Diagnostic Ionizing Radiation and Pregnancy: Is There a Concern?

Both pregnant patients and physicians may overestimate the risk of an ionizing diagnostic radiation examination on the conceptus. Fetal health effects of ionizing radiation vary according to the radiation dose absorbed and gestational phase at the time of exposure. The effects of ionizing radiation are cumulative. Performing multiple diagnostic radiation procedures on a pregnant woman may place the conceptus at risk for negative health effects. PA-PSRS has received more than 90 reports of pregnant patients being exposed to diagnostic ionizing radiation since the program’s inception in June 2004. Many involved performing a radiologic procedure on a patient who was unaware of the pregnancy. Risk reduction strategies include delaying nonurgent radiographs; using a diagnostic examination not involving ionizing radiation; ensuring radiographic equipment is in proper working order; and encouraging open communication among the healthcare team and patient to ensure that the most appropriate study is used to obtain the maximum amount of information while reducing exposure to the fetus. (Pa Patient Saf Advis 2008 Mar;5[1]:3-15.)

While medical uses of radiation have improved diagnostic, treatment, curative, and palliative capabilities, radiation may also be damaging or lethal\(^1\) to an embryo or fetus in certain circumstances. PA-PSRS has received more than 90 reports of pregnant patients being exposed to diagnostic ionizing radiation (see “Ionizing Radiation Exposures Reported to PA-PSRS”). The PA-PSRS reports show that many women are not aware they are pregnant during diagnostic radiology procedures.\(^2\) About 50% of pregnancies in North America are unplanned.\(^3\) Therefore, the possibility of unanticipated radiation exposure to an embryo/fetus may occur when women of childbearing age undergo diagnostic radiation procedures. This article will present the effects of x-ray radiation, estimated fetal radiation doses of common diagnostic procedures, background incidence of fetal complications, risk reduction strategies, and resources. The article will not encompass nuclear medicine procedures, radiation therapy, or occupational exposure to x-rays. Moreover, in this article, the term “conceptus” is used to refer to any stage of conception: pre-embryo, embryo, or fetus.

What is Ionizing Radiation? Radiation is energy that is emitted from sources\(^4\) including heat and light from the sun, microwaves from an oven, or x-rays from an x-ray tube. The characteristics of the radiation depend on its energy. Ionization refers to the process in which the radiation has sufficient energy to remove an electron from an atom (e.g., gamma rays, x-rays) to form a pair of charged particles (i.e., ions). Lower energy radiation (e.g., radio waves, visible light) has insufficient energy to cause ionization. The resulting ions can be very destructive to biological material since they can break chemical bonds. Two types of cell damage occurs; the cell can die or be damaged. In the event of cell death, the damage to the overall organism will only be significant if a sufficient number of cells are killed. Cell death will occur with a sufficient dose. Cell damage is more complicated. The cell may simply become nonviable and eventually die. Alternatively, the damage to the genetic code may be repaired. In the event that the repair is flawed and the cell remains viable, then mutations may result, eventually manifesting as cancer many years later.\(^5,6\) Carcinogenesis may or may not occur.

Measurement Radiation is measured using different terms according to the aspect of radiation that is being measured. This includes exposure, absorbed dose, and effective dose (see Table 1). When measuring radiation exposure, one can directly measure the amount of ionization, which is the number of ions produced in a volume of air. When SI units (metric) are used, exposure is measured in coulomb per kilogram (C/kg). In the United States, exposure is traditionally measured in roentgen (R).

The biological effects from ionizing radiation depend upon the total energy of radiation absorbed (in joules) per unit of mass (in kilograms) in the sensitive organs or tissues.\(^7,8\) This amount is called the absorbed dose. Absorbed dose is expressed in gray (Gy). One gray equals the absorption of 1 joule of radiation energy by 1 kg of matter. The gray was adopted internationally in 1976.\(^9\) Calculation of absorbed doses of radiation provides a foundation upon which the probability of radiation-induced effects can be evaluated. In the United States the absorbed dose is often referred to as radiation absorbed dose (rad). One rad equals 10 mGy.\(^8,9\) The absorbed dose is important when considering the short term, or deterministic, effects of radiation.

To assess the biological risk of ionizing radiation after partial exposure of the body, other factors must be considered, such as the type of radiation, the varying sensitivity of different tissues, and absorbed doses of different organs.\(^5,9\) This risk is expressed as the effective dose. The metric unit is the sievert (Sv). Traditionally in the United States, the roentgen equivalent man (rem) is used instead of the sievert. One Sv equals 100 rem.\(^8,9\) The effective dose is used to assess the long-term, or stochastic, risks associated with radiation exposure.
Ionizing Radiation Exposures Reported to PA-PSRS

PA-PSRS has received more than 90 reports of pregnant patients being exposed to diagnostic ionizing radiation. Here are a few edited examples:

A patient was asked if she could be pregnant and the date of her last menstrual period. The patient responded that she receives contraception injections and does not get periods. The patient signed a release indicating she was not pregnant. An x-ray of the abdomen was performed, which revealed a fetus.

A patient presented to the [emergency department (ED)] with a chief complaint of back pain. She was asked if she was pregnant, and she stated no. X-ray films were read, revealing a fetus of over 31 weeks. The patient was notified of the pregnancy, at which time she stated her last menstrual period was seven months ago.

