A radiologist’s perspective on protection of the fetus in a paediatric hospital
Paediatric Perspective

Very distinct population

How do we sensibly interpret Medical Exposure regulations?

Apply logic and data to optimise practice
EU Medical Exposure Regulations

EU Directive 59/13

‘Basic safety standards for protection against dangers arising from medical exposure to ionising radiation’

Statutory Instrument 256/2018

Special protection during pregnancy and breastfeeding

16. (1) An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall -

inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned
Aspects for consideration

Legal responsibility
Clinical responsibility / Impact on the foetus if exposure occurs / Liability
Workflows

1. Patient factors
2. Is the question worth asking?
Main Concern as a Paediatric Radiologist

Patient vulnerability

Children who are pregnant are likely to reply in negative

• Because they do not realise that they are
• Because they do not have capacity to understand that they could be
• Because they are embarrassed
• Because they are hoping to protect the boy or man involved

This renders questioning unlikely to return intended result of a patient owning up to possibly being pregnant
Our Patients are Vulnerable

This is not accounted for in the legislation
Main Concern as a Medical Consultant

Are we asking to screen or to diagnose?

Different criteria for each type of question
Screening Tests - Wilson’s 10 Criteria (WHO)

1. The condition should be an important health problem ☐ (adverse outcome uncertain)
2. There should be a treatment for the condition ☑ (can opt not to image)
3. Facilities for diagnosis and treatment should be available ☐ (poorly set up)
4. There should be a latent stage of the disease ☐ (N/A)
5. There should be a test or examination for the condition ☒ (untruthful or unknowing)
6. The test should be acceptable to the population ☒ (parental anger, YAC refusal)
7. The natural history of the disease should be adequately understood ☑
8. There should be an agreed policy on whom to treat ☐ (N/A)
9. The total cost of finding a case should be economically balanced in relation to medical expenditure as a whole ☒ (primum non nocere not fulfilled for younger patients)
10. Case-finding should be a continuous process, not just a "once and for all" project ☑
Diagnostic Tests

A test needs to increase the probability of a condition being present in order to be worth doing

The lower the pre-test probability, the stronger the test needs to be to result in a worthwhile change in probability
The question is a bad test

Doesn’t meet screening criteria

Doesn’t meet diagnostic criteria
The question is a bad test

This is not accounted for in the legislation
Who do we have to ask?

With menarche occurring as early as 8 years of age, at what age should Radiology departments start asking children about the possibility of them being pregnant?
Who do we *have* to ask?

Existing guidance fails to offer unified practical approach for female paediatric population 1, 2, 3

- age range of 12-55 years, without provision of supporting evidence

- reference is made to females of reproductive capacity with no mention of age limits

“Particular problems may be experienced in obtaining this information from females under the age of 16 years.”
Who do we *have* to ask?

Can we say that being under 15 means that pregnancy...

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inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it *can be ruled out for obvious reasons* or is not relevant for the radiological procedure concerned
The Proposal

That, in places with low pregnancy rates in the relevant age group, it is both prudent and appropriate to exclude many young patients from the process of establishment of pregnancy status for radiological procedures that utilise ionising radiation, other than by assessment of age
### Example in Practice - Ireland

<table>
<thead>
<tr>
<th>Year</th>
<th>15yo Live Births</th>
<th>16-19yo Live Births</th>
<th>15yo No. of Terminations</th>
<th>16-19yo No. of Terminations</th>
<th>15yo No. of Pregnancies</th>
<th>16-19yo No. of Pregnancies</th>
<th>Population 15yo</th>
<th>Population 16-19yo</th>
<th>Live Birth Rate 15yo</th>
<th>Live Birth Rate 16-19yo</th>
<th>Pregnancy Rate 15yo</th>
<th>Pregnancy Rate 16-19yo</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>42</td>
<td>1,145</td>
<td>18</td>
<td>245</td>
<td>60</td>
<td>1,390</td>
<td>184,098</td>
<td>107,676</td>
<td>0.2/1000</td>
<td>10.6/1000</td>
<td>0.3/1000</td>
<td>12.9/1000</td>
</tr>
</tbody>
</table>
## Example in Practice - Ireland

<table>
<thead>
<tr>
<th></th>
<th>≤ 15yo</th>
<th>16-19 yo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2019</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Live Births(^{(av\ 2016-2018)})</td>
<td>22</td>
<td>1,019</td>
</tr>
<tr>
<td>No. of Termination(^{(NHS\ 2018\ data)})</td>
<td>16 (under 16)</td>
<td>195</td>
</tr>
<tr>
<td>No. of Pregnancies</td>
<td>38</td>
<td>1,214</td>
</tr>
<tr>
<td>Population</td>
<td>186,258</td>
<td>117,748</td>
</tr>
<tr>
<td>Live Birth Rate</td>
<td>0.12/1000</td>
<td>8.7/1000</td>
</tr>
<tr>
<td>Pregnancy Rate</td>
<td>0.2/1000</td>
<td>10.3/1000</td>
</tr>
</tbody>
</table>
## Context

<table>
<thead>
<tr>
<th>Method of Contraception</th>
<th>Failure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depo-Provera Injection</td>
<td>2 in 1000</td>
</tr>
<tr>
<td>Combined Oral Contraceptive Pill</td>
<td></td>
</tr>
<tr>
<td>Progesterone Only Pill</td>
<td></td>
</tr>
<tr>
<td>Evra Patch</td>
<td>3 in 1000</td>
</tr>
<tr>
<td>Nuvaring</td>
<td></td>
</tr>
<tr>
<td>Tubal Ligation</td>
<td>2-5 in 1000 at 10 years</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>1 in 1000</td>
</tr>
</tbody>
</table>
Girls aged 14 years and younger will be excluded from obligatory pregnancy status questioning for the purposes of radiological examination, just as is the case for adult women on methods of contraception that have rates of failure significantly higher than the rate of pregnancy in this age group.

Statutory notices detailing the small risk of radiation to the unborn will still be displayed in our departments, as is required by law.

Pregnancy rates in Ireland in this age range should be reviewed every 3 years to determine if the policy is appropriate to continue.
References

1. Radiological Protection Institute of Ireland (2010)
   Guidelines on the protection of the unborn child during diagnostic medical exposures (note that this agency was recently subsumed into the Environmental Protection Agency)

   Guidance for protection of unborn children and infants irradiated due to parental medical exposures, Radiation Protection 100

3. Advice from the Health Protection Agency, the RCR, and the College of Radiographers (2009)
   Protection of pregnant patients during diagnostic medical exposures to ionising radiation
Thank you