 303 of 2007).
- 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.
- 5. Hart D, Hillier MC and Wall BF, 'Doses to Patients from Radiographic and Fluoroscopic X-ray Imaging Procedures in the UK - 2005 Review', Chilton, HPA-RPD-029, 2006.
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- 8. Stephen A. Butler, Sarah A. Khanlian and Laurence A. Cole, 'Detection of Early Pregnancy Forms of Human Chorionic Gonadotrophin by Home Pregnancy Test Devices', Clinical Chemistry 2001, 47:12, 2131-2136.
- 9. International Commission on Radiological Protection, Publication 84, Pregnancy and Medical Radiation, 2000.
- 10. Health Services Executive, 'On Speaking Terms: Good Practice Guidelines for HSE Staff in the Provision of Interpreting Services', 2009.

#### Contact Us

Radiological Protection Institute of Ireland 3 Clonskeagh Square Dublin 14 Ireland

Tel: 01 2697766 Fax: 01 2697437 Website: www.rpii.ie



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