A patient was scheduled for a [computed tomography (CT) scan] of the abdomen and pelvis to rule out a mass. The patient was interviewed and signed a form indicating she was not pregnant. The patient stated she had a negative pregnancy test 10 days ago. The CT study was performed with contrast. The scan was aborted as soon as an image of fetus appeared.

A patient received a CT scan of the abdomen and pelvis in 60 slices. Prior to the procedure, she stated she did not believe she could be pregnant. The CT scan showed a viable fetus of 12 weeks gestation.

Over a seven-week period of time, a 19-year-old patient received the following studies: abdomen x-ray, CT scan of the abdomen and pelvis with and without contrast, retrograde x-ray, chest x-ray, and cystogram. For each visit, the patient was asked if she was or could be pregnant, and she denied pregnancy each time. At the end of the seven weeks, an ultrasound showed a viable intrauterine pregnancy of seven weeks and one day.

The patient had a CT scan of the abdomen and pelvis, and the radiologist’s interpretation revealed a fetus.

A patient presented to the ED with fever and abdominal pain. The patient had a history of [inflammatory bowel disease] and tubal ligation three years ago. The patient also reported her last menstrual period was within the past month. The patient had a CT scan of the abdomen, which revealed an intrauterine pregnancy. Upon notification, the patient stated she had been at another hospital the previous week and had an x-ray of the abdomen. The patient was seen by an obstetrician, and an ultrasound was performed, indicating an intrauterine pregnancy of 15 weeks gestation.

A patient was sent to the imaging department for a CT scan due to abdomen/pelvis bloating. She responded “no” when asked if there was a chance she could be pregnant, and she signed the consent form. The CT scan revealed an intrauterine pregnancy.

An ED patient underwent an x-ray of the abdomen. The patient had not voided prior to the x-ray, but the patient stated, when asked by the ED staff and the x-ray technician, that she had a period two weeks earlier and that she felt she was not pregnant. After the x-ray, the patient voided, and the dipstick was positive for pregnancy. A follow-up ultrasound indicated twins.

An ED patient denied the possibility of pregnancy and stated she had a miscarriage one month prior to admission. An abdominal CT scan was done, after which a urine specimen was obtained that was positive for pregnancy. A transvaginal ultrasound confirmed an intrauterine pregnancy. The patient is planning to terminate the pregnancy.

This article will refer to mGy and rad as units of measure (10 mGy = 1 rad).

Perceptions

When a pregnant patient is exposed to radiation during diagnostic radiology procedures, lack of knowledge may result in great anxiety after exposure and misinterpretation of the risk. A woman may believe she should abort her fetus after any exposure to ionizing radiation. One study revealed that up to 25% of exposed women believed their infants were at risk for major malformations after exposure to diagnostic imaging. Twenty-three percent of pregnancies in Greece were terminated because of unfounded concerns about fetal teratogenicity after the nuclear reactor accident in Chernobyl.

In Canada, the Motherisk Program conducted a survey of pregnant women who were told that the baseline risk of major malformations in the general population was about 3%. They were asked their perceptions of risk for fetal malformations when a pregnant woman underwent a diagnostic imaging procedure. The

<table>
<thead>
<tr>
<th>QUANTITY</th>
<th>METRIC (SI)</th>
<th>CONVENTIONAL</th>
<th>CONVERSION</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure</td>
<td>Coulomb per kilogram (C/kg)</td>
<td>Roentgen (R)</td>
<td>1 R = 2.58 × 10⁻² C/kg</td>
<td>Directly measured</td>
</tr>
<tr>
<td>Absorbed dose</td>
<td>Gray (Gy)</td>
<td>Radiation absorbed dose (rad)</td>
<td>10 mGy = 1 rad</td>
<td>Stochastic effects</td>
</tr>
<tr>
<td>Effective dose</td>
<td>Sievert (Sv)</td>
<td>Roentgen equivalent man (rem)</td>
<td>1 Sv = 100 rem</td>
<td>Stochastic effects</td>
</tr>
</tbody>
</table>
pregnant women who had actually been exposed to a diagnostic imaging procedure estimated the teratogenic risk as 25.5%. The nonexposed pregnant control group perceived the risk as 15.7%. This fear of radiation and misinterpretation of the effect on the fetus may persist even when evidence-based data of the safety of low-dose radiation exposure is provided.

Physicians may also overestimate this risk. One study indicated that physicians caring for pregnant women have unrealistically high perceptions of the teratogenic risk associated with abdominal radiographs/computed tomography (CT) scans administered during early pregnancy. This misperception might result in delay of necessary diagnostic procedures or inappropriate medical advice resulting in unnecessary termination of pregnancy.

A survey of family physicians and obstetricians in Israel revealed that 40% of responding family physicians and 70% of obstetricians recommended therapeutic abortion for women exposed to radiation from a diagnostic imaging procedure in early pregnancy. In another survey in Ontario, Canada, of randomly selected family practitioners and obstetricians, the respondents were informed of the baseline risk of major fetal malformations (1% to 3%) without medical diagnostic imaging. They were asked about their perceptions of fetal risk associated with the following two imaging procedures at six weeks gestation: (1) radiograph (kidneys, ureters, bladder) and (2) abdominal CT scan.

