Radiation Management for Interventions Using Fluoroscopic or Computed Tomographic Guidance during Pregnancy: A Joint Guideline of the Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe with Endorsement by the Canadian Interventional Radiology Association

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ABBREVIATIONS

CIRSE = Cardiovascular and Interventional Society of Europe, IQ = intelligence quotient, P_{KA} = Kerma–area product

PREAMBLE

The memberships of the Society of Interventional Radiology (SIR) Safety and Health Committee and the Cardiovascular and Interventional Society of Europe (CIRSE) Standards of Practice Committee represent experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally, these Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid broad expert constituency of the subject matter under consideration. In addition, the authors also include other experts in radiation safety.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document, are available upon request from SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR and CIRSE produce their safety-related documents using the following process. Documents of relevance and timeliness are conceptualized by SIR Safety and Health Committee members and the CIRSE Standards of Practice committee. A recognized expert is identified to serve as the principal author for the document. Additional authors may be assigned dependent upon the magnitude of the project.

An in-depth literature search is performed using electronic medical literature databases. Then, a critical review of peer-reviewed articles and regulatory documents is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is evaluated and used to write the document such that it contains evidence-based data, when available.

When the literature evidence is weak, conflicting, or contradictory, consensus is reached by a minimum of 12 Safety and Health Committee

members. A Modified Delphi Consensus Method (1) is used when necessary to reach consensus. For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter. Recommendations are derived from critical evaluation of the literature and evaluation of empirical data from the Safety and Health Committee and the Standards of Practice committee members' practices. Agreement was reached on all statements in this document without the need for modified Delphi consensus techniques.

The draft document is critically reviewed by the SIR Safety and Health Committee and separately by the CIRSE Standards of Practice Committee by means of telephone, conference calling, or face-to face meeting. The finalized draft from the Committees is sent to the SIR membership for further input and criticism during a 30-day comment period. These comments are discussed by the SIR Safety and Health Committee and CIRSE Standards of Practice Committee, and appropriate revisions are made to create the finished document. Before its publication, the document is endorsed by the SIR Executive Council and the CIRSE Executive Committee.

INTRODUCTION

Fluoroscopically guided interventional procedures are performed frequently throughout the world, with the number of these procedures performed annually having increased significantly over the past two decades (2). While the benefits of interventional radiology procedures to patients are well documented, many of these procedures have the potential to deliver radiation doses that may cause radiation effects (2–7).

Pregnant women are, on occasion, exposed to ionizing radiation in the course of medical examinations (8). In this guideline, the term "conceptus" is used to describe the product of conception at any time between fertilization and birth. In some instances, women known to be pregnant require these examinations or procedures, and in other instances, exposure may occur inadvertently as a result of an undiscovered pregnancy (9). It is important to attempt to determine whether a female patient is pregnant before performing any procedure that uses ionizing radiation. Fluoroscopy and computed tomography (CT) exposure during pregnancy require specific consideration because of the radiation sensitivity of the developing conceptus (10).

Lay individuals and some medical professionals (11) have many misconceptions about the risks of ionizing radiation on the developing fetus (12). Even minimal radiation exposure to the conceptus can provoke significant concerns on the part of the referring physician or the expectant mother (13). Often, patients receive misinformation concerning the reproductive and developmental risks of radiation exposures from physicians, nurses, doctors in training, other health care professionals, friends, the news media, and the Internet. A lack of accurate knowledge of the risks associated with such exposures, or misinformation regarding these risks, can cause great anxiety (14,15) and potentially even the unnecessary termination of pregnancy (15).

Despite the large amount of epidemiologic, clinical, and experimental data, the risk associated with prenatal exposure to radiation remains uncertain. Extraabdominal radiologic examinations render exposures to a pregnant uterus that are so low that pregnancy status need not be considered as part of the decision to proceed with a medically indicated examination, as long as the beam is properly collimated (16). Fluoroscopically or CT-guided interventional procedures should be carefully considered during pregnancy (17,18). However, such procedures should not be withheld for those clinical situations in which an appropriate alternative is not available or when the use of radiation for diagnosis (19), intervention, or therapy is necessary for the clinical management of the pregnant patient (20–22). Clearly, an appropriate benefit and risk perspective is necessary to properly care for the ill or injured pregnant patient (16). Decisions whether to proceed with the intervention should be based on clinical circumstances and an evaluation of associated benefits and risks.

This guideline is intended to assist interventionalists and their staff in managing and counseling pregnant patients who need fluoroscopically or CT-guided interventional procedures. Guidance is also provided on evaluating possible pregnancy before the interventional procedures and avoiding accidental exposure of conceptus during the first postconception weeks, or performing a necessary urgent procedure under detailed informed consent. Interventionalists and their staff should use x-ray and CT equipment and procedures in a manner that ensures consistency with the recommendations in this guideline and the requirements of their nation, state, or political jurisdictions. When there are discrepancies between these recommendations and legal requirements, the more rigorous shall take precedence.

DEFINITIONS

Absorbed Dose

Absorbed dose is the energy imparted per unit mass by ionizing radiation to matter at a specified point. For purposes of radiation protection and assessing dose to humans in general terms, the quantity normally calculated is the mean absorbed dose in an organ or tissue. For the purposes of this guideline, the radiation dose of interest is the absorbed dose to the conceptus and not to the mother (15). The special name for the SI unit of absorbed dose is the gray (Gy), and is defined as the absorption of 1 J of ionizing radiation by 1 kg of organ or tissue. Absorbed radiation doses to the conceptus are properly expressed in Gy or milligrays (mGy): 1 Gy is equal to 1,000 mGy. For comparison with earlier units, 1 Gy is equal to 100 rad.

Air Kerma

Air kerma is the energy extracted from an x-ray beam per unit mass of air in a small irradiated air volume. Air kerma is measured in Gy.

Conceptus

The conceptus is the product of conception at any time between fertilization and birth.

Deterministic Effect

Deterministic effects, also termed tissue reactions, are those for which the severity of the resultant detrimental health effect varies with the dose of radiation, and for which a threshold usually exists, below which such detrimental health effects are not observed (see *Threshold Dose*). The effect is not observed unless the threshold is exceeded, although the threshold dose is subject to biologic variation. Deterministic effects to the conceptus and individuals vary. In cases in which the threshold dose to deterministic effect is exceeded in an organ or tissue, the severity of possible injury increases with increasing dose. Examples of deterministic effects to individuals include skin injury, hair loss, and cataracts. Examples of deterministic effects to the conceptus may include malformations, growth retardation, mental disability, and microcephaly.

