

Appropriate Imaging of the Pregnant Patient: Bump in the Road

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RSNA[®] 2021
REDEFINING RADIOLOGY
November 28 to December 2

UCSF

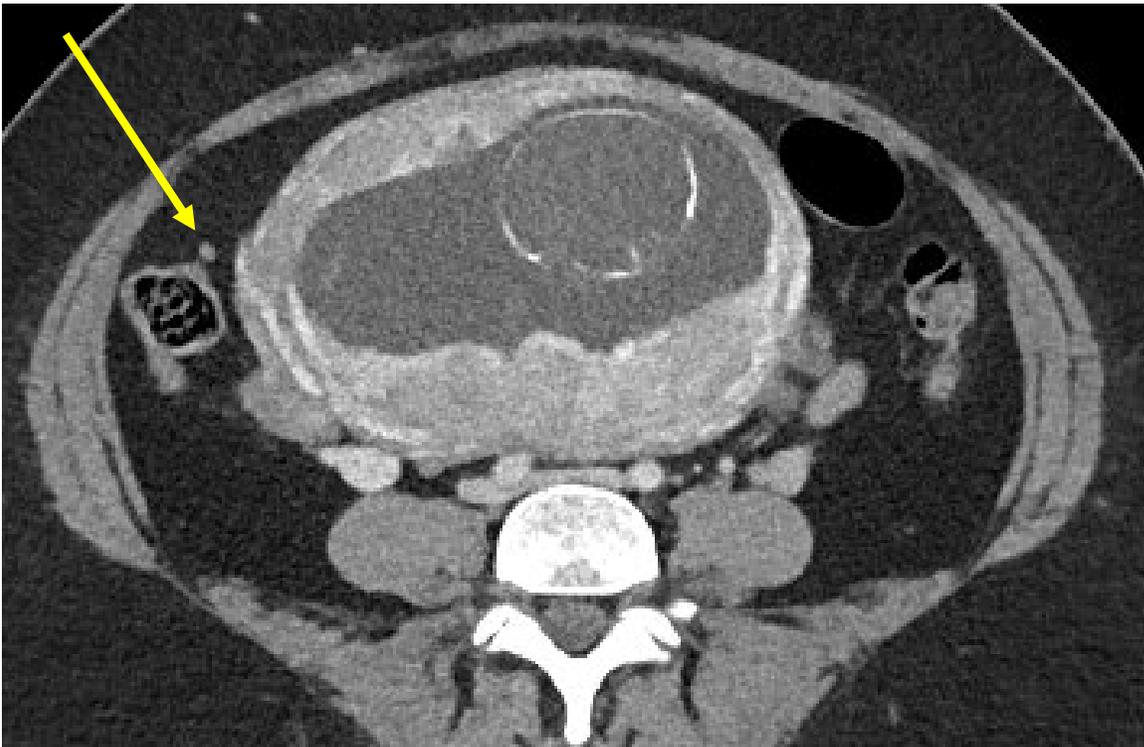
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Quality & Safety Issues

QUALITY & SAFETY ISSUES:

- Inappropriate CT scans performed on non-trauma pregnant patients.
- Inconsistent pattern of obtaining consent for CT and MRI by ordering clinicians.
- Delayed throughput for premenopausal females due to confusion about pregnancy status screening requirements.

Figure 1: 38-year-old female in second trimester with diffuse abdominal pain, slightly more tender in the right lower quadrant. Arrow on axial CT with intravenous contrast shows normal appendix.



Inappropriate use of ionizing radiation in pregnancy in the non-trauma acute setting.

Example 1 (see Figure 1 on left):

- No discussion with on-call radiology team regarding appropriate options i.e. use of US or MRI first. US and MRI is available on call at our institution by calling an assigned on-call technologist.
- Referring team, radiology technologists, and radiology residents were unaware of existing (though old) institutional policy of requiring on-call attending radiologist approval prior to CT abdomen and pelvis in a non-trauma pregnant patient.
- No adequate documentation of risk-benefit discussion with pregnant patient was recorded in the electronic medical record.
- No informed consent was obtained (although this was not required by old institutional policy).

Inappropriate use of ionizing radiation in pregnancy in the non-trauma acute setting.

Figure 2: 37-year-old female at 32 weeks gestational age with nausea and vomiting, concern for small bowel obstruction.