More than 30% of the responding facility practitioners and 20% of the responding obstetricians would have overestimated the risk of major malformations as a result of this radiation exposure. The physicians’ misperceptions might have produced increased anxiety among women seeking counseling, unnecessary pregnancy terminations, and/or delays in necessary diagnostic procedures for pregnant women.

### Risks in the General Population

In order to understand the risks to the conceptus associated with exposure to diagnostic x-rays, one needs to understand the risks to the conceptus without exposure to diagnostic radiation. It is also important to know the conceptus usually receives less than 1 mGy (0.1 rad) of natural background radiation during a nine-month gestation. This background radiation is from four major sources: cosmic radiation, solar radiation, external terrestrial sources (e.g., rocks, soil), and radon gas. Table 2 specifies the incidence of the risks to the fetus associated with pregnancy without acute radiation exposure. The general population’s total risk of spontaneous abortion, major malformations, mental retardation, and childhood malignancy is approximately 28.6% (286 per 1,000 deliveries).

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**Table 2. Background Incidence of Conceptus Complications without Diagnostic Imaging Radiation**

<table>
<thead>
<tr>
<th>RISKS</th>
<th>INCIDENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous incidence of major malformations</td>
<td>Approximately 1% to 3%</td>
</tr>
<tr>
<td>Intrauterine growth restriction</td>
<td>4%</td>
</tr>
<tr>
<td>Spontaneous abortion</td>
<td>At least 15%</td>
</tr>
<tr>
<td>Genital disease</td>
<td>8% to 10%</td>
</tr>
<tr>
<td>Mental retardation (intelligence quotient less than 70)</td>
<td>Approximately 3%</td>
</tr>
<tr>
<td>Severe mental retardation (unable to care for self)</td>
<td>0.5%</td>
</tr>
<tr>
<td>Heritable effects</td>
<td>1% to 6%</td>
</tr>
<tr>
<td>Spontaneous risk of childhood leukemia and cancer (ages 0 to 15)</td>
<td>0.16%</td>
</tr>
<tr>
<td>Children developing cancer up to age 15 (United Kingdom)</td>
<td>0.15%</td>
</tr>
<tr>
<td>Children developing leukemia only to age 15 (United Kingdom)</td>
<td>0.03%</td>
</tr>
<tr>
<td>Lifetime risk of contracting cancer</td>
<td>33%</td>
</tr>
<tr>
<td>Lifetime risk of contracting fatal cancer</td>
<td>20%</td>
</tr>
</tbody>
</table>


For sources associated with specific values, contact the Pennsylvania Patient Safety Advisory staff.
Approximate Fetal Radiation Doses of Common Diagnostic Procedures

The majority of diagnostic procedures provide a fetal dose much less than 50 mGy (5 rad).\(^\text{15}\) (Table 3 presents the approximate fetal doses of common diagnostic procedure using ionizing radiation.) These estimated fetal doses, however, could vary by a factor of 10 to 100 for the same study, based on the techniques and equipment used.\(^\text{1,7,15,16}\) Variables include

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>mSv</th>
<th>MEAN DOSE mGy (rad)*</th>
<th>MAXIMUM DOSE mGy (rad)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>X-ray</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdomen</td>
<td>1</td>
<td>1.4 (0.14)</td>
<td>4 (0.4)</td>
</tr>
<tr>
<td>Kidney, ureter, and bladder</td>
<td>1.7</td>
<td>2.9 (0.29)</td>
<td>15 (1.5)</td>
</tr>
<tr>
<td>Chest</td>
<td>0.02</td>
<td>less than 0.01 (0.001)</td>
<td>less than 0.01 (0.001)</td>
</tr>
<tr>
<td>Intravenous urogram/pyelogram</td>
<td>10 to 20</td>
<td>1.7 (0.17)</td>
<td>10 (1); 0.37 to 2.64 (0.037 to 0.264)</td>
</tr>
<tr>
<td>Lumbar spine</td>
<td>1.3</td>
<td>1.7 (0.17); 0.9 (0.09)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Pelvis</td>
<td>0.7</td>
<td>1.1 (0.11); 3.4 (0.34)</td>
<td>4 (0.4); 22 (2.2)</td>
</tr>
<tr>
<td>Skull</td>
<td>0.07</td>
<td>less than 0.01 (0.001); 0.04 (0.004)</td>
<td>less than 0.01 (0.001)</td>
</tr>
<tr>
<td>Thoracic spine</td>
<td>0.7</td>
<td>less than 0.01 (0.001)</td>
<td>less than 0.01 (0.001); 0.03 (0.003)</td>
</tr>
<tr>
<td>Dental</td>
<td>less than 0.001 (0.0001); less than 0.01 (0.001)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Computed Tomography</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdomen</td>
<td>10</td>
<td>8 (0.8); 7.6 (0.76)</td>
<td>49 (4.9); 26 (2.6)</td>
</tr>
<tr>
<td>Chest</td>
<td>8</td>
<td>0.06 (0.006)</td>
<td>0.96 (0.096); less than 1 (0.1)</td>
</tr>
<tr>
<td>Hand</td>
<td>less than 0.005 (0.0005)</td>
<td>less than 0.005 (0.0005)</td>
<td></td>
</tr>
<tr>
<td>Lumbar spine</td>
<td>2.4</td>
<td>2.4 (0.24); 7.50 (0.75)</td>
<td>8.6 (0.86); 40 (4)</td>
</tr>
<tr>
<td>Pelvis**</td>
<td>7.1</td>
<td>25 (2.5)</td>
<td>79 (7.9)</td>
</tr>
<tr>
<td>Head</td>
<td>2.3</td>
<td>less than 0.005 (0.0005)</td>
<td>less than 0.005 (0.0005)</td>
</tr>
<tr>
<td>Pelvimetry</td>
<td>0.2</td>
<td>0.2 (0.02)</td>
<td>0.4 (0.04)</td>
</tr>
<tr>
<td><strong>Fluoroscopy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper GI</td>
<td>1.1</td>
<td>1.1 (0.11)</td>
<td>5.8 (0.58); 0.56 (0.056)</td>
</tr>
<tr>
<td>Barium enema**</td>
<td>7</td>
<td>6.8 (0.68); 10 (1)</td>
<td>24 (2.4); 130 (13)</td>
</tr>
<tr>
<td>Barium swallow</td>
<td>15</td>
<td>1.1 (0.11)</td>
<td>5.8 (0.58)</td>
</tr>
</tbody>
</table>