Dose

Dose is a general term used to denote an amount of radiation. The particular meaning of the term should be clear from the context in which it is used. In this document, dose means the absorbed dose to tissue unless otherwise specified.

Interventional Reference Point

For isocentric fluoroscopic systems, the interventional reference point is located along the central x-ray beam at a distance of 15 cm from the isocenter in the direction of the focal spot. The interventional reference point is close to the patient's entrance skin surface. The Food and Drug Administration prescribes the location of the interventional reference point for several nonisocentric geometries (3).

Kerma

Kinetic energy released in matter is the energy extracted from an x-ray beam per unit mass of a specified material in a small irradiated volume of that material (eg, air, soft tissue, bone). Kerma is measured in grays. For the x-ray energies covered in this report, the kerma produced in a small

volume of material delivers its dose to the same volume (which is not true in high-energy radiation therapy).

Kerma–Area Product

The integral of air kerma across the entire x-ray beam emitted from the x-ray tube. Kerma-area product (P_{KA}) is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. P_{KA} is measured in $Gy \cdot cm^2$. P_{KA} is usually measured without scatter. This quantity was previously called dose-area product. Earlier publications used the abbreviations "KAP" and "DAP" for this quantity.

Qualified Medical Physicist or Medical Physics Expert

A qualified medical physicist is an individual who is competent to practice independently one or more of the subfields of medical physics. The American College of Radiology recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics (2). Certification by the American Board of Health Physics, or in Canada, by the Canadian College of Physicists in Medicine, may also be relevant for evaluation of conceptus dose and risk determinations and evaluations. The medical physicist must also be familiar with the relevant clinical procedures.

In Europe, the recognized term (23) is "Medical Physics Expert" and is defined in the Medical Exposure Directive as "an expert in radiation physics or radiation technology applied to exposure, within the scope of this Directive, whose training and competence to act is recognized by the competent authorities; and who, as appropriate, acts or gives advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimization, on quality assurance, including quality control, and on other matters relating to radiation protection, concerning exposure within the scope of the Directive."

Reference Point Air Kerma

Reference point air kerma is the air kerma accumulated at a specific point in space relative to the fluoroscopic gantry (see *Interventional Reference Point*) during a procedure. Reference point air kerma does not include backscatter and is measured in grays. Reference point air kerma is sometimes referred to as reference dose, cumulative dose, or cumulative air kerma. Earlier publications used the abbreviations "CD" and "RPDose" for this quantity.

Stochastic Effect

Stochastic effects are the radiation effects with increasing likelihood of occurrence with increasing dose, when the severity of occurrence is independent of dose (ie, there is no threshold dose). Radiation induced cancers are examples of stochastic effects. The cancer most closely associated with intrauterine exposure to ionizing radiation is childhood leukemia (24).

Threshold Dose

A threshold dose is the lowest radiation dose at which a specified deterministic effect is likely to occur. The International Commission on Radiological Protection defines the threshold dose as the dose estimated to result in only a 1% incidence of the specified deterministic effect (10). Threshold doses differ among individuals as a result of biologic variation. The threshold dose for skin injury also differs for different anatomic sites of the same individual. With respect to intrauterine exposure, threshold dose is most closely determined for subsequent mental disability and microcephaly.

RISKS OF IONIZING RADIATION ON THE CONCEPTUS

It has long been known that the developing conceptus is highly radiosensitive (25). Exposure of the conceptus to ionizing radiation can potentially lead to two types of adverse health effects, deterministic effects and stochastic effects. Deterministic effects (ie, tissue reactions) result from damage to multiple cells and may be severe enough to cause cell sterilization or death. Stochastic effects originate from damage to single cells that is sufficient to cause a mutation but that does not impair cell division. Stochastic effects (principally cancer) increase in likelihood as dose increases. Two types of risks must be addressed: the likelihood of an adverse outcome and the severity of such an outcome (16,22,26).

The developing conceptus is radiosensitive throughout the prenatal period (27). The effects of radiation exposure on the conceptus depend on multiple variables including the gestational age, fetal cellular repair mechanisms, and the absorbed radiation dose level. Higher doses of ionizing radiation can cause embryonic death, congenital malformations, growth retardation, and neurologic detriment (20). However, there is little support in the epidemiologic literature for the hypothesis that very low doses of radiation adversely affect pregnancy outcome (27). Much of the current knowledge of the harmful effects of ionizing radiation is from the follow-up of atomic bomb survivors, from patients who received radiation therapy for nonmalignant conditions, and from animal studies. Considerable uncertainty still exists about the risks associated with radiation in the diagnostic dose range. The current scientific basis for these effects on the conceptus is discussed later.

Biologic Effects of Ionizing Radiation on the Conceptus

Radiation-related risks are present throughout gestation. The magnitude of these risks is highly dependent on the gestational age during which exposure takes place and the conceptus absorbed dose. Biologic systems with a high fraction of proliferating cells show high radiation responsiveness (25). Radiation risks are most significant during preimplantation and organogenesis and portions of the first trimester (10), somewhat less in the second trimester, and least in the third trimester (15,27). There is no evidence that radiation dose in the diagnostic ranges (ie, < 100 mGy) is associated with an increased incidence of congenital malformation, stillbirth, miscarriage, growth, or mental disability (28). As seen in **Table 1** (9,14,15,22,25,26,28–32), specific radiation effects to the conceptus are associated above a threshold dose of greater than 100–200 mGy, with increasing risks at doses greater than 200 mGy.

Central Nervous System Effects

Development of the central nervous system occurs over a prolonged period during the first and second trimesters, throughout which there remain vulnerabilities to radiation exposure. A review of human atomic bomb survivor data (25) concerning the radiation-induced severe mental disability revealed that the most sensitive prenatal period occurs during the "window of cortical sensitivity" (8–15 weeks post conception), with a dose threshold of approximately 300 mGy or more (25). The associated data on mild retardation, as measured by decreases in intelligence quotient (IQ), suggest a loss of approximately 25–31 IQ points per Gy at a threshold greater than 100 mGy. These data are more difficult to interpret, as any effects on IQ following in utero doses of a few tens of mGy would be of no practical significance for the vast majority of individuals (10,25). It is possible that school achievement may be reduced following exposures of more than 1,000 mGy (25).

Of note, there is no evidence that radiation exposure in typical diagnostic ranges (< 100 mGy) is associated with a measurably increased incidence of congenital malformation, stillbirth, miscarriage, growth, or mental disability (25).