Example 2 (see Figure 2 above):

- No discussion or approval from on-call radiology team.
- A KUB radiograph would have been a good first line (no dilated loops seen on CT scout image on right). MRI could have been second-line.

Delayed throughput for imaging premenopausal females due to confusion about pregnancy status screening requirements.

Example 3 (no images):

- A woman of child-bearing age presented with new onset mild headache and neck pain after minor motor vehicle crash. GCS 15. No restriction for neck movements. ED physician Dr. X was not very concerned but ordered a CT head and cervical spine given symptoms and history of trauma.
- Patient arrives at CT scanner and CT technologist asks pregnancy status (part of state requirements to verify pregnancy status prior to ionizing radiation)
- Patient is unsure, with no serum or urine test on file. CT technologist sends patient back to ER. Lab verification of negative pregnancy test delays imaging by over 1.5 hours.
- **Irate Dr. X wonders of we could have just done the CT head and cervical spine without verification. There was no guidance for this scenario in our existing instutional policy.**

DATA COLLECTION:

- Extensive literature review
- Society guidelines (ACOG, ACR)
- Survey of other Level 1 trauma centers

Summary of Literature Review

1 – Approximate fetal dose from diagnostic imaging

- Based on literature reviewed, there was general consensus that for all radiographs of the body (including those with direct fetal exposure) and CT scan of the head, neck, chest, extremities where there was below 1 mGy.
- For CT scans of the abdomen and pelvis, the fetal dose was less than 50 mGy.
- For multiple fluoroscopy exams, the fetal dose could exceed 50 mGy.

Fetal dose references:

1. Sensakovic WF, Royall I, Hough M et al. Fetal Dosimetry at CT: A Primer. RadioGraphics. 2020;40(4):1061-1070.
2. Woussen S, Lopez-Rendon Y, Vanheckevoort D, et al.

Questions for Literature Review:

1. What is the approximate fetal exposure to ionizing radiation from routinely used diagnostic exams?
2. What is the latest regarding fetal risk from ionizing radiation and MRI?
3. What is the latest regarding fetal risk from intravenous contrast use for CT and MRI?
4. Should we use a shield in CT ? (question posed to us by ED frequently)

2 – Latest on safety of ionizing radiation

- As was formerly believed, the risk of deterministic effects that can result in congenital malformations, growth restriction or microcephaly/lowered IQ, is definitely non-existent for exposures < 50mGy and likely non-existent between 50-100mGy. No new data to suggest otherwise.

CT safety references:

1. Brent RL. Carcinogenic risks of prenatal ionizing radiation. Seminars in Fetal and Neonatal Medicine. 2014;19(3):203-213..
2. Wakeford R. The risk of childhood leukaemia following exposure to ionising radiation—a review. J Radiol Prot. 2013;33(1):1-25.

2 – Latest on safety of ionizing radiation (continued)

- Risk of increasing the incidence of childhood cancer from fetal exposure to ionizing radiation ie. stochastic effect, is still highly controversial. Debates swing from fetus likely non-existing to definite risks based on case control and cohort studies. Problem is lack of consensus with regards to degree of risk, though most agree LOW. In the newer data, cohort of in utero exposures from Japanese bombings showed slight increased solid cancer risk in adulthood.
- Given uncertainty better to ERR ON SIDE OF CAUTION – avoid ionizing radiation if one can and if needed keep dose as low as possible
- But if needed – REASSURE PATIENT that the risk is over all low esp. if <10mGy exposure

3 – Latest on safety of MRI

- No ionizing radiation with MRI. However, there are theoretical effects of the magnetic fields and radiofrequency (RF) pulses from MRI as below.
- Tissue heating: thermal energy onto patient from RF pulse. SAR (specific absorption rate) limit of 4 Watts/kg set by the FDA for MRI. MRI on pregnant patients done at 1.5T or 3T to minimize SAR.
- Fetal hearing: rapid MRI gradients produce acoustic noise, which may affect fetal hearing once the ear develops (by 24 weeks gestational age). Noise limit of 90 dB during MRI per American Academy of Pediatrics.
- Latest ACR and ACOG guidelines agree that no *proven* bioeffects from MRI (only theoretical), therefore MRI okay in any trimester if clinically needed.