* Duplicate values represent different estimations in the literature.
** Highlighted rows indicate potential exposures of more than 50 mGy.

Sources:

For sources associated with specific values, contact the Pennsylvania Patient Safety Advisory staff.
filtration, presence of a grid, and x-ray parameters. Moreover, in fluoroscopy-based exams, fetal doses are difficult to calculate because it may be unknown how long the conceptus is actually in the primary beam, which the radiologist may move during the procedure. Additional factors affecting fluoroscopy doses include magnification, grid use, and whether conventional or pulse fluoroscopy is used. Fetal dose is also greatly affected by such patient anatomical factors as thickness of the patient, anteversion or retroversion of the uterus, and distension of the bladder.1

**Effects on the Conceptus**

Ionizing radiation can produce the following effects on the conceptus, which depend upon the fetal dose absorbed and the phase of gestation at the time exposure occurs.15,17,21 Below this threshold, the effects in exposed populations are similar to control populations who have received only background radiation.4 Deterministic effects are caused by cell killing, and the severity of the effect increases as the dose above the threshold increases.7,10,19 Cell killing can produce death; growth retardation; abnormal brain/central nervous system (CNS) development, including mental retardation and behavioral disorders; abortion; malformation; and cataracts.7,10

**Stochastic.** Stochastic effects can occur after any exposure and involve damage to the nuclear material in cells, causing hereditary mutations or radiation-induced cancer including leukemia.8,15,17 For such DNA damage or misrepair, there is no threshold dose below which the chance of these effects is zero.7,17,19 Stochastic effects also increase with radiation dose.

**Effects According to Stages of Pregnancy**

During the entire gestation, mammalian embryos and fetuses are radiosensitive. The type and severity of most induced biological effects depend on the developmental stage of the conceptus during which radiation exposure occurs.21 Most of the effects of ionizing radiation can be considered according to the following stages of pregnancy: pre-implantation, organogenesis, and fetal development.

**Pre-implantation.** The pre-implantation stage begins from the moment the egg is fertilized until the fertilized egg attaches to the uterine wall (zero to two weeks postconception).22

**Organogenesis (embryonic).** During the organogenesis stage (two weeks postconception until seven to eight weeks postconception), cell migration of multi-potential progenitor cells forms the major organs.22

**Fetal development.** In the fetal development stage (eight or nine weeks to delivery), differentiated organs undergo cellular growth. The three phases are as follows: early, mid, and late.22 Table 4 presents possible health effects to the conceptus, according to radiation dose and stage of pregnancy.

**Severe mental retardation.** While most major organs form and differentiate during the organogenesis phase of pregnancy, the CNS continues to differentiate during the organogenesis, early fetal, and mid-fetal stages of pregnancy.22 The risk of severe mental retardation varies with the stage of pregnancy. Table 5 displays the variations in this risk to the conceptus during gestation. During early fetal development (8 to 15 weeks), 50 mGy is associated with IQ reduction.23 This dose can be reached by a single CT scan of the abdomen and pelvis or by a barium enema (refer to Table 3).

**Carcinogenicity (radiation-induced cancer and leukemia).** Radiation has been shown to cause many types of cancer and leukemia in adults and children.1,21 However, the estimates of cancer risk related to diagnostic radiation vary considerably. Therefore, the risk of diagnostic-radiation-induced cancer and leukemia remains unclear. More recent, well-designed studies do not replicate an association between childhood malignancies and in utero diagnostic radiation exposure found in earlier studies.2,25 A recent analysis (ICRP 90) concludes that the relative risk of childhood cancer is 1.37 per 10 mGy (1 rad) of exposure.21

**Genetic/mutation/heritable effects (alteration of germ cell lines).** Radiation increases the frequency of mutations above mutations naturally occurring in the general population. However, no radiation-induced gene mutations have been demonstrated unequivocally in humans when the conceptus is exposed to diagnostic radiation.22 Therefore, the exposure risk is considered to be the same as the risk after birth, 1 in 4,200 per 10 mGy (1 rad), compared to the estimated
Low-dose radiation exposure. While low-dose diagnostic radiation is generally considered not harmful to the conceptus, some studies have indicated certain problems (refer to Table 6). Many of these studies have been criticized because of failure to control certain variables, the need to use retrospective methodology, study size, and/or lack of biological plausibility.26

Risk Reduction Strategies

Because some of the effects of ionizing radiation are cumulative, performing multiple diagnostic radiation procedures on a pregnant woman may place the conceptus at risk. Several strategies can be used to reduce this risk.

