
Diagnostic Services – Radiology

DS-R-05.52

SUBJECT/TITLE: PREGNANT OR POSSIBLY PREGNANT PATIENTS

PURPOSE: To provide an appropriate policy for handling pregnant or possibly pregnant patients requiring diagnostic examinations that involve ionizing radiation.

DEFINITION: None

BACKGROUND:

Available scientific data shows that the health risks associated with radiation to the fetus are small for the dose levels delivered by most diagnostic procedures. These risks can be classified as deterministic or stochastic. Deterministic effects are usually associated with a radiation dose threshold and the severity the effect increases with the radiation dose. Teratogenic effects are deterministic. Stochastic effects are considered to have no dose threshold and are characterized as random, all or nothing events. Although the severity of a stochastic effect is independent of the radiation dose, the risk (the likelihood that an effect will be expressed) is considered to increase linearly with radiation dose. The primary stochastic effect from radiation exposure is cancer and there is a lag time of 3 to 30 years before the cancer develops.

Most of the evidence for the effects of radiation on the fetus comes from atomic bomb survivor investigations and from animal experiments. From this information, it is known that the gestational age of the fetus is an important factor with the highest susceptibility occurring during organogenesis and neuronal development during the 3rd to 15th week. Extrapolations from high dose exposures puts the risk of radiation induced teratogenic effects at the level of 0.5-1%/10 mSv (0.5-1%/1 rem) (1-4). However, no proven effects have been observed for total radiation doses to the fetus less than 50 mSv (5 rem) at any gestational age (5, 6). The natural incidence of congenital defects when the fetus has not been exposed to radiation is estimated at 3-5% (7).

The risk of radiation induced cancer for the fetus is about the same as that for early childhood and is about 3 - 4 times higher than that of a 30 year old adult. However, the absolute risk of childhood cancer is quite low so that the overall risk of cancer despite the radiation exposure is still low. The chance that a fetus exposed to a 50 mSv (5 rem) radiation dose will NOT develop cancer is 99.7% (i.e. 0.3% cancer risk) while it is 99.93% for an unexposed fetus (0.07% cancer risk).

The radiation dose to the fetus from diagnostic procedures when the fetus is not in the x-ray beam is approximately the same as the daily background radiation dose received by the average American (approximately 0.01 mSv or 0.001 rem). Diagnostic studies in which the fetus is in the x-ray beam result in substantially higher doses. Examinations such as KUB, flat and upright views of the abdomen, lumbosacral spine examination and limited intravenous urogram typically deliver less than 10 mSv (1 rem) to the fetus (5)(See Appendix A). Examinations where the fetus can receive a radiation dose greater than 10 mSv (1 rem) include barium enema, CT studies of the abdomen and pelvis, and diagnostic or interventional procedures involving lengthy fluoroscopy with multiple filming of the pelvis and abdomen(5) (See Appendices B & C). It is important to keep in mind that the average background radiation in the U.S.A. is approximately 3 mSv/year (0.3 rem/year and the maximum allowable dose to the fetus of declared pregnant radiation workers is 5 mSv (0.5 rem) (10 CFR 20.1208).

The health risks associated with radiation to the fetus are cumulative. As a result, previous exposures to radiation during the pregnancy must be considered before new procedures are initiated.

Our primary goal is to protect the well being of the mother because her well being preserves the life of the fetus also. In achieving this goal, every reasonable attempt should be made at keeping the radiation dose to the fetus to a minimum when a diagnostic radiological exam is required to manage the health of the mother.

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POLICY:

- I. As stated in the Hospital Formulary, the Radiology Department should be notified when a patient is known or thought to be pregnant. This information should be entered electronically order on the order entry screen.
- II. Before every imaging or interventional procedure, the technologist should inquire from all female patients, in the child bearing age, as to whether she is, or may possibly be pregnant. If the patient is too sick to answer questions, the technologist should ask the family or treating physician. If all attempts do not result in a clear answer, if time permits a pregnancy test should be performed.
- III. If a patient responds that she is or may be pregnant, the radiologist assigned or scheduled for that particular service should always be contacted.

There are four possible scenarios to be considered:

- A. For examinations above the abdomen or below the hips, the patient should be assured that there is no scientific evidence that the examination will result in any detectable harm to the fetus. Shielding of the abdomen and pelvis with lead aprons should be used if feasible.
- B. For examinations where the fetus is in the direct beam and the estimated dose calculated from Appendix A, B or C is less than 10 mSv (1 rem), the radiologist should discuss the benefits versus the risks of the procedure with

the referring physician. Imaging techniques not involving ionizing radiation should be considered. If the examination is judged to be appropriate and necessary, the clinician responsible for the care of the patient will write a note in the chart stating that the imaging study is indicated for the management of the patient. The radiologist will explain the procedure to the patient with the assurance that the radiation dose will be kept as low as possible consistent with obtaining the required diagnostic information.

