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Pregnancy and Medical Radiation



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Pregnancy and Medical Radiation

Editor
J. VALENTIN

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Editorial

BACK TO BASICS

Sometimes it is useful to sit back and recall a bit of history. To the layman, protection against ionising radiation (if at all known to be something else than non-ionising radiation) is usually taken to be concerned with the nuclear fuel cycle. Yet the biggest man-made source of exposures is not at all nuclear power but medical uses of radiation. Radiation in medicine is a wonderful tool that has permitted amazing improvements in diagnostic capability, great curing capacity, and invaluable palliative treatments. That same tool can also be lethal unless treated with the utmost respect — and that is where ICRP, the International Commission on Radiological Protection, started.

The huge medical benefits of radiation were recognised almost immediately after the discovery of ionising radiation at the end of the 19th century. The dangers of radiation soon became increasingly apparent, and in 1928, what is now ICRP was established by the 2nd International Congress of Radiology under the name of the International X-Ray and Radium Protection Committee. Thus, it was the medical community that first saw the need for a specific international organisation devoted to protection and, to this day, the Commission retains a special relationship with the International Society of Radiology (the professional organisation catering for physicians specialising in the use of radiation).

Back in 1928, the primary concern was that occupational exposure of medical staff could, and did, lead to serious deterministic harm and even death. With improved standards, this hazard seemed to be virtually eliminated several decades ago. Increasing awareness about possible late stochastic effects necessitated a refocusing onto the risk of cancer and onto patients rather than staff.

At much the same time, increasing use of radiation in other contexts than medicine, and increasing attention to natural sources of radiation, were the main reasons why the Commission was re-organised and given its present name in 1950. Although one of the standing committees of ICRP is specifically devoted to radiation in medicine, the majority of the reports in the *Annals of the ICRP* deal with matters other than medical exposures.

Unfortunately, it has turned out that neither occupational hazards for medical staff nor deterministic harm from exposure to radiation are problems entirely of the past. Medical science is taking great strides all the time, and more and more subjects are competing for time on the syllabus of all medical students.

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Regrettably, this has often led to absurdly short or entirely missing education in radiological protection. As a consequence, really serious skin damage and worse is again being experienced, primarily in patients but also in staff. The situation may be aggravated if inexperienced staff encounter modern fluoroscopic equipment with easily operated, potent boost options that, if used indiscriminately, produces images of a clarity which may appear seductively ‘good’ but is not always clinically required.

There are also a number of other problem areas, among them accidents in radiotherapy, high patient doses in computed tomography, doses to family and public from radiopharmaceuticals used for therapy, and the topic of the present report, pregnant patients and staff exposed to medical radiation.

The Commission is planning to address all of these problems in forthcoming reports. In so doing, it will highlight specific situations, often drawing on existing information and reports, but organising the material in a different, more context-oriented way than the Commission’s existing reports on medical radiation which are laid out according to a logical hierarchy.

Furthermore, the Commission is keen to reach such ‘shop-floor’ medical staff who are involved in the day-to-day management of radiation. As a means towards this end, the style of this report, and the planned reports just described, is somewhat different than that of recent reports in the *Annals of the ICRP* (which has unfortunately come to be perceived by many physicians as aiming at health physicists, administrators, and regulators, but not at themselves). Wide-spread distribution will also be given major consideration.

This is not to say that the Commission plans to abandon its traditional type of report. Comprehensive scientific treatises will continue to be a mainstay in the Commission’s series of publications. However, the impact will be augmented by also supplying topical reports aimed at special user groups, in this case medical staff. In so doing, the Commission is targeting its classical, original audience, and using a style reminiscent of that in its earliest publications. In short, with this report and forthcoming companion reports on medical radiation problems, ICRP is going back to basics.

JACK VALENTIN

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Preface

Over the years, the International Commission on Radiological Protection (ICRP), referred to below as ‘the Commission’, has issued many reports providing advice on radiological protection and safety in medicine, most recently its *Publication 73* which is a general overview of this area. These reports summarise the general principles of radiation protection and provide advice on the application of those principles to the various uses of ionising radiation in medicine and biomedical research.