### Table 4. Effects of Ionizing Radiation on Conceptus

<table>
<thead>
<tr>
<th>PREGNANCY PHASE</th>
<th>WEEKS POST CONCEPTION</th>
<th>RADIATION EXPOSURE</th>
<th>POSSIBLE CONCEPTUS HEALTH EFFECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-implantation</td>
<td>0 to 2 weeks</td>
<td>Diagnostic exposure (less than 100 mGy [10 rad]) Greater than 100 mGy (10 rad)</td>
<td>Embryo implantation failure; embryo death by cytogenetic damage Lethality</td>
</tr>
</tbody>
</table>
|                   |                       |                                           | Low-dose radiation exposure. While low-dose diagnostic radiation is generally considered not harmful to the conceptus, some studies have indicated certain problems (refer to Table 6). Many of these studies have been criticized because of failure to control certain variables, the need to use retrospective methodology, study size, and/or lack of biological plausibility.26

#### Justification

The physician justifies each use of medical radiation during pregnancy—the benefits must outweigh the risks.25,26,27,32–34 Whenever possible, both parents are included in this decision-making process.3 There are, of course, two individuals involved in this evaluation. The mother may receive direct benefit from the diagnostic procedure, her fetus may be exposed without direct benefit. While the mother’s medical problem is serious, diagnostic radiation may lead to lifesaving medical interventions that may directly benefit the fetus.1 Another consideration is determining whether the diagnostic procedure is useful—will its outcome strengthen confidence in the diagnosis and influence patient intervention? The physician balances the medical needs against potential radiation risks on a
Table 5. Fetal Effects of Ionizing Radiation: Severe Mental Retardation

<table>
<thead>
<tr>
<th>PHASE</th>
<th>WEEKS POST CONCEPTION</th>
<th>RADIATION EXPOSURE</th>
<th>RISK OF MENTAL RETARDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organogenesis</td>
<td>2 to 8 weeks</td>
<td>Diagnostic radiation</td>
<td>No increased risk</td>
</tr>
<tr>
<td></td>
<td>100 mGy to 200 mGy</td>
<td>Mental retardation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(10 rad to 20 rad)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,000 mGy (100 rad)</td>
<td>Reduction of IQ (25 to 30 points); severe mental retardation in 40% of cases</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,500 mGy (150 rad)</td>
<td>Severe mental retardation in 60% of cases</td>
<td></td>
</tr>
<tr>
<td>Fetal development</td>
<td>Early</td>
<td>Diagnostic radiation</td>
<td>No increased risk</td>
</tr>
<tr>
<td></td>
<td>8/9 to 15 weeks</td>
<td>Malformation of forebrain producing mental retardation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>200 mGy (20 rad)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,000 mGy (100 rad)</td>
<td>Reduction of IQ (25 to 30 points); severe mental retardation in 40% of cases</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,500 mGy (150 rad)</td>
<td>Severe mental retardation in 60% of cases</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mid</td>
<td>Diagnostic radiation</td>
<td>No increased risk</td>
</tr>
<tr>
<td></td>
<td>16 to 25 weeks</td>
<td>Less risk of IQ reduction and severe mental retardation</td>
<td></td>
</tr>
<tr>
<td>Late</td>
<td>26 to delivery</td>
<td>Central nervous system is relatively radioresistant</td>
<td></td>
</tr>
</tbody>
</table>


For sources associated with specific values, contact the Pennsylvania Patient Safety Advisory staff.

Case-by-case basis, rather than solely on numerical calculations. Radiographs that are ordered will ideally not only meet the criterion of medical necessity but also be in accordance with appropriate published guidelines. Usually, the risk of not making a correct diagnosis is greater than the radiation risk involved. If the mother’s condition requires x-rays, there usually should be no hesitation in ordering a needed study.

Delay

If radiographic information is not likely to alter immediate medical management, it may be prudent to delay nonurgent radiographs, particularly during the sensitive CNS period of early fetal development from 8 to 15 weeks after conception. Any delay until after pregnancy must be considered in light of the clinical status of the mother and unborn child, balancing the risks and benefits to both. Because of some studies linking maternal, prenatal dental x-rays with low-birth-weight babies, the American Dental Society recommends that pregnant women postpone elective dental x-rays until after delivery.

Avoidance

Avoid studies in pregnant patients that do not influence patient care. Moreover, consider whether follow-up diagnostic studies involving ionizing radiation are medically necessary. Also, consider whether repeat studies are necessary if such studies were recently performed at another hospital or outpatient setting.

The following diagnostic studies may be medically unjustified during pregnancy:

- Lower lumbar radiographs in patients with stable degenerative conditions of the spine
- Routine chest x-rays at hospital admission or before surgery in the absence of cardiac or pulmonary disease/insufficiency

The World Health Organization concluded that routine screening chest x-rays during pregnancy are not indicated unless there is a high incidence locally of clinically silent chest disease. CT of the fetus should be avoided in all trimesters of pregnancy. Moreover, x-ray pelvimetry is of limited medical value and should not be performed on a routine basis. There is a poor statistical correlation between pelvic measurements and the course of labor. If x-ray pelvimetry is medically necessary, the reasons should be clearly documented.

