Revised 2013 (Resolution 48)*

ACR–SPR PRACTICE PARAMETER FOR IMAGING PREGNANT OR POTENTIALLY PREGNANT ADOLESCENTS AND WOMEN WITH IONIZING RADIATION

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care[1]. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

[1] Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, Stanley v. McCarver, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR).

Radiation exposure to a pregnant or potentially pregnant patient from a medical imaging procedure and the management of such patients are complex topics. Patients, their families, radiologists and physicians, or other medical practitioners who refer patients for imaging procedures or perform imaging in their own offices, are understandably concerned about the possible detrimental effects of radiation exposure to the developing embryo and fetus. This concern is in addition to medical concerns about the potential risks to a pregnant patient when, out of unnecessary or inordinate concern over radiation, she forgoes a necessary imaging procedure. Clearly, an appropriate benefit/risk perspective is necessary to properly care for the ill or injured pregnant patient.

Since there is no universally recognized threshold for some radiation effects (stochastic effects), it has been argued that there is "no safe level" of radiation exposure. "No safe level" is a sweeping statement, often applied without scientific evidence that should be used only when no benefit is derived from an activity or intervention. It is not applicable when benefits of an activity far exceed risk. Furthermore, we live in a radioactive world in which some geographic areas contain more natural background radiation than others. Many people are exposed to naturally existing environmental radiation in excess of what others receive. This includes people who live at mountain elevations and others who frequently use air travel. These behaviors are considered beneficial to their lifestyle. Neither of these situations is considered inherently unsafe due to the extra radiation that results. Use of the term "safe" in any setting, clinical or nonclinical, should be understood within the context of benefit versus risk. Safety is a matter of taking appropriate actions to limit the risk to a level well justified by the benefit. To maintain a high standard of safety, particularly when imaging potentially pregnant patients, the degree of medical benefit should outweigh the well-managed levels of risk.

This practice parameter has been developed to provide current practical information to radiologists, other physicians, and medical practitioners implementing policies for imaging pregnant and potentially pregnant patients. Individual institutions and facilities should develop their own policies. As with all imaging procedures, the specifics of an individual case should always be considered and may lead to the modification of even the most strongly suggested guidelines.

Throughout this practice parameter, the radiologic technologist is considered to be the person in the radiology department who is most likely to communicate with the patient about the potential for pregnancy. Nurses, registered radiologist assistants, physician assistants, physicians, and receptionists might also do so. For example, a receptionist might provide the patient a questionnaire about her reproductive history that is to be completed before admission to the radiographic suite. Therefore, whenever this practice parameter refers to technologists as responsible personnel for certain actions, it should be understood that others might share in or be assigned this responsibility.

When managing the pregnant patient, the major role of the medical physicist is to estimate absorbed dose to the conceptus of a pregnant patient from selected diagnostic or interventional procedures, either prospectively or retrospectively. The physicist also consults with the radiologist regarding risk associated with radiation and means by which this risk can be reasonably limited.

This practice parameter addresses the imaging of pregnant and possibly pregnant adolescents and adult women with ionizing radiation (i.e., planar radiography,[2] fluoroscopy, and computed tomography [CT]). It does not address issues related to nuclear medicine, the lactating woman, or the use of iodinated contrast or gadolinium contrast during imaging (see the ACR Manual on Contrast Media [1] and the ACR Guidance Document on MR Safe Practices [2]). Neither does this practice parameter address pregnant and possibly pregnant patients

[2]Planar radiography refers to all standard forms of 2-dimensional X-ray projection imaging such as computed radiography (CR), digital radiography (DR), and screen-film imaging.

undergoing radiation treatment or pregnant and possibly pregnant medical personnel working with ionizing radiation.

The objective of this practice parameter is to assist practitioners in identifying pregnant patients, preventing unnecessary irradiation of pregnant adolescents and women, tailoring examinations to effectively manage radiation dose, and developing strategies to quantify and evaluate the potential effects of radiation delivered to pregnant patients.

Specific goals of this practice parameter are to: 1) outline the body of knowledge about the risks to the conceptus from ionizing radiation, taking into account gestational age at time of exposure, 2) provide guidance on when and how to screen for pregnancy prior to imaging examinations using ionizing radiation, including evaluation of the adolescent and the adult woman, 3) recommend means to control, manage, and practicably minimize radiation dose to pregnant or potentially pregnant patients, and 4) manage dose assessment, risk assessment, and communication issues following exposure of pregnant patients.

II. RADIATION RISKS TO THE FETUS

Potential effects of radiation have been extensively researched, resulting in a broad body of knowledge. As with any body of knowledge, uncertainties exist. The purpose of reviewing radiation research and the underlying uncertainties is to build a knowledge base from which reasonably informed clinical decisions can be reached about the risks of radiological examinations in pregnant or potentially pregnant women. Two issues of risk should be addressed: the likelihood of an adverse outcome, and the severity of the outcome. These should be weighed against the potential benefits to the pregnant patient and to the child.

The following information (Table 1) can be used to build perspective and to develop clinical guidelines in the management of pregnant or potentially pregnant patients. A more complete review is provided in Appendix A.