- C. For examinations where the fetus is in the direct beam and the estimated dose calculated from Appendix A, B or C is greater than 10 mSv but less than 50 mSv (1 rem but less than 5 rems), the radiologist and referring physician should work together to find options that will provide the needed information without the use of ionizing radiation such as ultrasound or MRI. If the radiological procedure is deemed essential, the patient should be involved in the decision to proceed with the examination. She should be informed by the radiologist of the risks and benefits of the diagnostic test or interventional procedure. The patient will be asked to sign an informed consent form (Appendix D). The clinician responsible for the care of the patient will write a note in the chart stating that the test is indicated for the management of the patient.
- D. For the rare occasion where the estimated dose to the fetus exceeds 50 mSv (5 rem), a formal calculation of the dose will be conducted by a radiation physicist (8). The patient and/or family should be counseled about the risks to the fetus. The referring physician, the radiologist and radiation physicist should all write notes in the patient's chart explaining the circumstances and medical justification for the examination or procedure. The patient will be asked to sign an informed consent form (Appendix E).

IV. Technical Principles to be Followed in every Pregnant Patient A. Limit exposures to those that are essential for a diagnosis.

- A. Use precise collimation and pelvic shielding whenever possible. Using collimation to limit the field of view is more effective in reducing dose than using lead shielding.
- B. Limit fluoroscopy to short bursts as needed. Pulsed fluoroscopy should be used if it will not limit the diagnostic quality of the exam. All fluoroscopic procedures must be timed and a written record of the fluoroscopy time, kVp and mA must be kept.
- C. Every effort must be made to eliminate repeat exposures resulting from technical errors. Repeat exposures should not be performed without consulting with the radiologist responsible for the patient.
- D. For CT examinations of the abdomen and pelvis, the radiation dose can most effectively be reduced by reducing the quality mAs with the tube current

modulation (Care Dose) applied. If the diagnostic information required to manage the patient does not require thin slices, the mAs can be reduced more if the slice thickness is increased to 5 mm.

- E. The average power setting for ultrasound studies in the vicinity of the fetus must be kept to a minimum consistent with achieving a diagnostic study.
- F. All contrast media should be used with caution in pregnant women.

V. Emergent Imaging

- A. In emergent situations, time may not permit time to contact legal representative or placing a phone call for consent. For patients who are critically ill or have life-threatening conditions and imaging is deemed medically necessary, imaging will be performed without a consent. Medical necessity will be documented in the radiology report.

Appendix A

Estimated fetal dose for a single radiographic view of the abdomen or pelvis with the fetus in the field of view.

Patient Thickness(cm)	Estimated Dose in mSv (rem)	
	AP View	Lateral View
14-15	1 (0.1)	0.7 (0.07)
16-19	1.5 (0.15)	1 (0.10)
20-23	2.1 (0.21)	1.5 (0.15)
24-26	3.1 (0.31)	2 (0.2)
27-30	4.3 (0.43)	3 (0.3)
31-34	5.6 (0.56)	4 (0.4)

Appendix B

Estimated fetal dose for fluoroscopy of the abdomen or pelvis with the fetus in the field of view.

7 mSv/minute (0.7 rem/minute) (80 kVp and 2 mA)

This is based on measured values of 2.5 R/min at the tabletop of the fluoroscopic unit.

Appendix C

Estimated fetal dose for CT of the abdomen or pelvis with the fetus in the field

For routine abdomen/pelvis CT procedure, the kVp is 120 kVp with an effective mAs of 250. Dose modulation (Care Dose) is used. The estimated fetal dose when the fetus is in the field of view of the scan is approximately **20 mSv (2.0 rem)**. The radiation dose can be reduced by reducing the quality mAs, but this should be done with caution so that the diagnostic information required for the management of the patient is not compromised.

References

1. Miller RW, Blot WJ. Small head size after in-utero exposure to atomic radiation. *Lancet* 1972; 2: 784-7.
2. Miller RW, Mulvihill JJ. Small head size after atomic irradiation. *Teratology* 1976; 14: 355-7.
3. Otake M, Schull WJ. Radiation-related brain damage and growth retardation among the prenatally exposed atomic bomb survivors. *Int J Radiat Biol* 1998; 74: 159-71.
4. Schull WJ, Otake M. Cognitive function and prenatal exposure to ionizing radiation. *Teratology* 1999; 59: 222-6.
5. Wagner L, Lester R, Saldana L. *Exposure of the Pregnant Patient to Diagnostic Radiations : A Guide to Medical Management*. 2nd ed. 1997, Madison: Medical Physics Publishing Corp. 259.
6. Otake M., Schull WJ, Lee S. Threshold for radiation-related severe mental retardation in prenatally exposed A-bomb survivors: a re-analysis. *Int J Radiat Biol* 1996; 70: 755-63.
7. Hall E. *Radiobiology for the Radiologist*. 5th ed. 2000, New York: Lippincott Williams & Wilkins Publishers;. 588.
8. Mann FA, Nathens A, Langer SG, Goldman SM, Blackmore CC. Communicating with the family: the risks of medical radiation to conceptuses in victims of major blunt-force torso trauma. *J Trauma* 2000; 48(2):354-7.