Most of these reports are of a general nature, and the Commission wishes to address some specific situations where difficulties have been observed. It is desirable that reports on such problem areas be written in a style which is accessible to those who may be directly concerned in their daily work, and that every effort is taken to ensure wide circulation of such reports.

A first step in this direction was taken at the Commission’s meeting in Oxford, United Kingdom, in September 1997. At that time, on the recommendation of ICRP Committee 3, the Commission established a Task Group to produce this report on pregnancy and medical radiation. The purpose was to cover the basic issues of pregnancy and ionising radiation in medicine in a concise report, including and coherent with the Commission’s current recommendations, that could be easily understood by the medical community and easily translated. The report should cover the most commonly asked questions, discuss the management of pregnant patients as well as pregnant workers, and provide a practical approach that can be used in varying situations.

The membership of the Task Group was as follows:

F.A. Mettler, Jr. (Chairman)	R.L. Brent	C. Streffer
L. Wagner		

Corresponding members were:

M. Berry	S.-Q. He	T. Kusama
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The membership of Committee 3 during the period of preparation of this report was:

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L.K. Harding (Secretary)	J. Liniecki (Vice-Chairman)	S. Mattsson
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W.Y. Ussov		

This report aims to serve the purposes described above. Since the report is intended for a very wide audience, its style differs in some respects from the usual style of the Commission's publications in the *Annals of the ICRP*. For instance, literature references are not given along the lines common in scientific reports; instead, a bibliography including the source material as well as useful further reading is supplied at the end.

The report was approved for publication by the Commission through postal ballot in November 1999.

Pregnancy and medical radiation

ICRP Publication 84

Approved by the Commission in November 1999

Abstract—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 pregnancies. For many patients, the exposure is appropriate, while for others the exposure may be inappropriate, placing the unborn child at increased risk.

Prenatal doses from most properly done diagnostic procedures present no measurably increased risk of prenatal death, malformation, or impairment of mental development over the background incidence of these entities. Higher doses, such as those involved in therapeutic procedures, can result in significant fetal harm.

The pregnant patient or worker has a right to know the magnitude and type of potential radiation effects that might result from in utero exposure. Almost always, if a diagnostic radiology examination is medically indicated, the risk to the mother of not doing the procedure is greater than is the risk of potential harm to the fetus. Most nuclear medicine procedures do not cause large fetal doses. However, some radiopharmaceuticals that are used in nuclear medicine can pose significant fetal risks.

It is important to ascertain whether a female patient is pregnant prior to radiotherapy. In pregnant patients, cancers that are remote from the pelvis usually can be treated with radiotherapy. This however requires careful planning. Cancers in the pelvis cannot be adequately treated during pregnancy without severe or lethal consequences for the fetus.

The basis for the control of the occupational exposure of women who are not pregnant is the same as that for men. However, if a woman is, or may be, pregnant, additional controls have to be considered to protect the unborn child. In many countries, radiation exposure of pregnant females in biomedical research is not specifically prohibited. However, their involvement in such research is very rare and should be discouraged.

Termination of pregnancy is an individual decision affected by many factors. Fetal doses below 100 mGy should not be considered a reason for terminating a pregnancy. At fetal doses above this level, informed decisions should be made based upon individual circumstances.

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Keywords: Pregnancy; Radiation; Protection; Fetal dose; Termination

1. INTRODUCTION

(1) 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.

(2) One of the most commonly asked questions in relation to the use of ionising radiation in medicine concerns the management of the pregnant patient or worker. Instinctively, one might want to avoid use of radiation with a pregnant patient; however, there are a number of situations in which the use of radiation for diagnosis or therapy is appropriate. In addition to patient irradiation, there are many female physicians and technicians who are employed in medical settings involving radiation and they often wish to begin a family while remaining employed.