Table 1: Summary of Suspected In-Utero Induced Deterministic Radiation Effects* [3,4]

Menstrual or Gestational age	**Conception age**	**<50 mGy (<5 rad)**	**50-100 mGy (5 - 10 rad)**	**>100 mGy (>10 rad)**
0 - 2 weeks (0 - 14 days)	Prior to conception	None	None	None
3rd and 4th weeks (15 - 28 days)	1st - 2nd weeks (1 - 14 days)	None	Probably none	Possible spontaneous abortion.
5th - 10th weeks (29 - 70 days)	3rd - 8th weeks (15 - 56 days)	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable.	Possible malformations increasing in likelihood as dose increases.
11th - 17th weeks (71- 119 days)	9th - 15th weeks (57 - 105 days)	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable.	Risk of diminished IQ or of mental retardation, increasing in frequency and severity with increasing dose.
18th - 27th weeks	16th - 25th weeks	None	None	IQ deficits not detectable at

(120 - 189 days)	(106 - 175 days)			diagnostic doses.
>27 weeks (>189 days)	>25 weeks (>175 days)	None	None	None applicable to diagnostic medicine.

*Stochastic risks are suspected, but data are not consistent [5]. For exposure to a newborn child, the lifetime attributable risk of developing cancer is estimated to be 0.4% per 10 mGy (1 rad) dose to the baby. The potential risks in-utero for the second and third trimesters and part of the first trimester may be comparable, but the uncertainties in this estimate are considerable.

III. SCREENING FOR PREGNANCY

The purpose of screening patients for the possibility of pregnancy is to reasonably minimize the number of unexpected exposures of pregnant patients who have entered a potentially vulnerable stage of gestation. In developing a screening policy it should be realized that no screening policy will guarantee 100% detection. The effort made to identify unsuspected pregnancy should be commensurate with the risk of not detecting a pregnancy. Therefore, different screening policies might apply for high-dose procedures versus low-dose ones, such as an interventional procedure in the pelvis versus planar radiography of the pelvis. The vast majority of routine diagnostic studies typically deliver far less than 20 mGy to the uterus. A single-phase acquisition CT of the abdomen including pelvis usually delivers less than 35 mGy [6-8] and typically on the order of 15 to 20 mGy. Because fluoroscopically guided interventional procedures in the pelvis might deliver doses above the teratogenic threshold (~100 mGy), a stricter method to screen for pregnancy might apply than that for a diagnostic procedure.

According to the International Commission on Radiological Protection (ICRP), thousands of pregnant women are exposed to medically indicated ionizing radiation each year [3]. The frequency at which pregnant adolescents and women are unintentionally exposed to ionizing radiation is unknown. One study reported that 1% of women of child-bearing age who underwent abdominal images were unknowingly pregnant in their first trimester [9]. Another study of female trauma patients reported that 2.9% were pregnant and that the unidentified pregnancy rate was 0.3% [10].

A. Examinations of Concern

While pregnancy status is a standard part of medical history, some radiological examinations render exposures to a pregnant uterus that are so low that pregnancy status need not alter the decision to proceed with a medically indicated examination, as long as the beam is properly collimated and the patient is positioned to avoid direct irradiation of the pelvis. Such studies include, but are not limited to:

1. Chest radiography during the first and second trimesters.
2. Extremity radiography or CT (with the possible exception of the hip).
3. Any diagnostic examination of the head or neck.

Chest radiography in the third trimester is likely to expose part of the conceptus to the direct beam, but this too can proceed when needed and when good technique is used because the dose to the conceptus remains very low and the fetus is less radiosensitive than in early pregnancy. Mammography can also be performed safely at any time during pregnancy. Radiation exposure to a conceptus from a properly performed screening mammogram is inconsequential [11]. Thus decisions as to whether to proceed with the examination should be based on clinical circumstances, not radiation risk [12].

Radiologic tests that involve direct exposure of the female pelvis to ionizing radiation require pregnancy status as part of the history. In many cases, especially with inpatients, pregnancy history is often available in the medical record. In some facilities pregnancy status must be documented before an order for radiological examination is accepted. While this information is helpful in screening for pregnant patients, it should not be the sole record of

pregnancy status for women in whom pregnancy has not been diagnosed. Additional assessment of the reproductive status just prior to an examination will help decrease the likelihood of imaging patients with an unsuspected pregnancy. When possible, an interactive electronic order entry system should embed a query about pregnancy status when imaging the abdomen and pelvis of an adolescent girl or woman of child-bearing age.

B. Pregnancy Tests

If the results of a pregnancy test are available, the information should be used with discretion. A positive test indicates the need to follow protocols for patients known to be pregnant, and the information must be brought to the attention of a radiologist prior to proceeding with an examination, except in the case of a life-saving emergency procedure. A negative pregnancy test should not be used by technologists as a reason to forgo standard screening procedures for pregnancy. If a patient does not pass standard verbal or written screening queries about menstrual history or potential for pregnancy, the radiologist should be notified and the date and results of the negative pregnancy test should be included in the notification.

For some procedures that are expected to deliver relatively high doses to a conceptus, a pregnancy test should be obtained within 72 hours prior to commencement of the procedure unless medical exigencies prevent it. These procedures might include any examination that involves an unpredictable duration of fluoroscopy of the pelvis and some abdominal/pelvic CT protocols. Interventional procedures, diagnostic angiography of the pelvis, hysterosalpingography, or standard-dose dual-phase CT protocols of the pelvis are examples. If a patient is found to be pregnant beforehand, the procedure might be modified or canceled so as to reduce the likelihood of direct exposure to the conceptus, or imaging that doesn't use ionizing radiation (e.g., ultrasound or magnetic resonance imaging [MRI]) might be substituted, if appropriate. Additionally, dose monitoring using external monitors, such as unused personnel monitors placed above and below the patient's pelvis, should be considered in order to document the radiation dose, which might be important information in later decisions about medical management and counseling.

Procedures that require a pregnancy test in normal circumstances should be documented in the facility's policies.

C. Questioning the Patient

Prior to an examination, the patient usually can supply adequate information to assess the possibility of pregnancy [3]. All patients of menstrual age (typically ages 12 through 50 years) [3] should be questioned about pregnancy status using a standardized form and/or through direct questioning by the technologist. A standardized form has the advantage of ensuring uniformity in the questioning process, and it can serve as documentation of pregnancy status for the medical record (see Appendix B).