Cardiovascular Effects

Although some have proposed that hypertension may manifest in adolescence following in utero radiation exposures at levels even below 1 Gy (33), others have shown that no significant radiation dose effects exist for any cardiovascular sequelae in the entire in utero–exposed group among atomic bomb survivors (34).

Table 1. Deterministic Radiation Effects at Different Stages of Gestation (9,14,15,22,25,26,28–32)

Stage of Gestation (wk)	Possible Radiation Effect	Dose Characteristic	Estimated Threshold Dose (mGy)
3–4	Most sensitive period for the induction of embryonic death	Minimum lethal dose (from animal studies)	100–200
4–8	Embryo is also predisposed to the induction of major malformations and growth retardation	Minimum lethal dose (from animal studies)	250 (at 18 d), >500 (at >50 d)
		Minimum dose for growth retardation	200–500
8–15	Most sensitive period for irreversible whole-body growth retardation, microcephaly, and severe mental disability	Minimum dose for growth retardation	250–500
		Threshold for severe mental disability	60–500
		Decrease in IQ can occur at lower doses	~100
		Microcephaly	≥20,000
16-Term	Higher exposures can produce growth retardation and decreased brain size and intellect, although the effects are not as severe as occurs from similar exposures during midgestation	Minimum lethal dose (from animal studies)	>1,500
		Minimum dose for severe mental disability	>1,500
		Decrease in IQ can occur at lower doses	>100

Note.—IQ = intelligence quotient.

Cancer

Although some studies suggest an appreciable childhood cancer risk from in utero radiation, methodologic weaknesses and substantial uncertainties exist in the data (25,35–37). Other studies on cancer risk following irradiation of the conceptus have found that the lifetime cancer risk from in utero exposure is no greater than that from exposure in early childhood (and may perhaps be considerably lower than for early childhood exposure [(38)]), but further follow-up is needed (38–45). Cancer induction is at least as likely following exposure in the first trimester as in later trimesters (10). From a radiation protection perspective, and given these uncertainties, it seems prudent to assume that in utero radiation exposure confers a nontrivial risk to the conceptus for future cancer induction. It is also reasonable to assume that this risk is, at most, a few times that of the population as a whole (25) (currently estimated at approximately 5% per Gy for lifetime risk of fatal cancer [(10)]), with no dose threshold. Therefore, a conservative estimate is that the risk of childhood fatal cancer is approximately 5%–15% per Gy (15,46,46). In addition, for the whole population, the risk of hereditary genetic effects is approximately 0.2%–1% per Gy (10,47). Associated risks can be estimated roughly by multiplying the conceptus dose by these estimated rates. These risk estimates can and should be used in shared medical decision-making.

Congenital Malformations and Growth Retardation

For early weeks after conception, the only established deterministic effect of radiation is induced abortion (16,22,26), with high doses of 1 Gy or more resulting in a high rate of lethality. However, the likelihood of inducing this effect at doses of less than 50 mGy is unlikely and not distinguishable from zero (28). After 4 weeks of gestation, there may be a risk of radiation-mediated malformation of most organs and to generalized growth retardation, believed to result from cell depletion. The threshold for major effects during this period is approximately 100–200 mGy (16,22,26). The type of vulnerability depends on the timing between radiation delivery and the developmental stage of differentiated and undifferentiated cells. The likelihood of inducing an effect and its severity increase as dose increases beyond this threshold range. As seen in **Table 1**, as the stage of gestation progresses, the threshold doses for congenital malformations typically increase.

CLINICAL MANAGEMENT OF PREGNANT PATIENTS

Evaluation of Pregnancy before Interventional Procedures

The issue of radiation exposure to the conceptus arises when the question of pregnancy is raised by the patient, the referring physician, or the interventionalist, or when it is discovered that a patient has undergone an intervention while not knowing she was pregnant (48). Clearly, whenever possible before interventional procedures are performed, it should be determined whether a patient is, or may be, pregnant; whether the conceptus will be in the direct beam; the estimated conceptus dose; and whether the procedure is relatively high dose. In Europe, regulations (23) require that "[i]n the case of a female of child bearing age, the prescriber and the practitioner shall inquire as specified by Member States whether she is pregnant, or breast feeding, if relevant." These inquiries may be made on behalf of the prescriber or the practitioner by other members of the staff. The outcome of the questioning should be recorded.

Because fluoroscopically and CT-guided interventional procedures in the pelvis might deliver doses higher than the teratogenic threshold (approximately 100 mGy), a stricter method to screen for pregnancy might apply than that for a diagnostic/therapeutic procedure (26). Therefore, before fluoroscopically or CT-guided interventions, female patients of childbearing potential should be evaluated and an attempt made to determine whether the patient is pregnant (26). A woman who is or thinks she could be pregnant or is uncertain about her pregnancy status should be encouraged to give this information to the physician (49); radiology requisition forms that are ordinarily filled out by referring physicians should also include a section dealing with the possibility of pregnancy; and technologists should be encouraged to ask each patient whether she is pregnant (27,50). Interventional suites should use signs displayed in the waiting area that state, "If you are pregnant or think you are pregnant, please notify a technologist or physician before the examination" (48). Amenorrhea occurring in a regularly menstruating woman should be considered to be a result of pregnancy, unless there is information that precludes a pregnancy (eg, hysterectomy) (15). In cases in which an interventional procedure is contemplated that is expected to deliver relatively high doses to the conceptus, the physician should order a pregnancy test within 72 hours before commencement of the procedure unless medical emergencies prevent it (26). Pregnancy status and the method used to

determine it should be included as part of the patient's medical record (26). The use of a standard urine or serum β-human chorionic gonadotrophin testing is a useful approach to this issue, especially if the procedure is an emergency and/or the woman is obtunded.

When a patient has been determined to be pregnant or possibly pregnant, the interventionalist must be informed. The physician should then carefully evaluate the justification for the procedure, determine whether the conceptus is going to be in the primary x-ray beam, and plan for optimization as discussed later.

Justification: Benefit Must Exceed Risk

As in all medical practices involving radiation exposures, fluoroscopically and CT-guided interventions should be justified, with the aim for medical exposures doing more good than harm to the patient (10,23,51–53). The referring physician and the interventionalist are responsible for justifying the procedure. This includes balancing individual patient medical needs against potential radiation risks for the mother and the conceptus. For high-dose examinations, such as complex diagnostic, interventional, or cardiac procedures, individual justification is particularly important. The process should include consideration of all available information.

In an urgent or emergent clinical setting, the interventionalist must make decisions and recommendations that include the knowledge that the life of the conceptus depends upon the life of the mother and that speed may be a crucial factor in decision-making. In a more elective clinical setting, deliberations should weigh performing the procedure during the gestational period least likely to be associated with risk to the conceptus.

