

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



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Summary of Advice

- 1 The radiation dose to the embryo or fetus that is likely to result from any diagnostic procedure in current use should present no risk of causing fetal death, malformation, growth retardation or impairment of mental development.
- 2 For the majority of diagnostic medical procedures, giving fetal doses up to about a milligray, the associated risks of childhood cancer are very low (below 1 in 10,000) and judged to be acceptable when compared with the natural risk (around 1 in 500). Consequently, all such examinations can be carried out on pregnant women, as long as they have been clinically justified and the dose is kept to a minimum consistent with the diagnostic requirements. The very low risks of childhood cancer from these examinations are certainly not sufficient to justify termination of the pregnancy (particularly in view of the associated risks to the health of the mother).
- 3 Exposure of pregnant women to higher dose procedures leads to fetal doses in excess of a few milligray, and – at the highest doses – may result in a doubling of the childhood cancer risk compared to the natural rate. Consequently, such examinations should be avoided on pregnant women, if this can be achieved without serious detrimental effects to their health. However, if such examinations are considered to be clinically justified or are carried out inadvertently, the childhood cancer risk associated with them is still low in absolute terms (below 1 in 200 and mostly below 1 in 1000) and termination of the pregnancy would not be justified solely on the basis of the radiation risk to the unborn child.
- 4 For most diagnostic radiation exposures of women in the first three to four weeks post-conception when the pregnancy is unrecognised, the risks of childhood cancer will be very small (and probably much smaller than if the exposure had occurred later in pregnancy). However, those few examinations yielding fetal doses in excess of about 10 mGy could involve levels of risk that should be avoided, if possible, even in unrecognised pregnancies.
- 5 Radiation doses resulting from diagnostic procedures in pregnancy present a negligible risk of causing radiation-induced hereditary disease in the descendants of the unborn child.
- 6 Guidance is provided in the document on the practical implementation of the above advice in the everyday practice of diagnostic radiology and nuclear medicine.

1 Introduction

This document provides information on the health effects that are likely to occur in the embryo or fetus following exposure to ionising radiation during pregnancy and practical guidance on how and when to prevent or reduce unnecessary fetal exposures when pregnant women are referred for diagnostic medical procedures involving X-rays or radionuclides.

It is a revision of the guidance produced in 1998 by the National Radiological Protection Board (NRPB) (now part of the Health Protection Agency), The Royal College of Radiologists (RCR) and the College of Radiographers (CoR) (NRPB et al, 1998).

The previous advice was based on an assessment of health effects following *in utero* irradiation published in *Documents of the NRPB*, 4(4), 1993, which included a statement by the NRPB on diagnostic medical exposures to ionising radiation during pregnancy (NRPB, 1993). In particular, because of new concerns (at the time) that *in utero* irradiation during the first three weeks of gestation could possibly lead to the induction of postnatal cancer, this statement included the recommendation that diagnostic medical procedures involving high fetal doses (some tens of milligray) should be avoided, if possible, during early (unrecognised) pregnancies. It was suggested that one way of doing this was to restrict the use of such higher dose examinations on all potentially pregnant women to the first ten days of their menstrual cycle when conception is very unlikely to have occurred (the so-called ten-day rule).

In this 2009 revision, the scientific basis of the advice is reviewed in the light of the latest epidemiological and radiobiological evidence. Data on typical fetal doses and the associated childhood cancer risks from common diagnostic medical procedures have been updated, and practical guidance is provided on how to implement the advice in the everyday practice of diagnostic radiology and nuclear medicine.

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) have been in force in the UK since 2000 (GB Parliament, 2000). They have specific requirements for the justification and optimisation of medical exposures on females of childbearing age where pregnancy cannot be excluded. The duties of employers, referrers, practitioners and operators in this regard are clearly defined in the regulations. Following the practical guidance given in this document will assist the various duty holders to comply with the relevant IR(ME)R requirements.

2 Scientific Basis for Advice

Exposure of the embryo or fetus to ionising radiation can potentially lead to two types of adverse health effect:

- a deterministic effects (tissue reactions) resulting from damage to a number of cells, for which there is a dose threshold before any clinical effect occurs,
- b stochastic effects which originate from damage to single cells, for which there is no dose threshold but an increased probability of induction as the dose increases.

