Radiation Protection of the Fetus during Diagnostic Radiology in an Adult Hospital

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Radiation Protection of Pregnant Women

- **Radio-biological**
  - Scientific basis for risk

- **Legal Framework**
  - European/national

- **Communication**
  - Communication of risk
  - Knowledge base of clinical staff
  - Education of patients
  - Informed consent

- **Personal/Individual**
  - Perception and acceptance of risk
For diagnostic radiology

- Radiation Dose to the embryo or fetus should present no risk of causing fetal death, malformation, growth retardation or impairment of mental development (HPA UK, 2009)

- Majority of diagnostic medical procedures, [giving fetal doses up to 1mGy], additional risk of childhood cancer is less than 1 in 10,000 (HPA UK, 2009)

- Patients and their unborn children are protected by legislation

- Many guidance documents available

- No dose limits
Requirements of 2013/59/EURATOM

Article 62

1. Referrer or practitioner, as appropriate, must inquire, whether the individual subject to medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure.

2. If pregnancy cannot be ruled out and depending on the medical radiological procedure, in particular if abdominal and pelvic regions are involved, special attention shall be given to the justification, particularly the urgency, and to the optimisation, taking into account both the expectant individual and the unborn child.
Guidance Documents

− RP 100 developed to support 97/43/Euratom

− Variations in approach between different documents

− No consensus on how to deal with various issues

− Differences in how and when 10 and 28 day rules applied

− Need for robust, clear, agreed local protocols that are in line with current legislation
Issues

- What exams?
- What age groups?
- When do we ask?
- Who asks?
- How do we capture response?
- How do we deal with patients where status is unknown?
- How do we deal with patients on contraceptives?
- How do we deal with urgent exams?
- Do pregnancy tests have a role in this?
- How do we carry out the exam safely?
National Policy

- BSS does not prescribe exactly how this is done.
- National legislation should provide the framework
- Standardised approach across healthcare institutions can be helpful
- Irish policy developed with input from radiologists, radiographers, physicists, regulators, GPs, lawyers,...
What exams & age groups

Relevant exams :-
- Any radiography, fluoroscopy or computed tomography examination involving irradiation between the diaphragm and symphysis pubis
- Any radionuclide imaging procedures
- 12 to 55 years
Exam Numbers Within Scope of Policy

- 900 Bed Hospital
- >120,000 X-ray and radionuclide imaging exams per year

<table>
<thead>
<tr>
<th>Modality</th>
<th>Total number of Exams</th>
<th>Percentage within Scope of Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>24,986</td>
<td>11%</td>
</tr>
<tr>
<td>Radiography</td>
<td>89,117</td>
<td>&lt;2%</td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>2,509</td>
<td>20%</td>
</tr>
<tr>
<td>Nuclear Medicine</td>
<td>2,023</td>
<td>31%</td>
</tr>
<tr>
<td>PET CT</td>
<td>3,229</td>
<td>10%</td>
</tr>
<tr>
<td>Interventional</td>
<td>2,327</td>
<td>22%</td>
</tr>
</tbody>
</table>

- Female patients 12-55 years
- X-ray exams irradiation between the diaphragm and symphysis pubis
- Any radionuclide imaging procedures
**CT & General Exam Numbers Within Scope of Policy**

<table>
<thead>
<tr>
<th>Age Band</th>
<th>No of CT Exams</th>
<th>No of Radiographic X-ray Exams</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-20</td>
<td>50</td>
<td>66</td>
</tr>
<tr>
<td>21-30</td>
<td>223</td>
<td>192</td>
</tr>
<tr>
<td>31-40</td>
<td>418</td>
<td>314</td>
</tr>
<tr>
<td>41-50</td>
<td>1665</td>
<td>539</td>
</tr>
<tr>
<td>51-55</td>
<td>410</td>
<td>376</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2766</strong></td>
<td><strong>1487</strong></td>
</tr>
</tbody>
</table>

- 3 CT scanners, 5 general rooms
- 25,000 CT scans per annum
- 90,000 general x ray exams
What needs to be done?