If the conceptus is going to be in the direct beam, it should be determined whether another type of examination that does not use ionizing radiation (eg, ultrasound [US] or magnetic resonance [MR] imaging) could provide the desired diagnostic and interventional results (54). If this is not a feasible alternative, there should be an analysis of the stage of gestation, the estimated anticipated fetal dose, the medical indication for the interventional procedure, and the risk of delaying the procedure (which often depends upon the stage of pregnancy). The interventionalist should discuss these issues with the referring physician. It should be emphasized that, in many cases, and especially when the conceptus is not in the primary beam field, the medical benefit to the mother may outweigh potential risk to the conceptus.

Pregnant women should not be involved in biomedical research projects involving fluoroscopically guided interventions (or other radiation exposure) unless the pregnancy itself is central to the research and only if alternative techniques involving less risk cannot be used.

Optimization: Maintain Appropriate Clinical Purpose while Minimizing Detriment

All fluoroscopically and CT-guided interventions should be optimized to achieve the clinical purpose with no more radiation exposure than is absolutely necessary, given the available resources and technology. Optimizing patient or conceptus dose is not the same as minimizing patient or conceptus dose (2). Some interventional procedures require high-quality images, long exposure time, or both. It is critically important to always strive to achieve the maximum possible dose reduction consistent with acceptable image quality (21). Simple techniques exist that can accomplish this. These include excluding the conceptus from the primary beam path, using reduced dose modes or collimation, as well as proper selection of the numerous technical factors that affect dose (55,56). General guidelines for patient radiation dose management are important for optimizing pregnant patient and conceptus doses (3,4,57–60). **Figures 1 and 2** (4,5,22,55,56,61–68) summarize practical actions to control dose to the patient and conceptus. These techniques require modern imaging equipment with dose reduction technology and a trained, experienced operator who has the skills and judgment to modify technical aspects of the case to optimize dose within the technical constraints of the diagnostic/therapeutic goals of the procedure.

Interventions in anatomic regions remote from the conceptus, such as the chest, skull, or extremities, can typically be performed safely at any time during pregnancy with proper collimation (16,20,24,69,70). If the

Figure 1. Practical actions to control dose to the pregnant patient and conceptus when performing image-guided fluoroscopic interventions (4,5,55,56,61).

abdomen, pelvis, uterus, and/or conceptus is likely to be in the direct beam or proximal to a scattered beam, high conceptus doses can occur and absorbed doses can approach or exceed 50 mGy (15,71). In such cases, care should be taken to minimize the absorbed dose to the conceptus and to also recognize that the larger body habitus caused by pregnancy will likely cause an increase in skin entrance dose for the mother (59). The interventional procedure can and should be tailored to reduce overall dose by applying each of the practical actions outlined in **Figure 1** for fluoroscopic interventions and **Figure 2** for CT interventions, including conventional CT guidance as well as CT fluoroscopy. Note that any alterations in technique should not unduly reduce the diagnostic or interventional value of the x-ray procedure (4,15).

Although the use of lead, bismuth, or antimony shielding between the patient abdomen and pelvis and the beam has been suggested and shown to be somewhat effective if properly placed (60,72,73), depending on the procedure, such shielding may be of limited effectiveness (74). In fact, for many procedures outside of the abdomen or pelvic region (eg, cardiac catheter ablation), most of the conceptus dose is attributable to internal scatter from the thorax of the mother (72,74). Providing lead shielding to wrap the pelvis of the pregnant patient during nonpelvic CT interventions may help the emotional well being of the patient, but the dose to the uterus (primarily from internal scatter radiation) is not materially altered by this shielding (26,75).

During the first trimester, the conceptus dose rate is dependent on the distance between the conceptus and the maternal skin surface opposite the beam entrance (74). In addition, it has been shown that the conceptus depth is strongly influenced by the fullness of the mother's bladder (76). Therefore, during the first trimester, the optimal status of the bladder (pre- or postvoid) should be determined with regard to conceptus placement and dose rate effects. For example, it has been shown that if it becomes necessary for a pregnant woman to undergo a posteroanterior cardiac catheter ablation procedure during the first trimester, fluoroscopic imaging

- Exclude the conceptus from the direct beam if at all possible.
- Minimize craniocaudal scanning length and beam width. Note that the scanogram only indicates where the image data are to be acquired and not where the x-ray beam starts and stops.
- Use the quick-check or intermittent acquisition method instead of real-time acquisition during interventional device placement.
- Minimize total exposure time.
- Keep the tube current (mAs) per rotation as low as possible to achieve the appropriate compromise between image quality and low patient and conceptus dose. Consider the use of automatic exposure control modes. The dose is directly proportional to the selected mAs per rotation. Use more recently available novel reconstruction algorithms to reduce noise in images, thus allowing reduction of tube current or increase of noise level requirements during scanning.
- Reduce tube voltage (kV) to achieve the appropriate compromise between image quality and low patient and conceptus dose. Decreasing the tube voltage from 140 kV down to 110 kV will decrease the dose by approximately 60% with constant mA.
- Use pitch values greater than 1. Doubling the pitch will reduce the dose by a factor of two.
- Use coarser beam collimation. Fine collimation increases the dose.
- Obtain a single scout view and avoid directly imaging the conceptus for planning purposes.
- Avoid imaging in multiple phases.
- Exclude the conceptus from the direct beam if at all possible.
- Minimize craniocaudal scanning length and beam width. Note that the scanogram only indicates where the image data is to be acquired and not where the x-ray beam starts and stops.
- Utilize the quick-check or intermittent acquisition method instead of real-time acquisition during interventional device placement.
- Minimize total exposure time.
- Keep the tube current (mAs) per rotation as low as possible to achieve the appropriate compromise between image quality and low patient and conceptus dose. Consider the use of automatic exposure control modes. The dose is directly proportional to the selected mAs per rotation. Use more recently available novel reconstruction algorithms to reduce noise in images, thus allowing reduction of tube current or increase of noise level requirements during scanning.
- Reduce tube voltage (kV) to achieve the appropriate compromise between image quality and low patient and conceptus dose. Decreasing the tube voltage from 140 kV down to 110 kV will decrease the dose by about 60% with constant mA.
- Use pitch values greater than 1. Doubling the pitch will reduce the dose by a factor of two.
- Use coarser beam collimation. Fine collimation increases the dose.
- Obtain a single scout view and avoid directly imaging the conceptus for planning purposes.
- Avoid imaging in multiple phases.