2.1 Deterministic effects of ionising radiation

The principal deterministic effects (tissue reactions) of ionising radiation in the developing embryo or fetus are death, malformation, growth retardation and abnormal brain development leading to severe mental retardation. The International Commission on Radiological Protection has reviewed the risks of harmful tissue reactions and malformation after prenatal irradiation (ICRP, 2003) and in its 2007 recommendations concluded that no deterministic effects of practical significance would be expected to occur in humans below a dose of at least 100 mGy (ICRP, 2007). Normal diagnostic medical exposures using X-rays or radionuclides should never result in fetal doses in excess of 100 mGy (see the table, page 8).

Advice

The radiation dose to the embryo or fetus that is likely to result from any diagnostic procedure in current use should present no risk of causing fetal death, malformation, growth retardation or impairment of mental development.

2.2 Stochastic effects of ionising radiation

The stochastic effects resulting from irradiation of the embryo or fetus are the possible induction of cancer after birth and of hereditary disease in their descendants. The probability of these effects occurring is considered to be directly proportional to the radiation dose received by the embryo or fetus and is now believed to be fairly independent of the stage of pregnancy after the first three to four weeks of gestation (ICRP, 2003). It is useful to consider the risks of such effects relative to their natural incidence.

2.2.1 Cancer induction following fetal exposures after the first three to four weeks of pregnancy

There is stronger scientific evidence for cancer risks from radiation exposure after the first three to four weeks of pregnancy than for exposures earlier in pregnancy, so these will be considered first. In the previous advice, information from a very large case-control study of obstetric X-ray examinations in the UK (the Oxford Survey of Childhood Cancers, OSCC) and subsequent reviews of the data by many experts were used to determine the risk of childhood cancer following fetal exposure after a gestational age of three to four weeks (NRPB, 1993; NRPB et al, 1998). A primary result of these studies was that a fetal dose of roughly 25 mGy was estimated to double the natural rate of childhood cancer. When this doubling dose was applied to the natural baseline risk of childhood cancer incidence of 1 in 650 (1.5×10^{-3}) prevalent in the 1980s, an excess absolute risk coefficient of 1 in 17,000 per mGy ($6 \times 10^{-5} \text{ mGy}^{-1}$) was obtained (NRPB, 1993; NRPB et al, 1998).

No new radiobiological or epidemiological evidence has arisen, nor have there been any new assessments of the dosimetry for the OSCC, to suggest that a revision of the estimated doubling dose is required. However, data collected by the National Registry of Childhood Tumours from 1991–2000 indicate that the natural baseline risk of childhood cancer in the UK has now risen to about 1 in 500 (2×10^{-3}), rather than 1 in 650 (Stiller, 2007), resulting in an increased excess absolute childhood cancer risk coefficient of about 1 in 13,000 per mGy ($8 \times 10^{-5} \text{ mGy}^{-1}$).

In contrast, survival rates for childhood cancer have improved since the 1980s, resulting in substantial reductions in the *fatal* childhood cancer risks that were based, in the previous advice, on baseline incidence data and an assumed survival rate of about 50%. In view of the probable continuing improvements in survival rates and the natural concern of parents for the risk of their children developing cancer irrespective of how successfully it can be treated, childhood cancer risks will be expressed and compared in terms of incidence rather than fatality here.

The fetal doses associated with modern diagnostic medical procedures range from a few microgray to a few tens of milligray, so the associated risks of childhood cancer will range from less than 1 in 1,000,000 to about 1 in 200 (5×10^{-3}). The table (which is intended to be illustrative rather than exhaustive) shows a number of common diagnostic X-ray or radionuclide examinations in five broad groups according to the typical fetal doses and associated childhood cancer risks involved. The actual fetal dose can vary quite considerably from hospital to hospital and patient to patient for any given type of examination, depending on the imaging equipment available, the examination techniques used and the size of the patient. Also, the relationship between the fetal dose and the risk of radiation-induced cancer is not precisely known and could vary by a factor of at least two or three from the figure quoted above of 1 in 13,000 per mGy ($8 \times 10^{-5} \text{ mGy}^{-1}$) (Wakeford and Little, 2003). Therefore it is better to show broad groupings as used in the table, with each group (apart from the last one) spanning a factor of ten in dose and risk. Moreover, the risk coefficient has been rounded up to 1 in 10,000 per mGy (10^{-4} mGy^{-1}), so that the risks shown in the last column of the table are unlikely to be underestimated. It is not expected that fetal doses will exceed 50 mGy for any normal diagnostic medical procedure that has been optimised in accordance with the requirements of the Ionising Radiation (Medical Exposure) Regulations (GB Parliament, 2000).