(3) This document is written primarily for physicians, but it will also be useful for medical and health physicists, radiation protection staff, nurses, technicians, and administrators. The document is not intended as a complete scientific reference work, nor as a collection of inflexible recommendations, but rather to provide a practical approach that can be used in varying situations. A bibliography is provided at the end of the document, should the reader wish to obtain additional information. This document will not consider exposures to diagnostic ultrasound or magnetic resonance imaging.

(4) Management of the pregnant female in a radiation setting takes several forms. If the patient or worker declares her pregnancy or is obviously pregnant, appropriate measures may be instituted. The situation is much more difficult when the female is not sure whether she is pregnant or is unaware of her pregnancy. The degree of concern, and whether informed consent for a procedure should be obtained, are dependent upon the degree of potential risk to the fetus and the mother. The potential risk to the embryo/fetus can vary widely depending on whether diagnosis or therapy is being contemplated. These issues will be covered in more detail in each section of the report.

(5) The International Commission on Radiological Protection has published a wide variety of recommendations in the past. These include general recommendations on radiological protection as well as advice on the application of radiological protection in medicine. In these and other Commission publications there has been information on pregnancy and radiation. This document will provide much of that information in condensed form and offer examples of its application.

1.1. Fundamental concepts

(6) In their daily practice, physicians and the medical community already use many of the concepts that form the basis for radiological protection.

(7) Each use of radiation in medicine should be justified (provide more benefit than harm). For example, radiotherapy is used because it has been shown that it can

reduce morbidity and mortality from cancer. After a type of examination or therapy has been justified generally, each specific instance should be justified. As an example, a standard radiotherapy protocol may be justified in a 50-year-old female but the same protocol may not be justified in a pregnant 25-year-old without more consideration and perhaps modification.

(8) Justification in medical practice is different from justification in most other practices that involve radiation. In almost all medical applications of radiation, the benefit and potential risks are to the same person. In many other radiation practices (such as the use of nuclear power) the potential benefit and potential harm may accrue to different population groups.

(9) Compared to routine medical radiation practices, medical exposure of a pregnant patient has additional ethical considerations. In evaluation of risks and benefits from medical exposures during pregnancy, at least two individuals need to be considered. The mother may receive direct benefit while the fetus may be exposed without direct benefit. On the other hand, if the mother's medical problem is life threatening, medical irradiation of the mother may lead to her survival, which obviously directly benefits the fetus.

(10) When it has been decided that a medical procedure is justified, the procedure should be optimised. This means that the conditions should achieve the clinical purpose with the appropriate dose. Too low a radiation dose will result in poor medical results, both in diagnosis and in therapy. In diagnosis the image will be too poor for diagnosis, while in radiotherapy the tumour will not be cured. Too high a dose in diagnosis increases the risk of a neoplasm, and too high a dose in radiotherapy can also result in serious and potentially fatal complications.

(11) Reducing radiation dose after a procedure has been performed is only rarely possible. One can envision a few situations in nuclear medicine in which the radiation dose can be reduced after the examination. For example, a patient may be asked to drink fluids and void after a bone scan in order to reduce bladder dose. For diagnostic radiology and most radiotherapy no intervention can be done to reduce dose after the procedure. The simple concepts of justification and optimisation will form the basis for the philosophy applied throughout much of this document.

(12) For purposes of this report, the radiation dose of interest is the absorbed dose to the conceptus (embryo or fetus) and not to the mother. Absorbed radiation doses to the conceptus are properly expressed in gray (Gy) or milligray (mGy). The gray is equal to 100 rad. One Gy equals 1,000 mGy. The unit of equivalent dose, and effective dose, is the sievert (Sv). The sievert is equal to 100 rem. Dose limits are given in Sv. In most medical decision-making applications, using X rays, gamma rays, or electrons, the numerical value of the absorbed dose in Gy is essentially equal to the numerical value of the equivalent dose in Sv. Given the homogeneity of most fetal doses in medical applications and for ease of understanding, in this document doses will only be given in Gy or mGy.

(13) For occupational and public exposure, there are recommended annual dose limits. These limits are intended to provide protection for the radiation worker and the public for sources such as nuclear power production. Dose limits do not apply for radiation exposure of patients, since the decision to use radiation is justified

depending upon the individual patient situation. As an example, a certain radiation dose may not be justified for medical screening, but it may well be justified for a very ill patient.