D. Patients Who Are Minors

In most states, a minor is a child under the age of 18. However, the definition and age of a minor may vary depending on state law. Generally, a minor is considered emancipated if married, on active duty in the armed forces, or otherwise living apart from her parents and managing her own finances. Although a parent or guardian is usually responsible for consenting to a minor's health care, in addition to the exceptions mentioned above, all states have specific laws for minors receiving medical treatment. Most states have laws that allow minors to have a pregnancy test without obtaining parental consent or notification. It is unclear, however, if those provisions apply only to situations where the minor is receiving prenatal care. It is important to be familiar with applicable state requirements.

In 1996, the United States Congress passed the Health Insurance Portability and Accountability Act (HIPAA). The resulting regulations contain numerous provisions that affect the patient's health care privacy rights, including those of minors. The regulations recognize that in specific circumstances parents are not necessarily the personal representatives of their minor children (a) when under state law the minor is legally able to consent to her care; (b) when the minor may legally receive the care without the consent of a parent, and the minor or

someone else has consented to the care; or (c) when a parent or guardian assents to a confidential relationship between a health care provider and the minor. In these situations, the radiologic technologists may ask a minor about her pregnancy status prior to a CT scan or other radiologic testing. The minor may exercise most of the same rights as an adult under the regulations, including limiting access by the parent or guardian to the minor's health care information. However, the regulations do defer to state laws, which might negate this aspect for specific states.

The minor is also particularly vulnerable to social and parental pressures that can potentially result in the patient providing misinformation about her reproductive status. One approach to rectify this situation is for the technologist to ask the parent or guardian for permission to prepare the patient in the examination room privately prior to the examination. In the private setting the technologist can either ask the patient the standard questions or ask the patient to fill out the standard form about menstrual history and the potential for pregnancy. If a private preparation is refused, then a backup screening policy may be put in place. The policy may require that a radiologist interview the patient prior to the examination, for example.

If the responses indicate that the patient is or could be pregnant, consent for a pregnancy test should be obtained from the patient and, when appropriate or when required by law, also from the minor's parent or guardian. The order for the pregnancy test can be initiated either by the technologist working under written protocol from the radiologist or by the radiologist. If this consent is refused, the radiologist should be informed of the circumstance before any examination is conducted. It should be documented in the patient's medical record that the patient and/or the guardian declined the pregnancy test.

As an alternative to the above method, the institutional policy might indicate that all minors who have begun menstruating and are not already known to be pregnant are to undergo a pregnancy test prior to any procedure expected to impart a level of radiation to the uterus above a specific dose. Procedures that would meet such a threshold could include pelvic CT and contrast enema, per institutional guideline. The pregnancy test should be ordered by the appropriate clinician. Such a policy has the advantage that it avoids questions that might confuse some minors or that some parents or guardians might find objectionable. It also provides a stricter method of screening for some of the higher dose procedures. If a pregnancy test is refused, this should be documented in the patient's medical record and the radiologist should be notified.

E. Deciding to Proceed with the Examination

If a patient can reliably answer that 1) she cannot be pregnant (for example, she is not sexually active, or she is using an effective form of birth control, or she is biologically incapable of conceiving) and that 2) she had a recent complete menstrual period, then it is reasonable to proceed with a medically indicated diagnostic X-ray test of the abdomen or pelvis. The last complete menstrual period should have occurred within the previous 4 weeks. During this interval diagnostic radiation represents no substantive risk to a conceptus. This conforms to statements previously put forth by the ICRP [3]:

> "Exposure of the embryo in the first two weeks following conception is not likely to result in malformation or fetal death despite the fact that the central nervous system and the heart are beginning to develop in the third week."

> "In order to avoid radiation exposure in the first two weeks post conception, some authors have suggested limiting non-essential examinations to the first 10 days of the menstrual cycle. In most situations, this has not proven to be necessary, based on the radiobiological and dosimetric considerations."

When the patient does not meet these criteria and when the need for the examination is not critically urgent, the technologist should contact the radiologist for further guidance or follow procedural instructions previously defined in a written protocol developed by the radiologist.

If pregnancy is established, the patient should be informed in a timely manner. While it is preferable that the referring physician inform the patient, this might not be practical, and the radiologist should assure that the patient is informed. The patient, referring physician, and radiologist can then make decisions on the optimal patient management and imaging needs.

If the procedure is of a critically urgent nature and pregnancy status cannot be verified, a note should be entered in the patient's record that verification of pregnancy status was waived due to the critically urgent nature of the study [13]. The radiologist should enter a note in the patient's medical record indicating the circumstances of the waiver and the physician who directed the waiver.

IV. IMAGING THE PREGNANT PATIENT

A. Patient Consent

For an imaging examination of the abdomen or pelvis using ionizing radiation, obtaining consent from a patient known to be pregnant is an essential component of providing comprehensive medical care in certain situations. This process requires: 1) a realistic overview of the limited risk to the patient and her developing child from the examination, and 2) the beneficial role of this imaging procedure in maternal or fetal health evaluation. Whether particular institutions use written consent forms or verbal consent, this interaction should be documented in the patient's medical record and in compliance with state law. The written consent form should be retained in the medical record.

The format of the consent may vary based on the clinical situation and local institutional guidelines. Because a detailed quantitative list of risks may be beyond the comprehension of some patients, some institutions prefer a limited consent process in which generalized benefits and risks to the pregnant patient and conceptus/fetus are described (see Appendix C). Other facilities might prefer a uniformly detailed, numerically oriented consent form that lists the radiation risks and potential adverse effects. Regardless of the format, the information communicated should accurately convey the benefits and risks posed by the procedure, in language understandable to the layman.

