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'

Ireland - Statutory Instrument 256/2018 (replaced SI 478/2002)



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)

9. The total cost of finding a case should be economically balanced in relation to medical expenditure as a whole 🗵

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)

10.Case-finding should be a continuous process, not just a "once and for all" project ✓

non nocere not fulfilled for younger patients)



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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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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

2015	≤ 15yo	16-19 yo
Live Births	42	1,145
No. of Terminations	18	245
No. of Pregnancies	60	1,390
Population	184,098	107,676
Live Birth Rate	0.2/1000	10.6/1000
Pregnancy Rate	0.3/1000	12.9/1000



Example in Practice - Ireland

2019	≤ 15yo	16-19 yo
Live Births (av 2016-2018)	22	1,019
No. of Terminations (NHS 2018 data)1	16 (under 16)	195
No. of Pregnancies	38	1,214
Population	186,258	117,748
Live Birth Rate	0.12/1000	8.7/1000
Pregnancy Rate	0.2/1000	10.3/1000



Context

Method of Contraception	Failure Rate
Depo-Provera Injection	2 in 1000
Combined Oral Contraceptive Pill	
Progesterone Only Pill	
Evra Patch	3 in 1000
Nuvaring	
Tubal Ligation	2-5 in 1000 at 10 years
Vasectomy	1 in 1000



Summary of Dublin Proposal

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)

2. European Commission (1998)

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