TABLE Typical fetal doses and risks of childhood cancer for some common diagnostic medical exposures

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

* Fetal doses derived from doses to the uterus seen in recent UK surveys (Hart et al, 2007; Shrimpton et al, 2005) and the ARSAC Notes for Guidance (ARSAC, 2006), so only apply to early stages of pregnancy when the fetus is small.

Those examinations lying in the highest fetal dose group in the table (10–50 mGy) could result in an approximate doubling of the natural baseline risk of childhood cancer. Such risks should be regarded as sufficiently high to justify rigorous efforts to avoid these examinations (ie those that deliver doses to the fetus of some tens of milligray during pregnancy), unless the health of the mother (and indirectly that of the unborn child) would be compromised by delaying the examination until after the baby has been born.

There is still a lack of human epidemiological evidence on *lifetime* cancer risks following fetal irradiation, but since the natural risk of developing cancer reaches about one in three over a lifetime, a comparison of radiation-induced and natural lifetime risks is deemed inappropriate for judging the acceptability, or otherwise, of fetal exposures. Nevertheless, it may be noted that, even if the lifetime risk of cancer from fetal irradiation is as much as four times greater than the risk arising in childhood, judgements based on comparing the childhood cancer risks will be conservative. Although a fetal dose of about 25 mGy would double the natural risk of childhood cancer, the absolute increase in the lifetime cancer risk is likely to be less than 1%. Furthermore, recent findings for those exposed *in utero* as a consequence of the atomic bombings of Hiroshima and Nagasaki (Preston et al, 2008) support the ICRP view that the lifetime cancer risk from *in utero* irradiation is unlikely to be greater than that following exposure in early childhood (ICRP, 2003).

Advice

For the majority of diagnostic medical procedures, giving fetal doses up to about a milligray (the first three groups in the table), the associated risks of childhood cancer are very low (less than 1 in 10,000) and judged to be acceptable when compared with the natural risk (of around 1 in 500). Consequently, all such examinations can be carried out on pregnant women, as long as they have been clinically justified and the dose is kept to a minimum consistent with the diagnostic requirements. The very low risks of childhood cancer from these examinations are certainly not sufficient to justify termination of the pregnancy (particularly in view of the associated risks to the health of the mother).

Exposure of pregnant women to the higher dose procedures (the last two groups in the table) lead to fetal doses in excess of a few milligray, and – at the highest doses – may result in a doubling of the childhood cancer risk compared to the natural rate. Consequently, such examinations should be avoided on pregnant women, if this can be achieved without serious detrimental effects to their health. However, if such examinations are considered to be clinically justified or are carried out inadvertently, the childhood cancer risk associated with them is still low in absolute terms (below 1 in 200 and mostly below 1 in 1000) and termination of the pregnancy would not be justified solely on the basis of the radiation risk to the unborn child.

2.2.2 Cancer induction following embryonic exposures during the first three to four weeks of pregnancy

So far the risks of fetal irradiation after the first three to four weeks of gestation have been considered, when a woman will usually have become aware of her pregnancy through having missed a menstrual period. The previous advice (NRPB et al, 1998) paid particular attention to one of the main objectives of the statement by the NRPB on diagnostic medical exposures to ionising radiation during pregnancy (NRPB, 1993), which was to minimise the likelihood of inadvertent exposure of the embryo before pregnancy is declared. This arose because of new evidence (available in 1993) for the possible induction of somatic mutations in embryonic stem cells that could potentially lead to postnatal cancer, rather than invariably lead to cell death with no biological consequences (apart from early termination of embryonic development), as was previously assumed. However, it was recognised that the total number of target embryonic stem cells for the induction of a cancer-associated mutational event in the first three to four weeks of gestation will be much smaller than in the later stages of pregnancy, so the cancer risk is likely to be much lower than in the subsequent stages of pregnancy, *but it could no longer be assumed to be zero.*

The current view of the Health Protection Agency is that there is no new radiobiological or epidemiological evidence that contradicts, or provides a better quantitative estimate of, the cancer risks associated with irradiation in very early pregnancy than that used in the previous advice. Although the ICRP did not recommend the need to avoid diagnostic medical exposures of undeclared pregnancies prior to 2003, in Publication 90 it stated that there was evidence for childhood cancer risks following radiation exposure during the early post-conception period, ‘albeit they were difficult to quantify because the numbers were small and the uterine doses had large uncertainties’ (ICRP, 2003). Given this uncertainty, the ICRP recommended that careful consideration needed to be given to radiological protection measures for the embryo particularly ‘in the early weeks after conception when medical radiation exposures may occur in the context of unrecognised pregnancies’ (ICRP, 2003). Consequently the precautionary approach advocated previously for protecting the embryo from the very small but uncertain risks of radiation exposure in early pregnancy will be maintained here.