CT safety references (continued):

1. Ray JG, Schull MJ, Urquia ML, You JJ, Guttman A, Vermeulen MJ. Major Radiodiagnostic Imaging in Pregnancy and the Risk of Childhood Malignancy: A Population-Based Cohort Study in Ontario. Franco EL, ed. PLoS Med. 2010;7(9):e1000337.
2. Bithell J, Draper G, Sorahan T, Stiller C. Childhood cancer research in Oxford I: the Oxford Survey of Childhood Cancers. Br J Cancer. 2018;119(6):756-762.

MRI safety references:

1. Bird, S. T., Gelperin, K., Sahin, L., Bleich, K. B., Fazio-Eynullayeva, E., Woods, C., ... & Krefting, I. (2019). First-trimester exposure to gadolinium-based contrast agents: a utilization study of 4.6 million US pregnancies. Radiology, 293(1), 193-200 Expert Panel on MR Safety; et al. "ACR guidance document on MR safe practices: 2013." Journal of Magnetic Resonance Imaging 37.3 (2013): 501-530.
2. Ray, Joel G., et al. "Association between MRI exposure during pregnancy and fetal and childhood outcomes." Jama 316.9 (2016): 952-961.
3. Tremblay, Emilie, et al. "Quality initiatives: guidelines for use of medical imaging during pregnancy and lactation." Radiographics 32.3 (2012): 897-911.
4. Tsai, Leo L., et al. "A practical guide to MR imaging safety: what radiologists need to know." Radiographics 35.6 (2015): 1722-1737.

3 – Latest on safety of intravenous contrast

- Iodinated contrast is considered safe but still FDA Category B, Gadolinium based contrast is FDA Category C. Animal studies have showed teratogenicity.
- Given unclear gadolinium safety in humans, MRI exams during pregnancy should NOT use gadolinium unless its use is critical for maternal or fetal health.
- Bottom line: Need attending approval and written informed consent if gadolinium is absolutely needed.

Intravenous contrast references:

- Bird, S. T., et al. (2019). First-trimester exposure to gadolinium-based contrast agents: a utilization study of 4.6 million US pregnancies. *Radiology*, 293(1), 193-200
- Ray, Joel G., et al. "Association between MRI exposure during pregnancy and fetal and childhood outcomes." *Jama* 316.9 (2016): 952-961.

#4 – Should we use shielding in CT when fetus is not in field of view?

- There could be inadvertent increased fetal and maternal dose if shield slips into FOV

Shielding reference:

- Radiation Protection Dosimetry (2020), Vol. 189, No. 4, pp. 458–465

Survey of Level 1 Trauma Centers

- We distributed a survey to other Level 1 trauma centers to assess if they have had similar issues with imaging of pregnant patients in the non-trauma setting, and if there is a consensus on how to screen and image these patients.
- Although the survey is ongoing, our preliminary results demonstrate no consensus. A few qualitative comments from a few other institutions are shared anonymously below.

Verbal screening only for pregnancy, unless patient is unsure of pregnancy status

We have had to meet up with our OB GYN colleagues to create guidelines and to streamline the process.

Radiology department created guidelines requiring urine or serum screening for CT or MRI in premenopausal females.

Road to Rollout

IDENTIFY KEY STAKEHOLDERS:

- Radiologists
- CT and MRI technologists
- Emergency medicine physicians
- Obstetricians
- Risk management
- Radiation safety officer

ROLLOUT:

- Clinical algorithm for ordering clinicians
- CT abdomen/pelvis informed consent form in pregnancy.
- Ionizing radiation in pregnancy info sheet.
- Update institutional guidelines on imaging in pregnancy.
- Update standard workflow for CT & MRI technologists.

NEW UPDATED POLICY

- Streamline screening of women of childbearing age for pregnancy status before exposure to ionizing radiation (see chart on slide 10)
- Identify need for informed consent – CT with fetus in field of view and Gadolinium based contrast administration
- Use a new consent form for CT with fetus in field of view and provide patient information to help clinicians counsel and ensure we **standardize** what we are telling the patients.
- Policy created in conjunction with emergency medicine department and risk, after internal radiology review, and subsequently approved by OB GYN.
- The next step is to disseminate this information to the attendings, residents, and fellows within all these departments...