(14) This document begins with short sections on the diagnosis of pregnancy, informed consent, and radiation effects on the embryo/fetus. Additional sections are concerned with the management of pregnant patients who are undergoing diagnostic radiology, nuclear medicine, or radiotherapy. Sections on occupational exposure of pregnant workers and on research involving pregnant females follow. At the end of the document, there is a section on consideration of termination of pregnancy after radiation exposure, and finally a concluding section with recommendations.

2. DIAGNOSIS OF PREGNANCY

(15) Amenorrhea occurring in a regularly menstruating woman should be considered due to pregnancy, until proven otherwise.

(16) The diagnosis of pregnancy can be challenging, especially in the early weeks of amenorrhea. For the most part, pregnancy is diagnosed on clinical grounds without resorting to laboratory or imaging tests. Signs of pregnancy are divided into presumptive, probable, and positive. The presumptive signs include pigmentation and discoloration of skin and mucous membranes. Probable signs are related to detectable physical changes in the size, shape, and consistency of the uterus. Positive signs include detection of physical heartbeat and recognition of fetal movements. Unfortunately, most of the above information related to the signs of pregnancy is not immediately or easily available when a patient presents for an examination in a radiology or nuclear medicine department.

(17) Menstrual history may or may not be reliable in determination of pregnancy. For example, a young girl who comes to the hospital with her parents may deny a pregnancy that she suspects. Urine and serum tests to detect early pregnancy have become widely available in developed countries and are quite sensitive and reliable, and are usually positive 10 days post conception or 24 days after the first day of the last menstrual period (if the menstrual period is regular). Such tests are not generally used for low dose diagnostic examinations, but they are useful in specific instances where high radiation doses are expected to be delivered to the pelvis.

(18) In order to avoid radiation exposure in the first 2 weeks post conception, some authors have suggested limiting non-essential examinations to the first 10 days of the menstrual cycle. In most situations, this has not proven to be necessary, based upon the radiobiological and dosimetric considerations that are covered in the next section of this report.

(19) Obstetricians usually express the stage of pregnancy as menstrual age/gestational age. The latter term is usually given in reports of ultrasound examinations done for fetal dating. The two terms used in this document will either be gestational age, based upon the first day of the last menstrual period, or post conception age. Effects of radiation exposure on the embryo and fetus are expressed as a function of gestational age. Development of the unborn child is expressed as post-conception age and can be approximately divided into three major phases. These include 1) the pre-implantation phase from conception to implantation, 2) the phase of major organogenesis which extends from the 3rd to approximately the 8th week post-conception, and 3) the phase of fetal development lasting from 9 weeks until birth (which includes the important period of central nervous system development from the 8th to 25th weeks).

3. EFFECTS OF IN UTERO IRRADIATION

3.1. General background

(20) Prenatal doses from most properly done diagnostic procedures present no measurable increased risk of prenatal death, malformation, or impairment of mental development over the background incidence of these entities. Higher doses, such as those involved in therapeutic procedures, can result in significant fetal harm.

(21) There are radiation-related risks throughout pregnancy, which are related to the stage of pregnancy and the fetal absorbed dose. Radiation risks are most significant during organogenesis and the early fetal period, somewhat less in the second trimester, and least in the third trimester.

(22) Both cell killing effects and induction of neoplasms may occur as a result of in utero irradiation. Clinical radiation effects are due either to (1) cell killing or (2) unrepaired/misrepaired DNA damage. Effects due to cell killing have a practical threshold below which the effect is not seen. The higher the dose above that threshold, the more severe is the effect. Leukaemia, cancer, and potential hereditary effects are due to unrepaired or misrepaired DNA damage. The probability of such an effect occurring increases with dose and there is no identifiable threshold dose below which the chance is known to be zero. Protracted radiation exposures may occur during pregnancy. In general, for a given period of gestation, protracted exposures probably have less overall effect than a brief radiation exposure of high intensity.