Advice

For most diagnostic radiation exposures of women in the first three to four weeks post-conception when the pregnancy is unrecognised, the risks of childhood cancer will be very small (and probably much smaller than if the exposure had occurred later in pregnancy). However, those few examinations yielding fetal doses in excess of about 10 mGy (the highest dose group in the table) could involve levels of risk that should be avoided, if possible, even in unrecognised pregnancies.

Suggested methods for avoiding such risks to the embryo are given in the practical implementation section of this document.

2.2.3 Heritable effects

The risks of heritable effects from ionising radiation exposure have been substantially revised in the past few years and the present estimate of the ICRP (2007) is about five times lower than that used in the previous advice (NRPB et al, 1998). The excess absolute risk of heritable effects from *in utero* irradiation at all stages of pregnancy is still judged to be the same as that applying to the reproductive population after birth, but this is now reduced to about 1 in 200,000 per mGy ($0.5 \times 10^{-5} \text{ mGy}^{-1}$) compared to 1 in 42,000 per mGy ($2.4 \times 10^{-5} \text{ mGy}^{-1}$) used in 1998. The risk of inducing heritable effects in the first two generations of descendants following *in utero* irradiation is thus over ten times lower than the risk of inducing childhood cancers (1 in 13,000 per mGy) and covers a diversity of disorders, many of which would be judged to be far less severe than cancer.

The natural frequency of congenital defects in the UK population has been estimated to be in the range 1–3%, rising perhaps to 5–6% with the inclusion of minor malformations (NRPB, 1993). The increased absolute risk of hereditary disease arising in the first two generations for the offspring of a fetus exposed to even one of the highest dose diagnostic procedures shown in the table (say a fetal dose of 25 mGy) is about 1 in 8000 (0.012%). This is very small when compared with the natural risk of congenital defects (of 1–6%).

Advice

Radiation doses resulting from diagnostic procedures in pregnancy present a negligible risk of causing radiation-induced hereditary disease in the descendants of the unborn child.

3 Practical Implementation

3.1 Diagnostic examination of females of reproductive potential

In view of the possibility of radiation-induced cancer in the offspring of mothers undergoing diagnostic medical exposures while pregnant, alternative imaging modalities which do not use ionising radiation, such as ultrasound or magnetic resonance imaging (MRI), should be considered before a decision is taken to use ionising radiation on female patients of reproductive potential. The few studies on pregnancy outcome in humans following MRI have not revealed any adverse effects, but are very limited. Consequently, the International Commission on Non-Ionizing Radiation Protection recommends that MRI may be used for pregnant patients only after critical risk–benefit analysis has been undertaken (particularly in the first trimester) to provide important diagnostic information that cannot be obtained with ultrasound or that would otherwise require exposure to ionising radiation (ICNIRP, 2004).

When there are no suitable alternatives and an imaging modality that uses ionising radiation (eg an X-ray or nuclear medicine examination) is considered to be necessary and is likely to irradiate the uterus, the likelihood of the patient being pregnant must be determined.

In the first instance the referring clinician should check on the pregnancy status of the patient and indicate the result on the request card. However, a further check must also be made (by an appropriately entitled IR(ME)R operator) when the patient attends for examination because her pregnancy status may have changed since the clinician completed the request card.

When a female of reproductive potential presents for an X-ray examination *in which the primary beam may irradiate the pelvis* (ie those involving the area between the diaphragm and knees), or for any nuclear medicine procedure involving radionuclides, she should be asked whether she is or might be pregnant. If the patient cannot exclude the possibility of pregnancy, she should be asked whether her menstrual period is overdue. This action, and the patient's response, should be recorded in accordance with local procedures and protocols.

Particular problems may be experienced in obtaining this information from females under the age of 16 years. There should be agreed procedures in place in all clinical imaging facilities to cover this and also to deal with unconscious patients, patients whose first language is not English and those with special needs. It may be helpful to consult the guidance given by the College of Radiographers in 'The Child and the Law: The Roles and Responsibilities of the Radiographer' (CoR, 2005).

Depending on their answers to these questions, patients can then be assigned to one of the following groups:

- 1 no possibility of pregnancy,
- 2 patient definitely or probably pregnant,
- 3 pregnancy cannot be excluded: low dose procedure,
- 4 pregnancy cannot be excluded: high dose procedure.