Conveying information in a positive, rather than negative, format is useful in helping a patient understand an accurate perspective of risk. Rather than telling the patient what the likelihood is that her child could develop cancer later in life, the message with a positive, accurate perspective is that the cancer risk is small and that the likelihood the child will remain healthy with no adverse radiation effects is only slightly different from that of any other child (see Appendix C for sample consent form).

B. Preplanning

The optimal time to modify standard imaging protocols to reduce radiation exposure to the pregnant patient and her conceptus/fetus is well before the radiologic examination is requested. It is best to create written protocols for all imaging of pregnant patients to avoid reactive, nonoptimal protocol adjustments by physicians attempting to reduce radiation exposures. Protocols devised for imaging pregnant patients can be developed to reflect accumulated experience, literature reviews, and respected medical points of view. When a conceptus/fetus dose estimation will likely be necessary following examination of a pregnant patient, the task can be facilitated by documenting relevant technique factors [14] and machine-recorded dose surrogates, e.g., kerma-area product (also known as dose-area product) and cumulative reference-point air kerma [15]. Alternatively, it might be advantageous to estimate dose to the patient's pelvis using personnel monitors that are sometimes set aside for such periodic needs.

The most effective way to limit radiation exposure to the pregnant patient is to discuss with the referring clinician the indications and necessity for any examination. Alternative procedures, including nonionizing imaging procedures such as ultrasound or magnetic resonance imaging, should be considered. If an X-ray or CT scan is deemed necessary, the imaging technologist and the imaging physician should work together to assure the best

benefit/risk for the patient and conceptus. Establishment of guidelines for imaging acute disease processes in pregnant patients can expedite patient evaluation.

An additional method for reducing maternal and fetal radiation exposure is the establishment of multidisciplinary guidelines for imaging pregnant patients. This can limit the number of incremental fetal exposures due to redundant or sequential examinations. Radiation exposure can be significantly reduced by establishing specific low-dose imaging algorithms for common abdominal diseases such as symptomatic urinary tract stone disease or abdominal pain with suspected appendicitis.

The maximal radiation exposure to the fetus occurs with direct maternal abdominal/pelvic radiologic examinations. Patient size variations may allow reduced exposure parameters. While reduction of exposure factors may decrease the absorbed dose to the fetus from a standard maternal diagnostic examination, those changes increase image noise which can reduce image quality. A low-dose limited examination should not lower the dose to the extent that would interfere with obtaining the needed diagnostic information.

Nearly all abdominal radiographic procedures can be modified to reduce radiation exposure to a pregnant patient and her fetus, including reducing the number of images or limiting CT phases through the abdomen/pelvis, such as to a single phase. Further imaging then should be obtained only as defined by the collaborative consultation of the interpreting radiologist and the referring physician. When possible, imaging should be confined to the area of interest to avoid unnecessary uterine exposure.

Improvements in imaging equipment can also contribute to reducing maternal and fetal radiation exposure. Automatic exposure control software on current generation multirow-detector CT (MDCT) scanners limits patient exposure, especially in smaller patients, by instantaneously modifying X-ray tube output to produce diagnostic images at a preset noise level. In the MDCT assessment of abdominal/pelvic trauma, the data from a single phase through the patient's body now can provide both a comprehensive evaluation of the abdominal contents and diagnostic quality reconstructed images of the spine, eliminating the need for a second series or additional images to examine the spine. The emergence of CT scanners with iterative reconstruction techniques has demonstrated the potential for improving image quality and reducing radiation dose in CT relative to the currently used filtered back-projection techniques. Providing lead shielding to wrap the pelvis of the pregnant patient during nonpelvic CT 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 [16].

All protocols for imaging in the pregnant patient should be evaluated for likely dose delivery to a conceptus prior to implementing those protocols. This can determine whether the anticipated savings have been achieved and provide information as to the magnitude of the risk relative to the anticipated benefits.

V. COUNSELING THE PATIENT NOT KNOWN TO BE PREGNANT AT THE TIME OF EXPOSURE

When a woman is discovered to be pregnant after having undergone an imaging procedure using ionizing radiation, counseling should be conducted to give her an objective assessment of and perspective of risk. In the vast majority of circumstances potential risks are very small and, on a scale with normally accepted risks of pregnancy, below the threshold for serious concern. Counseling statements such as, "there is a small chance your child will develop cancer or a birth defect" are honest but unnecessarily alarming because they are void of any indication of the likelihood the child will be healthy. Less alarming and more complete counseling might be, "your child will have nearly the same chances of living a healthy life as any other child under similar medical circumstances because the actual risk that your child might develop cancer from this X-ray exposure is very small. The risk of a birth defect from this X-ray exposure is negligible or nonexistent." If a quantitative evaluation is requested, it might be explained that compared to any other child in similar medical circumstances the chances of being healthy are about or better than 99% of the chances that others have. (Note: this does not mean that the chances of being healthy are better than 99% since, for example, the risk of non-radiation related congenital malformation is 3% or higher.)

Before meaningful risk assessment can take place, certain information should be gathered. No reasonable assessment of risk to a conceptus can be made without knowing 1) the age of the conceptus or fetus at the time of the examination, and 2) a reasonable estimate of the absorbed dose to the conceptus.

In the scenario where the pregnancy is discovered after the X-ray examination is performed, the woman is frequently in an early stage of pregnancy. (One exception to this situation is the adolescent who might not accurately recall her menstrual history, and in whom pregnancy may first be detected after imaging.) Obtaining information about time of conception is important because risk is dependent on gestational age.