Alternatives

If a patient is pregnant, consider whether another diagnostic examination can be substituted. Ultrasound and magnetic resonance imaging (MRI) have no known risks to a developing fetus and do not
Table 6. Fetal Effect of Low-Dose Diagnostic Ionizing Radiation Exposure

<table>
<thead>
<tr>
<th>STUDY</th>
<th>RADIATION DOSE</th>
<th>FETAL HEALTH EFFECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jacobson and Mellemaaard</td>
<td>Low dose</td>
<td>No increased rate of malformations or spontaneous abortions</td>
</tr>
<tr>
<td>Bohnen et al.</td>
<td>Diagnostic radiation of greater than 0.3 rad during second or third trimester</td>
<td>Significant reduction of infant head circumference</td>
</tr>
<tr>
<td>Hamilton et al.</td>
<td>Diagnostic radiation of greater than 0.3 rad during first trimester</td>
<td>No effect</td>
</tr>
<tr>
<td>Hujoel et al.</td>
<td>Dental radiographs during pregnancy (threshold dose 0.4 mGy [0.04 rad])</td>
<td>Increased risk of low birth weight babies</td>
</tr>
<tr>
<td>Boice et al., De Santis et al.</td>
<td>Diagnostic radiation with thyroid exposure during first trimester (threshold dose 0.4 mGy to 0.9 mGy [0.04 rad to 0.08 rad])</td>
<td>Slight reduction of birth weight</td>
</tr>
</tbody>
</table>


Optimization/Minimization/Protection

When a pregnant patient requires x-ray, the examination should be optimized to provide good diagnostic quality for the least possible exposure to the fetus. In certain circumstances, direct visualization of the mother’s pathology (e.g., using endoscopy or laryngoscopy) may promote accurate diagnosis. Diagnostic alternatives may be appropriate when cost, waiting time, or organizational difficulties are not prohibitive.

For example, if pelvimetry must be done, the obstetrician can obtain adequate information by ultrasound or MRI, thus avoiding ionizing radiation. For acute appendicitis during the first and second trimester, MRI and/or ultrasound can be considered instead of obtaining a CT scan. Ultrasound is the initial study of choice to identify renal calculi. For trauma, ultrasound may be sufficient, but CT may be necessary if specific anatomic injuries are suspected.

If fluoroscopy is required, it should be used sparingly and judiciously to reduce the time of fetal exposure, as fetal doses can exceed 50 mGy (5 rad), especially if fluoroscopy time exceeds seven minutes. Both shorter beam time and greater distance to the patient can reduce the radiation dose.

If CT of the abdomen or pelvis is absolutely necessary, consider single, low-dose CT scan. Techniques that may reduce dose during CT scans in general include establishing the optimal electrical current (mAs) through the x-ray tube, scanning only the area necessary, using multiple phase scanning only if needed, and using organ shielding that is designed for CT scans. Radiation reduction techniques may be used as long as they do not unduly reduce the diagnostic value of the x-ray examination. Tailoring each examination and reviewing each radiograph as it is taken until a diagnosis can be achieved, then terminating the procedure, will reduce radiation exposure.

If pulmonary embolism is suspected, a CT pulmonary angiogram exposes the fetus to less radiation than a VQ (pulmonary ventilation/quantification) scan. Lead shielding of the abdomen and pelvis will reduce radiation exposure to the fetus, but only slightly, since some exposure comes from internal scatter. The American Dental Society recommends that if a pregnant woman’s dental x-rays cannot be delayed until after delivery, abdominal shielding and a protective thyroid collar be applied during the procedure.
Calculation

In most cases of diagnostic radiology, fetal dose estimation is unnecessary unless the fetus is in the direct beam. If the fetus is in the direct beam or if a woman is unaware she is pregnant at the time of a high-dose x-ray procedure, a qualified expert (i.e., a medical physicist/radiation safety specialist who is experienced with dosimetry) can calculate the estimated radiation dose to the conceptus/fetus. The qualified expert calculates a case-specific, estimated fetal dose, rather than referring to average doses published in the clinical literature. Then, this dose is compared to the date of conception or date of last menstrual period to determine fetal risks associated with the length of the gestation.

Pregnancy Presumption/Determination

Until proven otherwise, amenorrhea occurring in regularly menstruating women should be considered due to pregnancy. All women of childbearing age should be questioned about the possibility of pregnancy prior to diagnostic radiation exposure. Pregnant testing may be necessary, however, because fetal doses are usually well below the 1 mGy (0.1 rad) used in diagnostic radiology, pregnancy tests are not usually performed. Moreover, in most diagnostic radiology situations, the “10-day rule” in women of childbearing age has been proven to be unnecessary. But in high-dose procedures involving the lower abdomen and pelvic area in which the embryo/fetus is in the direct beam, it would be prudent to conduct a pregnancy test and/or restrict such radiography to the first 10 days of the woman’s menstrual cycle. In high-dose procedures, the absorbed fetal dose might range by a factor of 10 to 100. Thus, the absorbed dose may be above the threshold dose for malformations, and cancer risk becomes appreciable.