The following steps should be taken for each of these patient groups to prevent unnecessary exposure of a fetus where the risks may be of concern.

1 No possibility of pregnancy

Proceed with the examination even if it has the potential for a high fetal dose.

2 Patient definitely or probably pregnant

If pregnancy is established or likely, review the justification for the proposed examination with the relevant practitioner (usually a radiologist, who may wish to consult the referring clinician), and decide whether to defer the investigation until after delivery (or until pregnancy has been ruled out), bearing in mind that:

- a a procedure of clinical benefit to the mother may also be of indirect benefit to her unborn child,
- b delaying an essential procedure until later in pregnancy may present a greater risk of harm to the fetus.

If, after review, a procedure is still considered to be justified and *is* undertaken, the fetal dose should be kept to the minimum consistent with the diagnostic purpose.

3 Pregnancy cannot be excluded: low dose procedure

A 'low dose procedure' is defined as any procedure in which the fetal dose is likely to be below 10 mGy (see the table, page 8). The vast majority of routine diagnostic examinations fall into the category of a low dose procedure. If pregnancy cannot be excluded, but the patient's menstrual period is not overdue, proceed with the examination. If the patient's menstrual period is overdue, the patient should be treated as probably pregnant and the advice in the previous paragraph should be followed.

4 Pregnancy cannot be excluded: high dose procedure

A 'high dose procedure' is defined as any examination falling in the highest dose group of the table, resulting in fetal doses of more than about 10 mGy (eg those involving CT scans of the lower abdomen and pelvis). However, it is important that each clinical imaging facility identifies any other examinations which, in their hands, fall into the high dose category. The evidence suggests that such procedures may double the natural risk of childhood cancer if carried out after the first three to four weeks of pregnancy and may still involve a small risk of cancer induction if carried out in the very early stages of an unrecognised pregnancy.

Either of two courses can be adopted to minimise the likelihood of inadvertent exposure of an unrecognised pregnancy and to prevent unnecessary exposure of potentially pregnant women to such high dose procedures:

- a apply the rule that females of childbearing potential are always booked for these examinations during the first ten days of their menstrual cycle, when conception is unlikely to have occurred,
- or*
- b female patients of childbearing potential are booked in the normal way but are not examined and are re-booked if, when they attend, they are in the second half of their menstrual cycle, *and* are of childbearing potential *and* in whom pregnancy cannot be excluded. *Experience suggests that the number of such patients is likely to be small.*

It should be emphasised that although there *may* be a small risk to the embryo if it is irradiated during the very early stages of an unrecognised pregnancy, this risk will be higher if the fetus is exposed in the months following the first missed menstrual period. Consequently, high dose examinations should only be re-booked if they can safely be postponed until after delivery, should the patient prove to be pregnant. This decision will usually require the input of a radiologist, and possibly also the referring clinician.

If, despite following this guidance, it becomes obvious that a fetus has been inadvertently exposed to doses in excess of 10 mGy, the small risk to the fetus of the exposure (less than a 1 in 200 increase in the risk of childhood cancer) will not justify the much greater risk (to the mother and fetus) of termination of the pregnancy.

3.2 Inadvertent fetal exposures

Inadvertent fetal exposures can arise in two circumstances:

- a a pregnant patient is asked whether she is or might be pregnant and denies it, either deliberately or in ignorance of her true condition, and the examination proceeds,
- b a pregnant patient is not asked whether she is or might be pregnant and the examination proceeds regardless.

Following any inadvertent fetal exposure (high or low dose), an investigation should be carried out by the Medical Physics Expert in accordance with the employer's IR(ME)R procedures. Counselling of the patient by the relevant radiologist/clinician, particularly for inadvertent exposures leading to high fetal doses, is likely to draw upon the results of this investigation. Any inadvertent exposure resulting in a significant fetal dose (above 0.1 mGy) may also be notifiable as an incident of 'much greater than intended exposure' to the relevant IR(ME)R Inspectorate, particularly if it were due to the second circumstance above. Detailed guidance on these matters was still awaited from the relevant IR(ME)R Inspectorates (the Healthcare Commission in England, the Scottish Ministers in Scotland and the National Assembly in Wales) at the time of publication of this document.

If the initial investigation following an inadvertent fetal exposure reveals that exposures ‘much greater than intended’ were delivered to the fetus as the result of an equipment fault, the incident will also be notifiable to the Health and Safety Executive under the requirements of the Ionising Radiation Regulations 1999 (GB Parliament, 1999) following the guidance in HSE Publication PM77 (HSE, 2006).

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