A. Radiation Exposure Prior to Conception

For exposures to ionizing radiation prior to conception, genetically heritable risks have not been documented in the human population. The heritable risks to progeny from diagnostic levels of radiation are not a realistic concern [6]. This might seem to contradict the emphasis on the proper use of gonad shielding during examinations. However, those recommendations are provided as a hedge against potential effects in the population as a result of effects in the gene pool [16].

B. Radiation Exposure at Less Than 2 Weeks Postconception

In the first 10 to 14 days after conception, the only potential risk is induced termination of the pregnancy, but doses normally delivered from diagnostic radiographic procedures (less than 50 mGy) have not been associated with such an effect [3,4]. However, in the population of women not exposed to radiation, approximately 50% of all conceptions are not viable and are spontaneously lost [17]. This is exhibited typically as a late or missed menstrual period, and the woman might not have known that she was pregnant. Doses from diagnostic fluoroscopy of the pelvis, CT or from multiple pelvic radiographic (planar) examinations are also not likely to result in induced termination, although the potential for crossing the threshold is the greatest in these scenarios. The threshold for loss of early pregnancy is thought to be at or above 40 mGy [3]. Many cases of exposures involving typical diagnostic radiology procedures during this conceptus development interval have been documented, with no corresponding increase in the rate of fetal anomalies [14]. There is no recommended medical intervention for this situation. Medical advice to the woman should be to seek standard obstetrical care.

C. Radiation Exposure Between 2 Weeks and 15 Weeks Postconception

For pregnancies that are more than 2 weeks and less than 15 weeks postconception, radiation exposure to the conceptus has different risk implications.

1. Radiologic procedures outside the abdomen/ pelvis

   For diagnostic radiologic procedures outside the abdomen/pelvis, including the head and neck, the chest, and all extremities, the only radiation to which the conceptus is exposed is that of scattered radiation, which characteristically results in a very low dose. Only under unusual circumstances does the conceptus incur significant radiation exposure. When standard precautions are taken to avoid direct irradiation of the abdomen/pelvis through the use of patient positioning and X-ray beam collimation, the dose delivered does not pose significant risk to the conceptus.

2. Radiologic procedures of the abdomen/pelvis

   For well-managed, common radiologic examinations of or including the pelvis, the dose to the conceptus is usually well below any threshold dose necessary to induce developmental abnormalities. The only potential risk might be a slight increase in the risk for cancer later in life. Such a risk is very small and under normal circumstances would not be justification for any medical intervention. To provide a comparison of relative risk, due to differences in environmental radiation, pregnant women who live in Denver, Colorado, expose their conceptuses to radiation levels measurably greater than those to which the

conceptuses of women in coastal cities are exposed (by about 0.6 mSv). Such differences theoretically place the conceptuses of the Denver women at an increased risk of about 1 additional cancer in 5,000 babies.

Most radiographic examinations deliver much less than 20 mGy to a conceptus. A dose of 20 mGy represents an additional projected lifetime risk of about 40 additional cancers or less per 5,000 babies or about 0.8%. In other words, there is above 99% likelihood the fetus will be unaffected by the radiation.
For diagnostic fluoroscopy of the abdomen/pelvis, doses may be more substantial, but are not likely to exceed the threshold for induced malformation (more than 100 mGy) in all but exceptional cases. Evaluation of the absorbed dose by a Qualified Medical Physicist, and assessment of the risk based on absorbed dose and gestational age, are recommended before definitive discussion with the patient.

CT studies can confer significant radiation exposure. Currently, the dose under well-managed conditions for a single-phase study of the abdomen/pelvis would be less than 35 mGy and typically about 10 to 25 mGy. This low level of exposure would not warrant interruption of pregnancy. Verification of the dose level by a Qualified Medical Physicist is appropriate.

For women with pregnancies between 2 and 15 weeks postconception who underwent multiple abdominal and pelvic CT examinations that directly expose the conceptus, a radiation dose evaluation by a Qualified Medical Physicist is recommended before definitive counseling of the patient.

For doses under 100 mGy, there are no identifiable induced developmental defects and interruption of pregnancy is not warranted based on radiation effects [18]. At doses above 100 mGy the risks for developmental deficits (e.g., gross malformations, growth retardation, mental retardation, small head size) start to appear but remain low until doses exceed 150 to 200 mGy [3,18].

Any medical consideration of intervention would be based on additional factors associated with the pregnancy. Situations that cumulatively lead to high doses (more than 100 mGy) are very rare and likely entail maternal medical circumstances that further complicate or are complicated by the pregnancy. In these cases, a Qualified Medical Physicist should conduct a radiation dose evaluation. The overall medical picture includes an assessment of other risks associated with normal pregnancies as well as risks specifically associated with the genetic background of the parents and specific medical issues of the pregnant patient. Counseling should take into account all factors of the individual patient's circumstances, including medical, social, and personal factors**.**

D. Radiation Exposure at More Than 15 Weeks Postconception

Potential risks to the developing central nervous system for fetuses that are more than 15 weeks postconception exist only at high doses (e.g., more than 200 mGy) well beyond those commonly delivered in multiple diagnostic examinations. During this period the only potential risk to the fetus from diagnostic doses of radiation is induced cancer. The cancer risk from well-managed radiologic procedures is too small to warrant any medical intervention. The lifetime attributed cancer incidence for a conceptus/fetal dose of 50 mGy in this gestational period is roughly estimated at 2%, but an accurate quantification is impossible [18,19]. Conversely there is about a 98% likelihood the child will be unaffected by the radiation. Most diagnostic examinations result in much less dose to the conceptus/fetus. Abdominal/pelvic CT imaging, which is one of the higher dose examinations, typically delivers 10 to 25 mGy.