For relevant exams referrer and/or practitioner must
– enquire about the pregnancy status of the patient & LMP.
– ensure that the examination is justified
– 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
– 10 day rule should be applied.
– timing scaled according to cycle length.
Issues with Establishing Pregnancy Status

- Long waiting times between referral and some exams
- Patient may not be certain of status
- Communication problems:
  - Language,
  - Deaf patients,
  - Cultural/social barriers
- Anaesthetised patients – need to establish pregnancy status as part of pre-op or admissions
- Unconscious/emergency patient – status may not be known
- Children
- Long term contraceptives
- Sometimes a urine pregnancy test is used to assist in decision making.
  - not reliable in early pregnancy,
  - should **not** be used to bypass the justification process
Use of Pregnancy Test

- **Legal requirement to enquire** if patient is pregnant, if relevant
- Pregnancy test not useful in ruling out pregnancy in very early stage of pregnancy (ie prior to day 28)
- Sensitivity typically >25mIU/ml HCG (point of care tests)
- Lab tests more sensitive but still not useful before 8-10 days post conception
- Range HCG level post conception
  - 3 weeks LMP: 5 – 50 mIU/ml
  - 4 weeks LMP: 5 – 426 mIU/ml
  - 5 weeks LMP: 18 – 7,340 mIU/ml
- Pregnancy tests may be a useful source of additional information under certain circumstances but should **not** replace proper and direct enquiry
10 & 28 day Rules

10 Day Rule
Examinations involving ionising radiation are only carried out in the first 10 days of the menstrual cycle.

28 Day Rule (Missed period)
Women of childbearing age could undergo medical exposures during the first four weeks following LMP. If a period is overdue and the patient can not be certain that she is not pregnant then consideration is given to postponing the examination.
Application of the 10 day Rule

- There are situations where 10 day rule can not be easily applied or is not appropriate eg adolescents, perimenopausal females, previous hysterectomy etc.
- Referrer has option to waive 10 day rule but patient will still be asked about pregnancy status and confirm answer in writing
- Waiver an important feature of request as it allows clinically justified exams during pregnancy or possible pregnancy
- The referrer is waiving ‘the use of the 10 day rule’
- They are not confirming that the patient is not pregnant
- Waiver can be used when
  - Exam urgent irrespective of status
  - 10 day rule impossible to apply
  - Pregnancy not possible (eg hysterectomy)
  - ........
- Each facility should establish the list of procedures for which 10 day rule will be applied
Example of Procedures where 10 day Rule applies

<table>
<thead>
<tr>
<th>Modality</th>
<th>Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoroscopy</td>
<td>Relevant x-ray guided procedures</td>
</tr>
<tr>
<td>CT</td>
<td>CT Pelvis, CT Abdomen Pelvis, CT Thorax Abdomen Pelvis..</td>
</tr>
<tr>
<td>Nuclear Medicine</td>
<td>Myocardial Stress Rest Study, I-131 imaging....</td>
</tr>
<tr>
<td>PET CT</td>
<td>F-18 FDG Whole body..</td>
</tr>
</tbody>
</table>

**Note:** Each facility should establish the list of procedures for which 10 day rule will be applied.
On the day of the exam

What happens when the patient presents for examination for which 10 day rule normally applies?

Establish and record the patients pregnancy status, LMP & explain reasons for enquiry

<table>
<thead>
<tr>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient has indicated she is not pregnant and is within the first 10 days of LMP</td>
<td>Patient has indicated she is not pregnant and is not within the first 10 days of their LMP but the 10 day rule has been waived</td>
<td>Pregnancy cannot be ruled out regardless of stage in menstrual cycle</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The procedure may go ahead</td>
<td>The procedure may go ahead</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Is an alternative imaging modality suitable?

Is Exam Urgent and Justified?

- No

No

Yes

No

Patien is rescheduled

The procedure may go ahead

The procedure may go ahead

The procedure may go ahead
For **relevant** exams, a record will be kept indicating:

- pregnancy status as advised by patient
- date of lmp

**If** the patient is outside the first 10 days of the menstrual cycle **and** the exam is one for which the 10 day rule is normally applied, then the exam is rescheduled or the radiographer documents why the 10 day rule is not being followed e.g.

- Exam urgent and justified
- Previous hysterectomy
- Periods absent/very irregular
- Contraception in use
- ....................