Figure 2. Practical actions to control dose to the pregnant patient and conceptus when performing image-guided CT interventions including conventional CT guidance and CT fluoroscopy (22,62–68).

Table 2. Spontaneous Risks Facing an Embryo at Conception in the General Population

Type of Risk	Spontaneous Risk to Embryo at Conception (0 mGy Radiation Dose above Natural Background)
Risk of very early pregnancy loss, before the first missed period	~1 in 3
Risk of spontaneous abortion in known pregnant women	~1 in 7
Risk of major congenital malformations	~1 in 33
Risk of severe mental disability	~1 in 200
Risk of childhood leukemia per year	~1 in 25,000 per y
Risk of early- or late-onset genetic diseases	~1 in 10
Prematurity	~1 in 25
Growth retardation	~1 in 33
Stillborn	~1 in 250 to 1 in 50
Infertility	~1 in 15 couples

Note.—Adapted from American National Standards Institute/Health Physics Society fetal radiation dose calculations (9) and Brent (12).

assist in the development of later conceptus dose estimates. The *Estimating Radiation Dose to the Conceptus* section includes additional guidance and generalized dose estimates.

Counseling Pregnant Patients

In any circumstances involving the potential or actual use of fluoroscopically or CT-guided interventional procedures, the pregnant patient may be extremely concerned about the outcome of the pregnancy, and a counseling session with the mother (and father if possible) is often useful. If possible, preprocedure and postprocedure counseling should take place. In some special cases or circumstances, counseling patients requires knowledge of embryology, genetics, radiation teratology, and the principles of teratology for the counselor to provide sympathetic and accurate advice (12), and may be best conducted by a team that includes the referring physician, the interventionalist, the qualified medical physicists/medical physics expert, and perhaps a genetics counselor. A systematic evaluation of the possible effects of radiation exposure with the background risk may require the following pieces of information: stage of pregnancy at the time of exposure; menstrual, medical, and reproductive history; date of conception (sometimes known); previous pregnancy history; family history of congenital malformations and reproductive problems; other potentially harmful environmental factors that occurred during the pregnancy; ages of the mother and father; types, dates, and number of procedures requiring exposure of the conceptus to ionizing radiation; as well as a calculation of conceptus exposure by a qualified medical physicist/medical physics expert (12).

Counseling should be conducted after estimating the absorbed dose to the conceptus from the procedure and comparing the radiation risk with the other risks of pregnancy. The patient and her referring physician should be informed about conceptus radiation doses and potential risks. The talking points in the Appendix 1. may be useful tools.

It is very important to also review with the patient the potential spontaneous risks in the nonexposed population (ie, those pregnant women who do not have a radiation procedure and are exposed only to natural background radiation), as shown in **Table 2**. These risks include a 15% or

with an empty bladder delivers the lowest absorbed dose the conceptus (74). Alternatively, for anteroposterior pelvic projections, a full bladder will decrease dose by pushing the uterus in the posterior direction.

When possible, an estimate of potential conceptus dose should be obtained before the procedure is performed, and this information used in the planning, optimization, and dose estimation practices for performing the actual procedure. This may not be possible if the procedure is an emergency. When a high-dose procedure is performed and when the conceptus is expected to be in the primary x-ray beam, all technical factors should be recorded to allow subsequent fetal dose estimation by a qualified medical physicist/medical physics expert. For fluoroscopy, these factors include kVp, dose rate, fluoroscopy time, P_{KA}, geometric description, projections, conventional or pulsed fluoroscopy use, magnification mode, and whether the grid was used. For CT, these factors include slice thickness, pitch and CT dose index as well as recorded dose–length product. Most of this information is included in the patient dose report that is produced by the modern interventional x-ray or CT systems at the end of the procedures. In addition, appropriate dosimetry should be employed whenever practical to gather actual measurements of entrance surface dose at several locations on the pregnant patient. Multiple dosimeters, placed in several locations on the patient (anterior and posterior to the uterus), will

Table 3. Probability of a Live Birth without Malformation or without Childhood Cancer as a Function of Radiation Dose

Dose to Conceptus above Natural Background (mGy)	No Malformations (%)	No Childhood Cancer (%)	No Malformations and No Childhood Cancer (%)
0	96.00	99.93	95.93
0.5	95.999	99.926	95.928
1.0	95.998	99.921	95.922
2.5	95.995	99.908	95.91
5.0	95.99	99.89	95.88
10.0	95.98	99.84	95.83
50.0	95.90	99.51	95.43
100.0*	95.80	99.07	94.91

Note.—Adapted from International Commission on Radiological Protection (15) and McCollough et al (20).
* For conceptus doses > 100 mGy, consult a qualified medical physicist/medical physics expert for risk estimates.

higher spontaneous abortion rate, a 1%–6% incidence of a major malformation, a 4% intrauterine growth retardation rate, and a 4%–10% incidence of genetic diseases (12,15,77,78). It is also important to discuss with the parents that, without additional radiation exposure above natural background, the lifetime risk of contracting cancer is approximately one in three; for fatal cancer, the risk is approximately one in five (15); and the natural risk of childhood cancer is less than one in 500 (78). When the potential spontaneous risks in nonexposed population have been discussed, the physician should provide information about the estimated probability of delivering a child free of radiation-related adverse outcomes (Table 3). Framing the discussion in this manner can help to maximize information transfer while minimizing fear. The counseling team must listen carefully to the parental questions and take as much time as is necessary to ensure that the parents understand the complex information being presented.

The pregnant patient, or her legal representative if she is incapacitated, has a right to know the magnitude and type of potential radiation effects that might result from in utero exposure before consenting to a medical procedure. There are usually five basic elements of informed consent, which includes whether one is competent to act, receives a thorough disclosure, comprehends the disclosure, acts voluntarily, and consents to the intervention. The need and degree of disclosure is usually measured by what a reasonable person believes is material to the decision to be exposed to radiation (15) as balanced by the potential benefits and other non–radiation-related risks of having or not having the procedure. For low-dose procedures such as a fluoroscopically guided central venous catheter insertion, the only information that may be needed is a verbal assurance that the risk is judged to be extremely low. When conceptus doses are estimated at 1 mGy or greater, usually a more detailed explanation is given. This explanation includes potential radiation-related and non–radiation-related risks, alternative modalities considered, and the potential risk of harm that might result from not having the fluoroscopically guided intervention or from having an alternative intervention.