VI. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings. Pregnancy status and the method used to determine it should be included as part of the patient's medical record in the radiology information system.

If a fetal dose estimate is necessary, it should be performed by a Qualified Medical Physicist and appropriately documented.

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (http://www.acr.org/guidelines).

Equipment performance monitoring should be in accordance with the ACR-AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluorscopic Equipment and the ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment.

To provide foreknowledge of the potential radiation doses delivered, an evaluation of the likely doses delivered to the conceptus of a patient in early pregnancy by protocols involving diagnostic examination of the abdomen/pelvis should be performed to assure that the delivered dose is within acceptable standards for that type of examination. For example, the conceptus dose from a CT protocol of the pelvis should not exceed 50 mGy and preferably should be below 30 mGy. (Note: testing a protocol requires that the cumulative dose from all exposures of the protocol be assessed, not just that from a single view, single procedure, or single phase of that protocol.)

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APPENDIX A

Potential Radiation Effects to a Conceptus/Fetus

Radiation effects can be classified into 2 categories, deterministic and stochastic.

A. Deterministic Effects

Deterministic effects are observed only if relatively large doses are applied and multiple cells are involved. Deterministic effects are the result of cell damage and do not occur at doses below certain threshold levels that are determined by factors such as type of effect and the developmental stage of the organism. The severity of deterministic effects increases with increased radiation dose above the threshold. An example of a deterministic

effect is radiation-induced malformations of a developing organ. Another example is skin injury, with severities ranging from skin erythema to ulceration and necrosis.

While exceeding a threshold dose is necessary to incur a deterministic effect, available data do not always allow for a clear identification of the value for that threshold. Furthermore, for some effects thought to be deterministic, the existence of a threshold dose cannot even be established. These uncertainties arise due to limited available data involving small numbers of human subjects. Therefore, caution should be exercised so as to avoid unwarranted conclusions based on limited and imprecise data.

B. Stochastic Effects

Stochastic effects can result from induced changes in single cells and can potentially result in neoplasia or in changes to reproductive genes. In contrast to deterministic effects, the severity of a stochastic effect does not increase as the radiation dose increases. Stochastic effects are believed to be possible at any level of radiation exposure, with the likelihood increasing as dose increases.

C. Conceptus Age at Time of Exposure

When addressing risk to the ovum prior to and during ovulation, to the conceptus after fertilization, and to the developing fetus prior to birth, the type and the severity of potential deterministic effects and the likelihood of stochastic effects vary with the stage at the time of exposure and with the dose of radiation delivered to the uterus [20]. To adequately assess the benefit versus risk, the radiologist who is responsible for conducting a given examination should be aware of the potential vulnerabilities of the ovum or conceptus and the level of risk involved for a given patient undergoing a specific examination. This information should be founded on explicit existing experimental and clinical data and on well-informed recommendations. During discussions between the patient and the radiologist, this information can be used to assuage any alarm that might arise from misconceptions related to relative risk during pregnancy. It can also be used in discussions between the referring physician and the radiologist when assessing the proper course of action for patients. The potential risks are summarized in the following sections and are outlined in Table 1.

1. The weeks prior to conception

   During the preconception interval from last menstruation to just prior to conception, the ovum is potentially susceptible to the genetic effects of radiation, a stochastic effect. While heritable effects have been demonstrated in experiments involving large doses of radiation to populations of mice and insects, the results of these investigations demonstrate that the likelihood of inducing a harmful effect from a dose of radiation typical of that from imaging is so small as to be undetectable in human populations. In fact no statistically significant heritable genetic effects have ever been observed in a human population, not even in those exposed to atomic-bomb radiation (mean dose approximately 200 mGy) or to radiation received in radiation accidents or as a result of medical radiation treatment. Any potential adverse effect to human progeny resulting from irradiation during this preconception interval is therefore unlikely and has not been documented at levels of imaging examinations.

2. Conception to implantation and pre-organogenesis

   For about 2 weeks after conception, the only established deterministic effect of radiation is induced abortion [3]. Much of the experimental data to assess this effect has involved rodents. While doses of 1,000 mGy (1 Gy) or more result in a high rate of lethality, the likelihood of inducing this effect at doses of less than 50 mGy (0.05 Gy) (i.e., at doses in the upper range of imaging radiological examinations) is unlikely and not distinguishable from zero [18]. Reported data for animal experiments suggest that the risk of embryonic loss at this stage increases incrementally between 0.5% and 1% per 10 mGy. Surviving conceptuses develop normally. If any potential for observable teratogenic effects in surviving embryos exists, these effects have not been observed at doses typical of any imaging examination. Because of this

"all-or-none" phenomenon, this stage of gestation is sometimes called the period of the "all-or-none effect."

3. Organogenesis

The period of organogenesis is one in which there is increased radiosensitivity to potential teratogenic effects of ionizing radiation. These are deterministic effects and therefore do not occur unless the dose to the embryo exceeds the threshold necessary to induce the effect. Organogenesis occurs after implantation and throughout the remainder of gestation but can be divided into 4 distinct intervals with different vulnerabilities.

a. Embryonic stage or major organogenesis (~15 to 56 days after conception)
In the embryonic stage, beginning near the end of the second postconception week and extending through the eighth week postconception (about 4 to 10 weeks menstrual age), major organogenesis occurs. This period is subject to 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 about 100 to 200 mGy [3]. At doses in the vicinity of the threshold dose, the likelihood of observing an induced effect is relatively small. The type of vulnerability depends on the timing between radiation delivery and the developmental stage of differentiated and differentiating cells. The likelihood of inducing an effect and its severity increase as dose increases beyond the threshold.

