

Title: <i>Radiology and the Pregnant Patient</i>			
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Endorsed: N/A Date	Endorsed: <i>Kristen Porter</i> 3/28/21 Kristin Porter, MD, PhD Section Chief MRI Date	Pages 1 of 4	
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PURPOSE: To establish guidelines for the care of the pregnant patient in the Radiology Department

SCOPE: This policy applies to all UAB Medicine Radiology Departments.

POLICY STATEMENT: It is our belief that pregnant patients receiving diagnostic and therapeutic radiological exams and procedures should receive the highest quality medical and technical services possible with minimum risk of harm to the mother and/or fetus.

ASSOCIATED INFORMATION:

A. **Definitions:**

1. **Ionizing Radiation:** X-ray radiation of sufficient energy to raise the possibility of causing harm to a fetus.

- B. **Background Information:** Most radiologic examinations not involving the abdomen and/or pelvic areas can safely be performed on patients that are pregnant.

POLICY:

- A. **Procedures Not Requiring Assessing Pregnancy Status.** No screening policy will guarantee 100% detection. The vast majority of routine diagnostic studies deliver less than 20 mGy to the uterus, and single-phase acquisition computed tomography (CT) of the abdomen including the pelvis usually delivers less than 35 mGy. Fluoroscopically guided interventional procedures in the pelvis might deliver doses above the teratogenic threshold (~100 mGy).
- B. Because of the very low dose to a fetus for some examinations, no special precautions other than good collimation and radiographic technique need to be taken with the following examinations:
 1. Chest radiography,
 2. extremity radiography
 3. Head radiography,
 4. Mammography
 5. Abdominal radiography (even if the pelvis is included)
 6. Other examinations that do not directly expose the pelvis.
- C. **Procedures Requiring Assessing Pregnancy Status and if Positive Informed Consent.**
 1. Abdominal/pelvic CT
 2. Intravenous urogram
 3. Lumbosacral spine radiographic series that includes multiple projections
 4. Fluoroscopy of the pelvis of unpredictable duration
 5. Diagnostic angiography of the pelvis
- D. **Procedures Requiring Assessing Pregnancy Status and a consent form even if negative.**
 1. Interventional procedures including the pelvis
 2. Hysterosalpingography

- E. **Assessing Pregnancy Status:** For patients who are in reproductive age (post menarche to menopause, e.g., age 12-50), the technologist should:
1. Ascertain by review of the medical record if a urine pregnancy test result is present within the last 72 hours or if there is a pregnancy test during the patient's **current** hospital admission.
 - a. If there is a negative test result, the technologist shall proceed with the exam.
 - b. If the patient has left the hospital or been discharged, for any amount of time, there must be another pregnancy test completed before the technologist can proceed.
 2. If no pregnancy test result is available, ask the following questions and document the responses in Technical Comments:
 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 is there any possibility that you could be)? Yes No Possibly/Not sure
 3. If the answer to Question 1 is greater than 4 weeks OR the answer to Question 2 is "Yes" or "Possibly/Not sure", the technologist should consult the radiologist, if the examination is not emergent.
 3. If the patient is of childbearing age (12-50) and has altered mental status and there is a possibility of pregnancy, a urine pregnancy test should be obtained.
 - a. The radiologist may be consulted to determine if this is appropriate.
 4. For patients with a positive pregnancy test, except in the case of a life-saving emergency procedure as determined by the referring practitioner, a radiologist should be informed prior to proceeding with an examination.
 - a. If the radiographic procedure is performed, the appropriate protocol to minimize radiation to the fetus should be employed.
- F. **Minors Who are or May be Pregnant:**
1. A minor age 14-18, or an emancipated minor, may provide consent for a medical procedure.
 - a. For a minor or emancipated minor, the questions in the section above should not be asked in the presence of the parents.
 - b. The minor has HIPAA rights that require you not to communicate the answers to these questions to the parents.
 - c. Therefore, it is prudent to indicate to the parents before asking these questions that the patient (minor) will be taken into the scanner room and that the parents are to stay in an appropriate waiting area.
 2. Results of a pregnancy test on a minor CANNOT be communicated to the parents without the patient's written consent, because of HIPAA regulations.
 - a. If the pregnancy test is positive, informed consent is required to perform the examination.
 3. If obtaining consent from a minor who has a positive pregnancy test without the knowledge of the parent or guardian, consent should be obtained from the minor alone. However, it should be explained to the minor that a bill will be arriving at her home and that the parents may learn of the pregnancy from that.
 - a. If the minor desires the parents to be involved in the informed consent process, the minor is required to sign an additional consent for disclosure of pregnancy status.
 4. If both the patient and the parent are involved in the consent process and there is a disagreement about consent between them, call Risk Management at 934-5382 or the on-call risk management person through paging.
 - a. Legally, only the minor's consent is required, but a lawsuit might stem from such a disagreement. Because of the sensitive nature of pregnancy in

minors, complete documentation should be placed in the radiology report or the medical record.

G. **Informed Consent:** When it is determined that informed consent is required, a radiologist or radiology resident who is familiar with the risks discussed in this document must obtain such consent.

1. It is not sufficient for a referring clinical attending or resident to obtain informed consent, because they are unlikely to be familiar with the details of the risks of radiation and IV contrast administration to a fetus.