Women should be counseled that x-ray exposure from most properly performed, typical diagnostic procedures present no measurably increased risk of prenatal death, malformation, or impairment of mental development compared with the background incidence of these entities (15), as exposure to less than 50 mGy has not been associated with an increased rate of fetal anomalies or pregnancy loss (17,28,77). Termination of pregnancy is an individual decision affected by many factors. Conceptus doses of less than 100 mGy should not be considered a reason for terminating a pregnancy (12,15,17,26,78,79). A conservative estimate of the lifetime risk of radiogenic induction of childhood cancer or leukemia at 100 mGy is approximately 0.6% (15). As discussed earlier, conceptus doses greater than 100–200 mGy have the potential for conceptus damage (ie, nervous system abnormalities, malformations, growth retardation, fetal death, or increased risk of cancer in later life) (25), the magnitude and type of which is a function of dose and stage of pregnancy. Conceptus doses greater than 500 mGy in the first trimester are likely to result in central nervous system

effects and growth retardation (27). Such a dose in later pregnancy is less likely to result in a birth defect. Therefore, in rare cases in which the estimated conceptus dose is greater than 100 mGy, the parents should be informed of the potential risks involved, based on gestational age, estimates of conceptus dose, and associated uncertainties.

Written informed consent should be obtained and documented in the patient's chart when a pregnant patient undergoes abdominal or pelvic irradiation, unless it is an emergency. Following an emergently performed procedure, similar counseling should take place and be documented in the patient's chart.

Other Potential Procedure-Related Risks for the Pregnant Patient and Conceptus

The risks of iodinated contrast media on the conceptus have not been fully investigated; however, there are no reports in the literature of any ill effects, despite the theoretical risk of contrast induced hypothyroidism (80). Both the American College of Obstetricians and Gynecologists and American College of Radiology recommendations on the use of CT in pregnancy note that iodinated contrast material is safe in pregnancy (22,26,81). However, thyroid function should be checked in the first few days of life if the mother received iodinated contrast material during pregnancy (19,22).

The effects of any associated chemotherapy (82) and/or radiation therapy may alter decision-making with regard to fluoroscopically or CT-guided interventional procedures on pregnant patients.

Recording Dose in Patient Medical Record

As in all fluoroscopically or CT-guided interventional procedures, patient dose data should be recorded in the patient's medical record at the conclusion of each procedure. Dosimetric information should be recorded in the patient's medical record as soon as is practical after the completion of the procedure. In addition to any conceptus dose estimates, this should include all of the following that are available from: peak skin dose, cumulative kerma at the interventional reference point, P_{KA}, fluoroscopy time, and number of fluorographic images (4).

Follow-Up Evaluations

Patients are advised if they have received a substantial radiation dose, defined as a maximum skin dose of 3 Gy, cumulative kerma at the interventional reference point of 5 Gy, or P_{KA} of 500 Gy·cm² (3). Standard clinical follow-up should be instituted if the patient's skin dose may possibly result in deterministic effects. Follow-up is appropriate at 10–30 days and may be appropriate for as long as 1 year after the procedure (4). This can be done by telephone, with a clinic visit needed only if the patient reports skin changes at the radiation entrance site (4,83). It is appropriate to make these arrangements before the patient leaves the facility.

Table 4. Estimated Conceptus Absorbed Dose from Common Extraabdominal Radiologic Procedures (9,15,20,70,87–94)

Examination	Nominal Fetal Dose "Typical Estimate" (mGy)	Reported Range (mGy)	References
Dental	—	~0–0.001	70, 88
Skull (radiographic)	~0	—	88
Head–cervical spine	—	<0.005–0.03	70
Cervical spine	<0.001	—	20
Extremities	—	<0.001–0.18	20, 70
Shoulder	—	<0.005–0.03	70
Thoracic spine	0.07	<0.001–0.55	9, 20, 70, 89
Chest	<0.01	0.0001–0.43	20, 70, 87–89
Mammography	<0.1	—	9, 90
Femur (distal)	—	0.01–0.50	70
Foot	<0.0001	—	88
Pulmonary embolism scan	—	0.64–0.8	91
CT , head	<0.005	—	9, 15, 92
CT, chest	0.06	0.02–0.2	9, 15, 20, 92
CT, pulmonary angiography	—	0.003–0.23	91, 93
CT, lung	1.2	1.0–1.4	89
CT, angiography of coronary arteries	0.1	—	20
CT, pulmonary embolism	0.7	0.2–0.7	20, 94

ESTIMATING RADIATION DOSE TO CONCEPTUS

Whether conceptus exposures occur from a planned exposure such as a fluoroscopically or CT-guided intervention or they have occurred inadvertently, it is important to be able to develop and provide an estimate of the radiation dose to the conceptus. This information is vital to evaluate or, in the case of planned exposures, to minimize the potential risks to the conceptus and patient. In addition, the information is required to provide proper advice and counsel the patient. It is important for physicians to have a good understanding of the radiation doses from standard radiologic examinations (84) to compare and evaluate various imaging and interventional techniques.

Although prospective dose estimation with the use of multiple dosimeters (eg, thermoluminescence crystals or optically stimulated luminescence dosimeters) placed in several locations on the patient (anterior and posterior to the uterus) to gather measurements of entrance surface dose at several locations on the pregnant patient is optimal, it is typically performed less often than retrospective dose estimation (22). Regardless, dose estimation should be performed in conjunction with a qualified medical physicist/medical physics expert (22). A quick screening rule of thumb is to estimate that the fetal dose is approximately one third of the entrance dose for the average patient for radiographic or fluoroscopic exposures (85). Retrospective dose estimation should be performed in conjunction with qualified medical physicist/medical physics expert and can initially be made through the use of tables of available estimates. In either case, if the initial estimation of dose is 10 mGy or greater (15), a more detailed dosimetry estimate should be developed by the qualified medical physicist/medical physics expert. All such dose estimates should be properly documented and included as part of the patient's medical record (22,26).

Radiographic, fluoroscopic, and CT examinations performed in extraabdominal areas typically deliver doses to the conceptus lower than 1 mGy, and conceptus doses from examinations of the abdomen and pelvis rarely exceed 50 mGy (86). **Table 4** (9,15,20,70,87–94) and **Table 5** (9,15,20,62,68,70,88,89,92,94–103) list estimated conceptus doses for typical diagnostic x-ray procedures. **Table 6** (9,20,70,74,89,92,96,104–112) lists estimated conceptus doses for a few representative fluoroscopic imaging procedures and fluoroscopically guided interventions. When evaluating estimated radiation doses to the conceptus, consultation with a qualified medical physicist/medical physics expert is strongly encouraged. Also, if rapid calculations or the use of lookup tables indicate conceptus doses greater than 10 mGy, more accurate dose assessments are recommended (104) and should be developed in conjunction with a qualified medical physicist/medical physics expert.