A finding of small head circumference, without cognitive effects, has also been reported in atomic-bomb survivors exposed during the organogenesis stage of intrauterine life [21]. There was no discernible threshold for this effect. The mechanism for such an effect is unclear. The finding has been interpreted as a result of generalized growth retardation. For the dose ranges of diagnostic examinations (less than 0.1 Gy), the effect, if it truly exists, is subtle, only identified under statistical analysis of physical characteristics in a study population, and the children have no cognitive or behavioral abnormalities [22].

b. Early fetal stage

In the early fetal stage, after the eighth and through the 15th week postconception (after the 10th and through the 17th weeks menstrual age or approximately days 56 to 105 postconception), the central nervous system (CNS) is very radiosensitive, due to the high neuronal mitotic rate and organized neuronal migration occurring during this time [21]. Radiation-induced CNS effects, particularly mental retardation (defined as inability to care for oneself or to make simple calculations or conversation), are among the most frequently occurring, identified teratogenic effects associated with intrauterine radiation exposure during this stage of development. A threshold dose for mental retardation has been estimated at 60 to 310 mGy, using the Japanese DS86 radiation data [23]. The broad range of the threshold estimate is a consequence of the very small sample size at this radiation level. Further, this threshold range is determined on the basis of one model for statistical analysis, and other higher thresholds are predicted by other models. The lowest clinically documented dose to produce severe mental retardation is 610 mGy. Thus, the putative threshold is an extrapolation from data observed at higher doses. The absolute risk of mental retardation is estimated at 44% for 1000 mGy exposure. The threshold range for CNS effects is significantly higher than the range of doses delivered from single well-managed imaging examinations (i.e., less than 50 mGy).

Dose-dependent radiation-mediated deficits in Intelligence Quotient (IQ) have also been observed when irradiation occurs in this interval [21]. No effects on IQ have been observed below 100 mGy**.** Beyond the dose of 100 mGy, the decline in IQ is estimated at 25 to 29 points per 1,000 mGy.

During the fetal period, radiation exposure is also associated with growth retardation, which tends to persist beyond birth into adulthood only when doses are well beyond those normally delivered by imaging radiological examinations.

c. Midfetal stage

Beginning with the 16th and extending through the 25th week postconception**,** the risk for mental retardation remains, but is less pronounced than in the earlier 8 to 15 week stage. It is estimated that the threshold dose for severe mental retardation is approximately 250 to 280 mGy. The decline in IQ is also less than for the early fetal stage. Beyond the dose of 100 mGy, the decline is estimated at 13 to 25 points per 1,000 mGy. The threshold dose during this period for other types of malformation is about 1,000 mGy.

d. Late fetal stage

After the 25th postconception week of pregnancy, exceptionally high doses of radiation are required to induce deterministic effects. For this stage of development the risks associated with medical imaging are stochastic risks, principally the potential for induced neoplasia. These are discussed below.

D. Risk of Cancer Induced by Imaging Procedures Using Ionizing Radiation

The relative risk of cancer development secondary to in-utero exposure has been debated in the scientific literature for years [19]. From studies on the offspring of mothers who received diagnostic pelvic radiation during pregnancy, there appears to be an increased risk of childhood leukemia with exposures as low as 10 mGy, although firmly establishing cause and effect has proven to be difficult. The findings in offspring of Japanese atomic bomb survivors are not consistent with the case-control studies of medical in-utero irradiation. After an exposure of 10 mGy to a newborn, the lifetime risk of developing childhood malignancy, particularly leukemia, might increase from a background rate of about 0.2% to 0.3% to about 0.3% to 0.7%, where the estimate varies depending on the methods used to assess the risk from statistical data. The lifetime risk of developing radiation-induced cancer from in-utero exposure has been estimated to be similar, but the uncertainties in the estimate are so great that it is only possible to say that doses on the order of 10 mGy are associated with a discernable increase in the risk of childhood cancer. The relationship of vulnerability to gestational age is additionally uncertain, but, within the uncertainties in the estimates of risk, it is assessed to be relatively constant from the beginning of major organogenesis to term.

APPENDIX B

Sample Policy and Form Regarding Pregnancy Determination

All technologists, prior to performing an abdominal or hip X-ray or abdominal or pelvic CT procedure, should query female patients of reproductive potential about the possibility of pregnancy. The following or a similar form is suggested, to be filled out before making any exposure and then entered into the medical record. The examination should proceed only if the patient's last complete menstrual period started less than 4 weeks prior to the examination date and if the patient responds "no" to the second question. If either condition is not met, a radiologist should be notified before proceeding with the study or consent should be acquired for a pregnancy test. The technologist should proceed according to verbal or written policy instructions of the radiologist. If a required pregnancy test is refused, the radiologist should provide instructions on how to proceed.

This form and the one in Appendix C are provided as EXAMPLES ONLY. They are not intended to be used without first consulting with legal counsel regarding your facility, local or state law requirements.

PRE-EXAMINATION PREGNANCY DETERMINATION

PATIENT: _____ **MRN:** _____
DATE: _____ **TIME:**
TECHNOLOGIST: _____

Pregnancy Check

For female patients of reproductive age (postmenarche to menopause [e.g., age 12 to 50]), indicate the patient's response to the following 2 questions:

1. What was the first day of your last complete menstrual period?

Month _____ Day _____ Year _____

2. To the best of your knowledge, are you pregnant (or do you think you could be)?

Yes _____ No _____ Possibly _____

Patient/guardian signature: _____ Date: _____

Pregnancy testing required (per department guideline)? Yes _____ No _____

Type: urine serum

Pregnancy Test Performed in Diagnostic Imaging

Verbal consent to test from: ____Patient ____Guardian (if appropriate)
Results: ____Negative ____Positive
Testing tech/nurse initials:_____

Pregnancy Test Performed Outside the Radiology Practice

Test date: _____
Results: ____Negative ____Positive

Source of results: _____

APPENDIX C

Sample Consent Form for Radiologic Procedure in Female Patients Known to be Pregnant

(This informed consent form applies only to single examination diagnostic radiographic studies and single-phase abdominal-pelvic CT studies.)