2. The clinical service should be instructed specifically not to obtain informed consent.

Given that there are no available data to suggest any potential harm to the fetus from exposure to iodinated contrast medium via maternal IV or intra-arterial injection, the American College of Radiology does not recommend routine screening for pregnancy prior to iodinated contrast media use. This recommendation is also supported by the FDA classification of most iodinated contrast agents as category B medications. Therefore, informed consent with not be required for the use of iodinated IV contrast in pregnancy.

3. **Informed consent must be obtained in the following situation:**

The patient's pregnancy status requires informed consent for designated radiographic procedures. The consent form used can be found on the SCR Website and it should clearly state "Risks of Ionizing Radiation Exposure" were discussed. This form should be placed in the medical record after completion.

a. Technical factors will be reduced, if possible and required, to provide the lowest exposure to the fetus consistent with a diagnostic examination. Certain CT units use dose modulation to reduce the radiation exposure to the lowest level appropriate.

b. Decisions regarding the use of contrast agents (oral, IV, or rectal) on pregnant patients will be made by the radiologist on a case by case basis.

c. Some areas within the radiology department have unique concerns regarding the pregnant patient.

d. In the case of a life-threatening emergency, a chief resident, fellow, or attending in the Departments of Surgery, Emergency Medicine, or Neurology; may determine that the patient's condition is such that the exam cannot safely be delayed until a pregnancy status and consent is obtained. In this situation, the physician will authorize the technologist to proceed with the exam. The technologist will notify the radiologist and will document in Technical comments, "Labs deferred per emergency order of Dr. _", noting the name of the requesting physician.

4. **Computed Tomography (CT, CAT Scan):**

a. CT scans involving the patient's abdomen and/or pelvis (CT abdomen, CT Pelvis, CT lumbar spine, etc.) must be approved by the radiologist and informed consent must be obtained according to the guidelines above, unless the requesting clinician declares this a life-threatening emergency.

b. CT exams not involving direct exposure to the patient's abdomen and/or pelvis (CT brain, CT C-spine, CT Chest, etc.) can be performed without the approval of the radiologist or informed consent. Lead shielding may be used over the pelvis to minimize scattered radiation to the fetus.

5. **Nuclear Medicine:**

a. Nuclear medicine scans are discouraged on pregnant patients due to the use of radiopharmaceuticals.

b. Non-emergent studies on pregnant patients are rescheduled if possible.

- c. A nuclear medicine physician or radiologist at the attending or resident level must approve any nuclear medicine study on a pregnant patient.
 - d. Informed consent for these studies must be obtained unless the examination is urgent or emergent.
6. **Ultrasound:**
- a. As there is no ionizing radiation associated with this modality, no consent specific to pregnancy is obtained. However, endovaginal exams on pregnant patients are discouraged after the 13th or 14th week of pregnancy. This is to prevent potential injuries to the fetus from the placement of the endovaginal probe itself.
7. **Magnetic Resonance Imaging (MRI):**
- a. Consent will not be required for a non-contrast MRI in the pregnant patient, however, a radiologist or radiology resident must discuss the case with the referring doctor to confirm the appropriateness of the exam and the lack of viable alternatives. The following documentation is to be entered into the MR report:

“To date no delayed sequela from routine MR examinations performed during any trimester of pregnancy has been documented, and it is expected that the potential risk for any delayed sequela is extremely small or non-existent. However, according to the FDA, the safety of MR procedures during pregnancy has not been definitively proven, and should only be performed when medically necessary. Dr. [] discussed the theoretical risks and available alternatives with the patient’s ordering clinician, Dr. [], and both agreed to proceed with the MR exam. Gadolinium (MRI contrast agent) should not typically be administered to pregnant patients, as studies suggest it can adversely affect the fetus.”
 - b. Gadolinium (MRI contrast agent) is generally not given in cases involving pregnancy. On a special case-by-case basis, an attending Radiologist may prescribe gadolinium based contrast agents. This should be accompanied with a well-documented risk-benefit analysis that defends the decision to administer contrast. This decision should only be made if there is an overwhelming potential benefit to the patient or fetus outweighing the risk of long-term exposure of the fetus to free gadolinium ions. The patient will be counseled and written informed consent obtained and placed in the EMR.

...REFERENCES:		
ACR practice guideline for imaging pregnant or potentially pregnant adolescents and women with ionizing radiation, 2008.		
Manual on Contrast Media from the American College of Radiology, Version 7, 2010.		
McCollough CH, Schueler BA, Atwell TD, et al. Radiation exposure and pregnancy: when should we be concerned? <i>Radiographics</i> 2007;27:909-917; discussion 917-908		
ACR Guidance Document on MR Safe Practice, 2013.		
Association Between MRI Exposure During Pregnancy and Fetal and Child Outcomes, 2016		
Manual on Contrast Media from the American College of Radiology, Version 10.3, 2017		
CMS:	N/A	TJCH: N/A
Cross-References (CR):		
<i>*Informed consent (CR)</i>		

ATTACHMENTS: None

INTERDISCIPLINARY COLLABORATION

None

Physician / Medical Committees

Endorsement Date

None

Committees / Councils

Endorsement Date

None

Hospital Department(s)

Endorsement Date

Tracking Record

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REVISIONS:	Consistent with the Joint Commission Standards, this policy is to be reviewed at least every 3 years and/or as practice changes.
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