



Review of existing issues and practices with respect to irradiation of patients and staff during pregnancy

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Introduction

The Medical Exposure Directive 97/43 requires special attention for the protection of offspring of pregnant and breastfeeding patients exposed to ionising radiation for medical purposes. This is because the unborn child is particularly vulnerable to ionising radiation.

As well as other risks, there is the risk of malformation and mental retardation for the unborn child and there is a risk of radiation induced cancer which may be three times as high as for the average population (ICRP 60).

Introduction



The potential benefit of the examination or treatment involving ionising radiation will in most cases be for the mother and only indirectly for the child, whereas it will incur a risk.

This is contradictory to the normal situation where one person namely the patient, incurs the risk but also derives the benefit from the examination or treatment.

Introduction



Pregnancy is also an important issue for staff working with ionising radiation. The moment the pregnancy is declared the employer is obliged to ensure the protection of the foetus.

The working conditions of a pregnant worker, after the declaration of pregnancy, should be such as to make it unlikely that the equivalent dose to the conceptus will exceed 1mSv during the remainder of her pregnancy.

Existing issues



■ What is the 10day rule?

NRPB issued ASR8(Exposure to ionising radiation of pregnant women: advice on the diagnostic exposure of women who are or may be, pregnant) in 1985. This advice suggested that there would be no risks to the conceptus following irradiation during the first 10 days of the menstrual cycle and that subsequent risks in the remainder of the first 4-week period would be likely to be so small that no special limitation on exposure was required – sometimes as the “28-day rule”.

Existing issues



ICRP 84 (2000)

Introduction:

“Thousands of pregnant patients and radiation workers are exposed to ionising radiation each year. Lack of knowledge is responsible for great anxiety and probably unnecessary termination of many pregnancies. For many patients, the exposure is appropriate, while for others the exposure may be inappropriate, placing the unborn child at an unjustified increased risk.”

Existing issues



- Important to inform the public of the risks of ionising radiation during pregnancy. Information leaflets.
- Lack of information on the risks of pregnancy and ionising radiation for the public as well as the healthcare personnel.
- Problem of language.
- The 10 day rule should be applied if a diagnostic examination or treatment is planned which involves a high dose to the uterus or else a pregnancy test should be carried out.

Existing issues



- Is it useful to carry out a pregnancy test on the patient?
- If a pregnant woman needs a radiological procedure it should be adapted so as to give as low a dose as possible.
- The procedure should be carried out by an experienced radiologist, cardiologist.
- A medical physicist should be involved.
- The pregnant patient has the right to know the magnitude and type of potential radiation effects.
- Limited information on research and pregnancy in the EU directive 97/43.

Existing issues



- Is it appropriate to apply the same dose limit to the foetus as a member of the public, given that the foetus is generally considered to have a higher radiosensitivity.
- Training of the personnel is very important.
- Radiophobia.
- Radiation protection issues should be properly explained to pregnant staff so that she can make an informed choice about what she should undertake.
- Female personnel should have the right to decide if they want to continue to work in a radiology Dpt. and not be automatically placed in another Dpt.

Review of existing practices in various European countries concerning the 10day rule

- 13 countries were reviewed.
- The U.K., Ireland, Cyprus, Bulgaria and Hungary apply the 10day rule.
- In Italy and Austria it is the prescribing physician and the radiologist who ask whether the patient is or might be pregnant.
- In Greece and in Luxembourg it is the radiographers who ask whether the patient is or might be pregnant.
- In Spain the 10day rule is not applied.

Review of existing practices in various European countries concerning the 10day rule

- In Poland and Luxembourg a pregnancy test is carried out on women of childbearing age for IR procedures.
- In Poland the 10day rule is applied only for IR procedures.
- In Holland and in Luxembourg a sign is usually present in the radiology Dpts (in the changing cubicles) on the risk of pregnancy and radiation.
- In Slovenia the 10day rule used to exist in the previous radiation protection legislation but it wasn't applied. In the new legislation there is no such rule.

Conclusions



- The 10day rule is not applied in all the countries reviewed.
- The manner in which this issue is treated differs from country to country.
- The person who determines whether a woman of childbearing age is or might be pregnant differs from country to country.
- In only two countries a pregnancy test is carried out regularly on women of childbearing age who have to undergo IR procedures.

Review of existing practices in various European countries concerning patients who are pregnant and need a radiological examination

- Thirteen countries were reviewed.
- In all the countries reviewed special attention to justification and optimisation issues is given when a pregnant patient needs a radiological examination.
- In Bulgaria, Italy, Austria and Poland X-ray examinations on pregnant women are not allowed unless it is an emergency and the life of the patient is in danger.
- In Hungary it is the prescriber who takes the decision.
- In Italy, Greece and Cyprus a medical physicist is involved.
- Italy seems to be the only country where this matter is regulated by law.

Conclusions



- Special attention is given to optimisation and justification of the examination.
- Who decides whether the examination should be done i.e. radiologist or prescriber differs from country to country.
- A medical physicist is involved only in a small number of countries.

Review of existing practices in various European countries concerning staff and carers who are or may be pregnant and who are working in a radiology Dpt.

- In Bulgaria, Slovenia, Hungary and Italy the worker is obliged to declare her pregnancy.
- In Luxembourg the worker is automatically placed in another Dpt.
- In Hungary the worker must announce her pregnancy. After this she isn't allowed to work with ionising radiation anymore. She can continue working in the X-ray Dpt. but only to carry out administrative work.
- In Bulgaria, Slovenia, Italy, Poland, Greece, Spain, Cyprus, Holland and Ireland the worker can continue to work as long as the dose to the child to be born doesn't exceed 1mSv.

Review of existing practices in various European countries concerning staff and carers who are or may be pregnant and who are working in a radiology Dpt.

- In Cyprus, Spain, Italy and Slovenia the worker can choose not to work with radiation.
- In most countries pregnant carers are not allowed to work in X-ray Dpts.

Conclusions



- The existing practices in various European countries concerning staff and carers who are or may be pregnant and who are working in a radiology Dpt. vary enormously.
- There is no harmonisation on this issue at a European level.

Review of existing practices in various European countries in Nuclear Medicine concerning staff, patients and carers who are or may be pregnant

- In all countries a nuclear medicine examination is carried out on a pregnant patient only if it is absolutely necessary and then it is optimised to give a dose as low as achievable.
- Breastfeeding patients are informed of the need to stop breastfeeding.
- In most countries the pregnant staff can continue working as long as there is no risk of contamination.
- In Luxembourg, Greece, Cyprus and Slovenia the pregnant staff is removed and placed in another Dpt.

Conclusions



- Special attention is given to optimisation and justification of the examination.
- A medical physicist is involved only in a small number of countries.
- The existing practices in various European countries concerning staff who are or may be pregnant and who are working in a Nuclear Medicine Dpt. vary enormously.
- There is no harmonisation on this issue at a European level.

Two questions to finish off with:

- Why is there no harmonisation at a European level?
- Why are the practices in the different EU countries so different?