INFORMED CONSENT FOR ABDOMINAL OR PELVIC X-RAY EXAMINATION OF PREGNANT OR POTENTIALLY PREGNANT PATIENT

PATIENT NAME: _____ MRN: _____
DATE: _____ TIME: _____

To the patient:

You are scheduled for an X-ray examination of your body. You and your unborn child will be exposed to X-rays. The risk to you is very small. The examination might slightly increase the possibility of cancer later in the child's life, but the actual potential for a healthy life is very nearly the same as that of other children in circumstances similar to yours but who are not provided the benefit of this medical examination. The examination does not add to risks for birth defects or miscarriage. Your physician has considered the risks associated with this examination and believes it is in your and your child's best interests to proceed. Any questions you have regarding this examination should be directed to the radiologist.

Radiologist or referring physician: _____ Date: _____

I, _____, have read and fully understand the above and hereby give my consent to have an X-ray procedure performed. I have been informed of the estimated risks to my embryo or fetus.
Patient/guardian signature: _____ Date: _____

This signed informed consent form shall be placed in the patient's medical record.

APPENDIX D

Pregnancy Screening

A. General Criteria
   1. Female patients' age ≥12 to 50 years will be screened for pregnancy.
   2. Screening of female patients <12 will be conducted at the discretion of the patient's care providers.

B. Policy Exceptions

This policy does not apply to:
   1. Emergency procedures and examinations.
   2. Female patients for whom pregnancy is anatomically impossible.
   3. Female patients receiving hCG (human chorionic gonadotropin) therapy.
   4. Patients undergoing diagnostic/therapeutic oncology procedures (e.g., bone marrow biopsy, lumbar puncture, intrathecal chemotherapy under anesthesia) in the Hematology Oncology Clinic.

C. Defining Procedures and Examinations Subject to Pregnancy Screening

   1. Radiologic procedures that pose a substantial risk to pregnancy or fetus
      Based on the *American College of Radiology's Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation,* the risks of diagnostic exams that could potentially harm the fetus or a pregnancy are:
      a. Negligible
         These include all examinations that do not directly involve exposure of the pelvis (other than Interventional Radiology).
      b. Low
         1) No probable (i.e., deterministic) radiation effect; but a theoretical (i.e., stochastic) risk.
         2) These include abdomen/pelvic images and single phase abdominal/pelvic CT.
      c. Substantial
         1) Examinations with possible deterministic radiation effects during some portions of the pregnancy.
         2) In general, these include dual phase abdominal and/or pelvic CT scans, and any examination that involves an unpredictable duration of fluoroscopy including all IR procedures.
      d. See APPENDIX E: Imaging Examinations Requiring Pregnancy Testing.

2. Elective surgical procedures performed in the perioperative area
   Note: Because of the operational complexity of limiting screening by laboratory test only to those procedures believed to pose a substantial risk (such as abdominal and pelvic procedures and procedures involving radiation exposure due to use of C arm), all females age ≥12 scheduled for elective procedures in the perioperative area (See section I.A.1.a-f above) will be screened for pregnancy by urine or serum test.

D. Pregnancy Screening Procedure

1. Negligible risk
   For negligible risk examinations (e.g., chest or extremity imaging), the pregnancy screening is unnecessary.
2. Low risk – Prior to the radiology examination involving ionizing radiation categorized as low risk to a pregnancy or fetus:
   a. The patient should be asked – *is there any possibility you could be pregnant?*
   b. This question should be posed when the patient is by herself, outside of hearing of those accompanying her,
   c. Document response in the patient's chart.
   d. If the patient response is other than no or is thought to be unreliable for any reason, an hCG test should be performed.

3. Substantial risk
   a. Examinations with possible deterministic radiation effects during some portions of the pregnancy, i.e., dual phase abdominal and/or pelvic CT, and any examination that involves an unpredictable duration of fluoroscopy including IR procedures.
   b. Obtain a urine hCG test prior to examination.
   c. The results are valid for seven days or the length of an inpatient stay.
   d. If pregnancy testing is refused, contact the attending physician and radiologist. Subsequent performance of the examination/procedure will be at the discretion of the attending physician or radiologist.

E. Positive Pregnancy Test Result

Note: The following may vary by jurisdiction, but in general, females 14 years of age and older may have the right to control decisions regarding their sexuality/reproductive rights and therefore have a legal right to confidentiality. If so, test results cannot be disclosed to parents/guardians without the patient's permission.

The ordering provider and radiologist may recommend to the patient, parent or guardian that the imaging examination may still be done; for example:

1. Low exposure examinations
   The benefit of providing the diagnostic imaging study outweighs the very low potential risk to the fetus during a well shielded patient examination.
2. Examinations categorized as substantial risk
   Risk vs. benefit dialogue provides rationale to move forward with the examination (i.e., no other study provides the needed information and it is not prudent to delay until after childbirth).

APPENDIX E

Substantial Risk Imaging Examinations For Which Pregnancy Testing Is Recommended

- Diagnostic, Interventional, or Intra-operative procedures involving fluoroscopy
- Multiphase CT~~,~~ or CTA of abdomen, pelvis, or both

- CT-guided interventional procedures of the abdomen

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*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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