When a patient is pregnant or possibly pregnant, the technician or clerk relates the information to the radiologist. The radiologist, in turn, determines whether the embryo/fetus will be in the primary x-ray beam. If not, the risk to the fetus is very low, and the best risk reduction strategy is good radiologic practice.

While pregnancy testing is not necessary for low-dose, low-risk diagnostic radiation procedures, testing may be prudent prior to high-dose procedures, particularly of the abdomen and pelvis. As communicated in PA-PSRS reports, patients who have firmly denied the possibility of pregnancy have undergone high-dose diagnostic procedures during which fetuses were revealed. Another issue identified in PA-PSRS reports is the performance of imaging procedures prior to the return of pregnancy test results. Facilities may address this issue by evaluating/improving systems and processes to improve turnaround time of pregnancy test results or implementing point-of-care testing that involves personnel who have the competencies to conduct and interpret these tests prior to conducting such diagnostic procedures.

Awareness

Increasing public awareness of the safety of low-dose diagnostic radiation may reduce anxiety and prevent test delays or termination of otherwise wanted pregnancies. Heightening physician awareness about diagnostic radiation doses and effects may promote accurate estimation of diagnostic radiation risk and therefore more appropriate patient counseling.

The medical professional who prescribes or uses radiation needs to be familiar with the effects of radiation on the conceptus. The associated risk is low with less than 100 mGy (10 rad) of radiation exposure, except during the pre-implantation stage of pregnancy (refer to Table 4). The risk of carcinogenesis related to ionizing radiation throughout pregnancy is unclear, but a study by ICRP indicates that it is discernable. Risks associated with greater than 100 mGy (10 rad) include CNS abnormalities, malformations, growth restriction, and fetal death.

Patient education brochures can provide information about risks associated with diagnostic ionizing radiation and pregnancy; for example, see http://www.familydoctor.org.

For a given radiographic examination, the range of entrance doses (doses measured at the body surface at the site where the x-ray beam enters the body) is very broad. At times, the lowest and highest doses measured at individual radiological installations vary by a factor of 100. Therefore, facilities can establish diagnostic reference levels for each of the principal studies. These levels can be used to identify x-ray machines in need of corrective actions, thus reducing the average facility-specific radiation dose to patients.

Moreover, regular preventive maintenance will help to ensure that the equipment is in proper working order and is providing an appropriate dose of radiation.

Good procedural technique can be promoted through confirming staff competencies and monitoring techniques utilized.

Notice

Consider posting notices in several places within diagnostic radiology departments or wherever diagnostic x-ray equipment is used, advising patients who are pregnant or could be pregnant to inform a staff person prior to the procedure. These notices could also be posted in reception/waiting areas and written in the predominant languages of the communities served by the facility. Using pictures instead of text in the notices may help to convey to individuals from different languages or cultures the need to report actual/potential pregnancies.

Documentation

When ordering diagnostic radiation procedures, providing to the radiologist adequate clinical information, the suspected diagnosis, and/or reason for the examination will prevent wrong procedures, techniques, and/or useless tests. When a high-dose diagnostic procedure is performed and the fetus is in
the primary x-ray beam, documenting the following technical factors will provide information required for the medical physicist/qualified expert to calculate an accurate fetal radiation dose.

For all modes of diagnostic radiation, document the following as applicable: film projections, geometrical description, dose area product, beam filtration, x-ray generator settings (mAs and kVp); and whether a grid was used. In addition, for x-rays, document the number of films and locations. For fluoroscopy, additional information includes beam time. For CT scans, additional information includes slice thickness, number of slices, pitch (distance between adjacent slices), and location of the uterus.

The healthcare professional should document the details related to counseling and consents in the patient’s medical record.

Counseling/Consent

A pregnant patient has a right to know the extent and type of potential radiation effects that might result from in utero radiation exposure. The extent of disclosure is determined by what a reasonable person believes is material to a mother’s decision to be exposed to radiation.

The scope of information provided to a pregnant patient is related to the level of risk to the fetus. For low-dose procedures such as a chest x-ray, verbal assurances can be provided that the risk is extremely low and this discussion can be documented in the patient’s medical record or radiology report. When fetal doses are 1 mGy (0.1 rad) or greater, more detailed information is given.

The clinician ordering the imaging procedure is responsible for counseling the pregnant woman and obtaining informed consent, in consultation with the radiologist. Women who have had routine plain films of the head, chest (including mammograms), and extremities (not the hip), or CT of the head or chest, may be counseled that the following risks to the fetus are not increased: miscarriage, growth restriction or congenital malformation (e.g., microcephaly), or mental retardation. The benefits outweigh most risks. While any one diagnostic radiology procedure is below the threshold, the fetuses of women exposed to radiation exceeding a cumulative dose of more than 50 mGy (5 rad) may be at risk.

Pregnant women may also be counseled that the risk of a fetus developing childhood cancer is less than 1%. Fetal exposures to diagnostic radiation in doses less than 100 mGy (10 rad) are not considered a reason for termination of pregnancy. One author has suggested that for direct fetal exposure of greater than 1 mGy (0.1 rad) a more detailed explanation can be given indicating minimal risk below 10 mGy (1 rad).