Patient and radiographer sign the form which is scanned into the patient record for that exam.
If patient is or might be pregnant and the exam is to go ahead, then a record is retained to indicate that this has been considered in the justification of the exam:

- The referrer or practitioner signs the form to confirm justification.
- The patient signs to confirm that the risks associated with ionising radiation during pregnancy have been explained and that she consents to proceed.

Form is scanned into the patient record for that exam.
Case Study 1

- 45 yo lady was referred for a CT Urogram
- For these exams, as fetal dose is likely to exceed 10mGy, 10 day rule usually applied
- Letter sent with appointment date, advising that it should be rescheduled if outside 10 days
- If the appointment date is not within 10 days LMP, patient rings to schedule an alternative date
  - Scheduling – 1/3 chance of appointment being within 10 day window
  - Long waiting lists mean that patients can be anxious about rescheduling
Case Study 1 (contd)

- On presentation it was discovered that LMP > 10 days but patient confirmed not pregnant; signed to that effect
- Patient believed she was in early menopause
- Scan completed without incident
- Some months later during a follow up ultrasound, pregnancy was noted
- Fetus approx. 18 weeks
- Patient would have been 4-5 weeks pregnant at time of CT
- Fetal dose estimated to be 38mGy
- This fell within category of notifiable incidents
- Reported to regulator who followed up with a visit

Key question: Was the process sufficiently robust?
Follow up and Recommendations

- Regulator asked that existing policy be revised to
  - improve communication processes with patients
    in advance of the exposure
  - document reasons for excluding pregnancy
  - include an agreed definition of menopause

- Other actions:
  - communicate to referrers about their
    responsibilities in the referral process
  - communicate changes in documentation and
    shared learning to relevant personnel through
    staff meetings and general education sessions.
Case Study 2

- 33 yo female patient referred for CT Abdomen/Pelvis.
- Letter sent asking to contact department for appointment
- Appointment scheduled within the first 10 days of LMP
- On attendance patient confirmed not pregnant, advised date of LMP as 5 days previously, signed form
- CT Abdomen/Pelvis completed, radiology report issued.
- Some days later patient discovered she was pregnant and contacted department
- Patient had mistaken bleed in early pregnancy for period
- Dose to fetus estimated to have been 11mGy
- Incident reported to regulator, investigation report requested

Key question: Was the process sufficiently robust?
Follow up and Recommendations

- 10 day rule had been applied appropriately
- Patient confirmed that staff had asked about pregnancy status and had explained risks but she had been confident that she couldn’t have been pregnant
- Communication and consent was documented
- Regulator satisfied that protocols had been robust and no further actions required
- Information and reassurance provided to patient
Notifiable Incidents

Exposure where none intended, including inadvertent Dose to fetus > 1 mGy.
What do we tell patients after inadvertent exposure?

Open disclosure
- Patients should be told when things go wrong
- Most patients want to be told the truth
- Management of radiation incidents should be within the existing risk management framework of the hospital
- Communication with patient should follow existing hospital policy/guidelines
- MPE can provide referrer/practitioner with appropriate information on dose
Scanning Pregnant Patients

- Document Justification
- Select lowest dose technology available
- Consider use of collimation and scan length taking account of fetal position
- For nuclear medicine scans, consider reduction in activity and increased scan time
- Assessment of fetal dose can assist in optimisation
- IAEA recommend that for high dose exams, tailor exam and finish once diagnostic information is acquired
- Scanning needs and optimisation steps should be considered on a case by case basis.
Risk Communication

Justification and Optimisation are fundamental principles of radiation protection

Significant effort expended in minimising risk

Precautions inherent in radiation protection can contribute to heightened perception of hazard

yet

When an incident occurs, often the message is one of reassurance that the actual risk is very low

Challenge of managing individual and collective risk

Quantifying and communicating risk needs a range of approaches and how we present the risk strongly influences interpretation
Summary

- European and national legislation provide framework for medical exposures and includes protection of the fetus.
- In diagnostic radiology, deterministic effects should not occur and effort directed towards minimising risk of stochastic effects.
- Individual perception of risk is influenced by factors other than magnitude of hazard and must be considered.
- Communication of risk should reflect uncertainty, be appropriate to the level of risk and should take account of the individual.
- Increased awareness and education of healthcare professionals and patients important.
- Appropriate and timely communication is central to managing this issue and requires input from scientific, technical, clinical and communication experts.