To estimate radiation dose to the conceptus accurately, scientifically sound methodologies such as those jointly developed by the Health Physics Society and the American National Standards Institute should be used (9). Several additional models and methodologies have also recently been developed to estimate conceptus doses because of the significant uncertainties involved in such estimations (113).

Determination of the absorbed dose to the conceptus from abdominal or pelvic radiography examination is complicated because doses can be significantly affected by patient anatomy, such as whether the uterus is anteverted or retroverted, and the degree of bladder distension at the time of the study. Still, conceptus doses can typically be estimated within a 50% error (15,68). Several models have been developed to estimate doses to conceptus and the patient from CT examinations. These models use direct measurements, "typical" values sometimes modified with additional information (9), and/or computer models (including Monte Carlo calculation methods) with an accuracy of approximately 20% (114). For CT, it has been shown that normalized fetal dose decreases with increasing patient perimeter and conceptus depth (103). Note that there are different methods for estimating conceptus doses for modern multidetector CT examinations than those for conventional axial and helical CT. Some models have been developed to estimate radiation dose to the conceptus from multidetector CT that allow for variations in maternal body size and conceptus position (86,115).

The evaluation of conceptus doses from abdominal or pelvic fluoroscopy is even more difficult and subject to greater uncertainty. With fluoroscopy and angiography, the x-ray tube position relative to the patient may change numerous times throughout the examination. In addition, radiation is not used continuously, but is employed intermittently at different times during the study. The exact parameters are almost never known, and conceptus dose estimates have often been based on an "average," "typical," or "available" study in the literature (eg, **Table 6**). However, with the help of a qualified medical physicist/

Table 5. Estimated Conceptus Absorbed Dose from Common Abdominal and Pelvic Radiologic Procedures
(9,15,20,62,68,70,88,89,92,94–103)

Examination	Nominal Fetal Dose "Typical Estimate" (mGy)	Reported Range (mGy)	References
Lumbar/lumbosacral spine	4	0.20–40.0	9, 20, 70, 88, 89, 92
Abdomen (KUB)	4	0.21–19.0	9, 20, 70, 88, 89, 92, 96
Abdomen	1.4	1.4–4.2	15
Abdomen (21-cm-thick patient)	1	—	20
Abdomen (33-cm-thick patient)	3	—	9, 20
Pelvis	2	0.16–22.0	9, 70, 89, 92
Film pelvimetry	10	0.35–55.0	70, 97, 98
Digital pelvimetry	0.5	0.05–0.35	70, 97
Hips and femur	3	0.73–14.0	70, 92
Hip fracture fluoroscopy, first trimester	—	0.09–0.125	95
Hip fracture fluoroscopy, second trimester	0.127	—	95
Hip fracture fluoroscopy, third trimester	0.155	—	95
Bone density: spinal and hip dual x-ray	—	0.002–0.005	99
Urography, IV or retrograde pyelogram	6	0.70–55.0	70, 89, 92
Urethrocystography	—	2.70–41.0	70
Urinary bladder (anterior–posterior)	3.9	0.56–11.0	89
CT, abdomen (routine)	10	4–60	15, 20, 70, 92, 94, 96, 103
CT, abdomen (renal stone protocol)	10	4–10	20, 94
CT, appendicitis	16	4–45	62, 94, 100
CT, abdomen, second trimester	—	30–44	101
CT, abdomen, third trimester	—	29–42	101
CT, pelvimetry (single slice)	2.5	1.6–5	70, 98
CT, trauma (chest/abdomen/pelvis) first trimester	—	9.25–37.7	102
CT, pelvis	25	6.7–114.0	9, 15, 68, 89
CT, lumbar spine	2.5	2–8.6	9, 15, 89
CT, liver	3.6	2.0–4.4	89

Note.—KUB = kidneys, ureters, and bladder.

medical physics expert, a "best guess" estimate, and a conservative "worst case" estimate of conceptus dose should be developed. These estimates, along with an assessment of the uncertainty range, can be expressed to the interventionalist, the referring physician, and the patient.

Direct measurement models in phantoms (21,74) have been performed for various diagnostic examinations, and investigators have measured uterine depth dose within a humanoid phantom for various kVp beams of diagnostic quality (116). Using tables of such dose measurements, conceptus doses could be estimated from the knowledge of the conceptus localization (perhaps by sonography or from the diagnostic x-ray images themselves) and the beam parameters used in the procedure.

Mathematical anatomic models have also been developed for conceptus dose estimation. In general, such models can be stylized models that contain organs described by simple surface equations (117), or tomographic models that contain digitally labeled voxel groups from segmented medical images (103,118). Recently, "virtual human" models have also been developed that use constructive solid geometry and boundary representations that may be computationally versatile (119).

Normalized conceptus doses for abdominal radiographic examinations have been estimated by using the aforementioned phantom models with Monte Carlo methods that use various radiation transport codes (eg, the Monte Carlo N-Particle code developed at the Los Alamos National Laboratory to simulate the transport of photons, neutrons, and electrons [(120)], or the PCXMC code developed spe-

cifically for medical x-ray imaging [(121)]). Typically, these methods use beam characteristics, such as kVp, total filtration values, and field size, to estimate organ or conceptus doses with results that can agree with reported published or measured dose data within approximately 10%–50% (104,113,122). Estimation of organ doses can also be made from entrance skin dose or P_{KA} measurements and Monte Carlo results. Although such methods may offer quick estimates and may be appropriate during the first trimester (in which the conceptus dose may be assumed to be approximately equal to the uterus dose), these entrance skin dose or P_{KA} methodologies may differ in accuracy and may not account for all scattering phenomena within the patient (95,87). In addition, mean fetal depth increases from approximately 5–15 cm over the duration of pregnancy, and models that do not use patient-specific conceptus depths may over- or underestimate doses by as much as approximately 80% (123).

RECOMMENDATIONS

All persons who perform fluoroscopically or CT-guided interventions in pregnant women should be aware of the potential for, and the nature of, radiation adverse effects to patients and the conceptus, as outlined in this guideline. Interventionalists and medical physicists should be knowledgeable of radiation effects and should initiate direct contact with patients and their families, as well as referring physicians, for discussion of these issues.