In the fetal dose range of 100 mGy to 200 mGy (10 rad to 20 rad), the situation is less clear. There appears to be a risk of measurable IQ loss if the fetus is exposed between 8 to 15 weeks gestation. At fetal doses greater than 500 mGy (50 rad), there can be significant fetal damage, of which the magnitude and type depend upon the dose and stage of pregnancy. Three to 16 weeks after conception, if the absorbed fetal dose is in excess of 500 mGy, there is a substantial risk of growth retardation and CNS damage. The fetus may survive, but the parents need to be informed of the high risks involved.

A qualified biomedical or health physicist should calculate the absorbed fetal dose as accurately as possible. Then the physician provides information and determines the situation/perspective of the parents. The parents will make decisions after being fully informed.

Information provided may include the following:
- Analysis of gestational age
- Estimation of fetal dose and risks of in utero radiation exposure
- Benefit of radiological examination for the mother and medical indication
- Maternal risk if the examination were postponed until after delivery
- Comparison of radiation risks with other environmental hazards in ordinary life
- Spontaneous incidence of fetal abnormalities in populations without diagnostic radiation exposure

One approach suggested is to indicate to the mother the probability of not having a child with a malformation or cancer and how that probability is affected by diagnostic radiation exposure. Another approach is to present a graph that compares the radiation dose of various diagnostic studies and/or environmental sources with the threshold limit of 5 rad. The patient’s specific study could be plotted on the graph for comparison.

For higher dose tests (e.g., CT of the abdomen or pelvis, barium enema, IVP, lumbar spine, hip radiograph), it may be prudent to obtain written informed consent. One example of such a form was developed by the University of California, San Francisco. If a patient states she is or may be pregnant and the procedure involves ionizing radiation, the procedure should not be performed unless a radiologist is consulted.

If the patient has limited English proficiency, obtaining consent before the procedure and counseling a pregnant woman after a procedure using ionizing radiation is considered critical communication. A certified language interpreter is required to ensure that the patient understands the information provided prior to making decisions.

Communication

Even though diagnostic radiation is unlikely to cause harm to the fetus, it is not appropriate to promise parents a perfect baby because there are baseline risks associated with pregnancy even without diagnostic radiation.
Open communication with the patient about the nature of the test, potential outcomes, and risks encourages a trusting relationship both before and after a diagnostic study. Such communication can alleviate patient concerns about the effects of radiation.

When healthcare workers (physicians, technicians, radiologists, nurses) work closely together with the patient, they can determine the most appropriate study that will obtain the maximum amount of information while reducing exposure of the fetus to ionizing radiation.

**Key Points**

The following key points can help promote the safe use of diagnostic ionizing radiation in pregnant women:

- Prenatal doses from most properly performed diagnostic procedures present no measurable increase of fetal death, malformation, or impairment of mental development over background incidence of these complications.
- If a diagnostic radiology examination is required to guide diagnosis and treatment, the risk to the mother of not performing the procedure is usually greater than the risk of potential harm to the fetus.
- Ultrasound and MRI are considered safe alternatives to ionizing radiation and can be used throughout the pregnancy.
- There are radiation-associated risks throughout pregnancy relative to the fetal absorbed radiation dose and the stage of pregnancy. The most significant radiation risks occur during organogenesis and the early fetal period. During those periods, non-urgent x-rays can be avoided.
- Many complex factors are involved in an individual’s decision to terminate a pregnancy, including fetal radiation exposure information and religious, ethical, and individual beliefs, as well as laws and regulations. However, a fetal dose below 10 rad (100 mGy) is not considered a reason for terminating a pregnancy.
- The majority of diagnostic procedures, excluding pelvic CT and barium enema, do not involve fetal exposure of greater than 50 mGy (5 rad) and are not, therefore, usually associated with known deterministic effects (malformation, mental retardation).
- The main practical issue following in utero exposure at diagnostic levels is the increased risk of cancer.
- It is important to know the patient’s pregnancy status with as much certainty as possible. One should not rely on the patient’s history alone.
- Pregnant women should be informed in writing of the radiation dose and date of the procedure so that cumulative effects can be appreciated.
- Patient counseling before and/or after diagnostic radiation exposure can help reduce anxiety and misunderstanding about the effects of such exposure on the conceptus.
- When healthcare workers (e.g., physicians, technicians, radiologists, nurses) work closely together with the patient, the study most appropriate for the situation can be determined so the pregnant patient obtains the maximum amount of information while reducing exposure of the fetus to ionizing radiation.

**Notes**


Self-Assessment Questions

1. The central nervous system of the fetus is most sensitive to ionizing radiation during which of the following?
   - a. Pre-implantation
   - b. Organogenesis
   - c. Early fetal development
   - d. a and b only
   - e. b and c only

2. Medically necessary x-rays of the head, chest, and arms can be performed on a pregnant woman at any time during the pregnancy.
   - a. True
   - b. False

3. Fetal radiation doses for a fluoroscopic procedure are as easy to calculate as for a radiograph.
   - a. True
   - b. False

4. During a nine-month gestation, the conceptus usually receives how much natural ionizing radiation?
   - a. 1 mGy (0.1 rad)
   - b. 10 mGy (1 rad)
   - c. 20 mGy (2 rad)
   - d. 30 mGy (3 rad)

5. Sources of natural background ionizing radiation include which of the following
   - a. Heat and light
   - b. Sound waves and microwaves
   - c. Sun and rocks
   - d. All of the above

6. Absorbed fetal radiation can be calculated accurately by referring to average doses published in the clinical literature.
   - a. True
   - b. False
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