(23) Above a practical threshold, damage from ionising radiation during pregnancy that results in cell killing can cause a wide range of effects, including lethality, central nervous system abnormalities, cataracts, growth retardation, malformations, and even behavioural disorders. Since the fetal neural system is most sensitive and has the longest period of development, radiation-induced abnormalities are rarely seen in humans without neuropathology. This syndrome is recognisable but can also be produced by other noxious agents.

(24) The effects of exposure to radiation on the conceptus depend on the time of exposure relative to conception and the amount of absorbed dose. When the number of cells in the conceptus is small and their nature is not yet specialised, the effect of damage to these cells is most likely to take the form of failure to implant or of an undetectable death of the conceptus; malformations are unlikely or very rare. Exposure of the embryo in the first two weeks following conception is not likely to result in malformation or fetal death, despite the fact that the central nervous system and the heart are beginning to develop in the third week. During the rest of the period of major organogenesis, conventionally taken to be from the third week after conception, malformations may be caused especially in the organs under development at time of exposure.

(25) These effects have a threshold of 100-200 mGy or higher. This dose is higher than what is reached in most diagnostic radiology or diagnostic nuclear medicine procedures. As an example, a fetal dose of 100 mGy would not likely be reached with 3 pelvic computed radiography (CT) scans, nor with 20 conventional diagnostic

x-rays of the abdomen or pelvis. At 100–200 mGy, the risk of malformations is low, but the risk does increase with increasing dose.

3.2. Effects on the central nervous system

(26) During the period of 8–25 weeks post conception, the central nervous system (CNS) is particularly sensitive to radiation. Fetal doses in excess of about 100 mGy may result in a verifiable decrease of IQ. During the same time, fetal doses in the range of 1,000 mGy (1 Gy) result in a high probability of severe mental retardation. The sensitivity is highest 8–15 weeks post conception. The CNS is less sensitive to these effects at 16–25 weeks of gestational age and rather resistant after that.

(27) Radiation effects on the developing central nervous system are probably the result of cell killing and of changes in cellular differentiation and neuronal migration. Values of intelligence quotient (IQ) lower than expected have been reported in some children exposed in utero at Hiroshima and Nagasaki. There have been two principal quantitative findings. The first one is a reduction of IQ with increasing dose. This effect is very dependent on fetal age. Regardless of the time of gestation, IQ reduction cannot be clinically identified at fetal doses of less than 100 mGy. In the period from 8 weeks to 15 weeks after conception a fetal dose of 1,000 mGy (1 Gy) reduces IQ by about 30 points. A similar, but smaller, shift is detectable following exposure in the period from 16–25 weeks.

(28) The second finding is of a dose-related increase in the frequency of children classified as ‘severely retarded’. This is not unexpected. If the fetal radiation dose is high and there is a large reduction in IQ, there will be more children born who are severely mentally retarded. At fetal doses of 1,000 mGy during 8–15 weeks gestational age, the probability of this effect is about 40%. The effects of all levels of dose are less marked following exposure in the period from 16 weeks to 25 weeks after conception, and these effects have not at all been observed for other periods.

(29) All the clinical observations on significant IQ reduction and severe mental retardation relate to fetal doses of about 500 mGy and above and at high dose rates. Direct use of the observations for risk estimation in relation to chronic exposure of workers probably overestimates the risks.

(30) It is important to relate the magnitude of radiation effects to those abnormalities that occur spontaneously in the population, in the absence of other radiation exposure than natural background. The normal incidence of mental retardation in the population depends on the definition of mental retardation that is used. At the present time, most organisations define an IQ below 70 as mental retardation. Current prevalence figures indicate that the ‘normal’ incidence of persons with an IQ below 70 is approximately 3 percent. In other words, in the absence of exposure to non-background radiation, 3 out of 100 pregnancies will result in delivery of a child with mental retardation. Severe mental retardation (in which affected individuals are unable to care for themselves) occurs spontaneously in about 1 in 200 births (0.5%).

(31) There are many modifying factors. At the present time, over 250 causes of mental retardation have been identified, including malnutrition, lead poisoning,