As in all medical practices involving radiation exposures, interventions should be justified, with the aim of medical exposures doing more

Table 6. Conceptus Radiation Dose Estimates from Common Fluoroscopic and Angiographic Procedures (9,20,70,74,89,92,96,104–112)

Examination	Estimate (mGy)	Range (mGy)	References
Cardiac catheter ablation, first trimester	0.15	0.04–0.20	9, 74
Cardiac catheter ablation, second trimester	0.3		74
Cardiac catheter ablation, third trimester	0.6		74
Pulmonary angiography for embolism, first trimester	0.02	0.006–0.05	105
Pulmonary angiography for embolism, second trimester	0.09	0.022–0.26	105
Pulmonary angiography for embolism, third trimester	0.46	0.278–0.86	105
Cholecystography/cholangiography	1	0.05–16.0	70, 89, 92
Hysterosalpingography	10	2.7–92	70, 92
Barium enema	10	0.28–130	9, 70, 89, 104, 92, 96
Barium meal (upper gastrointestinal)	1.5	0.1–5.8	9, 70, 89, 92
Small bowel study	7		20
TIPS creation, second trimester	5.5		106
CT, angiography of aorta (chest through pelvis)	34		20
CT, low-dose nephrostomy	0.1	0.094–0.16	107
Uterine fibroid embolization	42		108
Varicocele embolization	15.8		108
Transureteral stent	44		109
Antegrade ureteric stent	2.5		108
Retrograde ureteric stent	0.4	0.03–0.79	108
Nephrostomy	1.1		108
Intravenous urogram (intravenous pyelogram)		1.8–12.6	9, 108
Unenhanced CT, kidneys, ureters, and bladder	17.7		108
Transcatheter embolization for pulmonary AVM		<0.5–2.2	110
Cerebral angiography (four-vessel)	0.06		9
Endoscopic retrograde cholangiopancreatography	3.1	0.01–55.9	9, 109, 111, 112

Note.—AVM = arteriovenous malformation, TIPS = transjugular intrahepatic portosystemic shunt.

good than harm to the patient. Diagnostic and therapeutic modalities that do not use ionizing radiation (eg, US, MR imaging) should be preferred when clinically appropriate. However, concern about the possible effects of ionizing radiation exposure on the conceptus should not preclude medically indicated diagnostic or interventional x-ray procedures when the medical benefit to the mother is justifiable.

Before fluoroscopically or CT-guided interventions, female patients of childbearing potential should be assessed for the possibility of pregnancy. In cases in which nonurgent high-dose procedure of the abdomen or pelvis (eg, embolization) is contemplated, the physician should order a pregnancy test.

All facilities should possess, and make available for ready review, references (eg, those in **Tables 4–6**) that list general radiation dose estimates to the conceptus during radiographic and fluoroscopic imaging. When required, the physician and qualified medical physicist/medical physics expert should estimate radiation dose to the conceptus more accurately, by using scientifically sound methodologies such as those jointly developed by the Health Physics Society and the American National Standards Institute (9), or several updated models and methodologies recently developed. The range of uncertainties should also be determined.

All interventions should be optimized to achieve the clinical purposes with no more radiation than is necessary, given the available resources and technology. Optimizing patient or conceptus dose is not the same as minimizing patient or conceptus dose, and it is critically important to achieve the maximum possible dose reduction consistent with acceptable image quality. To that end, appropriate dose reduction techniques, as outlined in **Figures 1 and 2**, should be employed.

All equipment should be properly maintained and periodically in-

spected for radiation safety. Radiation output should be monitored and patient dose recorded according to local regulations and hospital policy.

Pregnant patients should be counseled based on sound information about the risks of radiation exposure. All discussions with patients about radiation risks, as well as the results of any conceptus and/or patient radiation dose assessments or estimates, should be documented in the procedure report and the patient's medical record. Patients should be given the results of these assessments or estimates.

Termination of pregnancy as a result of radiation exposure is an individual decision affected by many factors. An evaluation of overall risks should be undertaken at all dose levels. Conceptus doses lower than 100 mGy should not be considered a reason for terminating a pregnancy. Note that radiographic, fluoroscopic, and CT examinations performed in extraabdominal areas typically deliver doses to the conceptus lower than 1 mGy and that conceptus doses from examinations of the abdomen and pelvis rarely exceed 50 mGy. Estimated doses greater than 100 mGy should initiate an overall review of the potential risks, given the gestational age and patient history.

Pregnant women should not be involved in biomedical research projects involving fluoroscopically or CT-guided interventions (or other radiation exposure) unless the pregnancy itself is central to the research and only if alternative techniques involving less risk cannot be used.

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APPENDIX A: TALKING POINTS FOR PREGNANT PATIENT DISCUSSION

There are times when the use of radiation for diagnosis, intervention, or therapy is necessary for the clinical management of the pregnant patient. Fluoroscopically or CT-guided interventional procedures are carefully considered during pregnancy. Decisions whether to proceed with the procedure are based on clinical circumstances, an evaluation of associated benefits and risks, and discussions with the patient.

When a patient has been determined to be pregnant or possibly pregnant, the interventionalist carefully evaluates the justification for the procedure and makes plans to minimize the conceptus dose consistent with the clinical requirements for the procedure. This may be accomplished by excluding the conceptus from the primary x-ray beam, using reduced dose modes, using a smaller field of view, shielding (when appro-

Appendix. Probability of a Live Birth without Malformation or without Childhood Cancer as a Function of Radiation Dose

Dose to Conceptus above Natural Background (mGy)	No Malformations (%)	No Childhood Cancer (%)	No Malformations and No Childhood Cancer (%)
0	96.00	99.93	95.93
0.5	95.999	99.926	95.928
1	95.998	99.921	95.922
2.5	95.995	99.908	95.91
5	95.99	99.89	95.88
10	95.98	99.84	95.83
50	95.90	99.51	95.43
100	95.80	99.07	94.91

Termination of pregnancy is an individual decision affected by many factors; however, the doctors in professional radiology and gynecology societies have agreed that radiation doses to the conceptus that are lower than 100 mGy should not be considered a reason for terminating a pregnancy.

priate), and using modern imaging equipment with radiation dose reduction technology operated by a trained and experienced operator.

It is important to recognize that, even without any radiation dose above natural background, there are normal risks associated with pregnancy, including an approximately one in seven risk of spontaneous abortion, a one-in-33 risk of major congenital malformations, a one-in-33 risk of intrauterine growth retardation, a one-in-10 risk of genetic diseases, a one-in-500 risk of childhood cancer, and a one-in-three risk of developing cancer over a lifetime.

Radiation risks are most significant during the first trimester, somewhat less in the second trimester, and least in the third trimester. Estimates of the probability of a live birth without malformation or childhood cancer as a function of radiation dose are given in the table below.

SIR DISCLAIMER

The clinical practice guidelines of SIR attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.