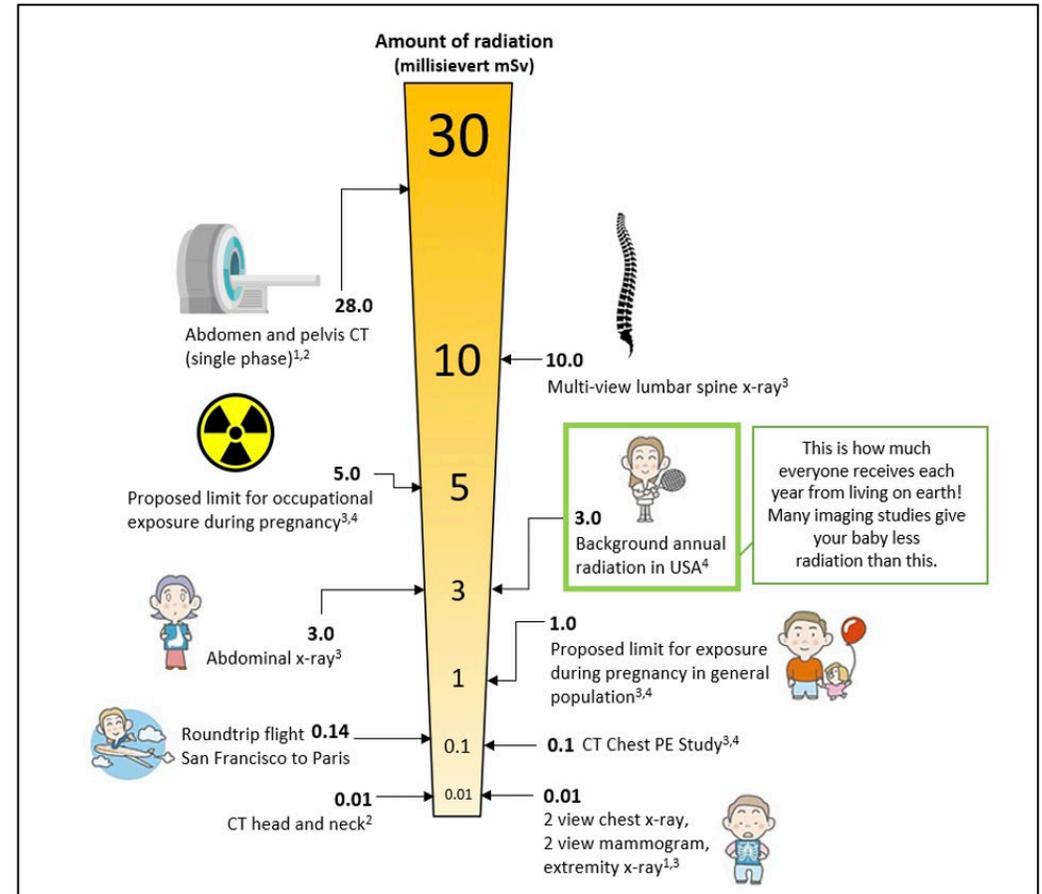


Figure 3. Diagram from patient information sheet

RELEVANT VERBIAGE FROM PATIENT INFORMATION SHEET:

“You and your baby are exposed to radiation in the natural world. The chart below compares this radiation amount with that from x-rays used in medical exams. As shown, the exam you shall get today where your baby is not directly in the picture has very low radiation exposure to the baby and hence very low risk. Scientific studies suggest that if medical exams using under 10mGy of radiation have any effects on the baby, these effects are too small to be measured. If you have any questions or concerns before your imaging exam, please talk to your doctor or the technologist. “

RELEVANT VERBIAGE FROM INFORMED CONSENT:

“Risk of having a CT scan when pregnant

Radiation can cause cancer in adults and children. This is the main risk to your baby from a CT scan of the abdomen and pelvis. The risk to your baby is extremely low, but not zero. Scientists continue to debate exactly how much a CT scan of the abdomen/pelvis during pregnancy increases the risk of your baby potentially getting childhood cancer. Even without getting a CT scan, all babies have approximately a 1 in 300 risk of developing cancer before the age of twenty. Scientists currently think that a CT scan of the abdomen/pelvis could increase the risk of cancer by up to another 1 in 300. We make every effort to keep the amount of radiation as low as possible so that the risk to your baby is as low as possible.”

GOALS:

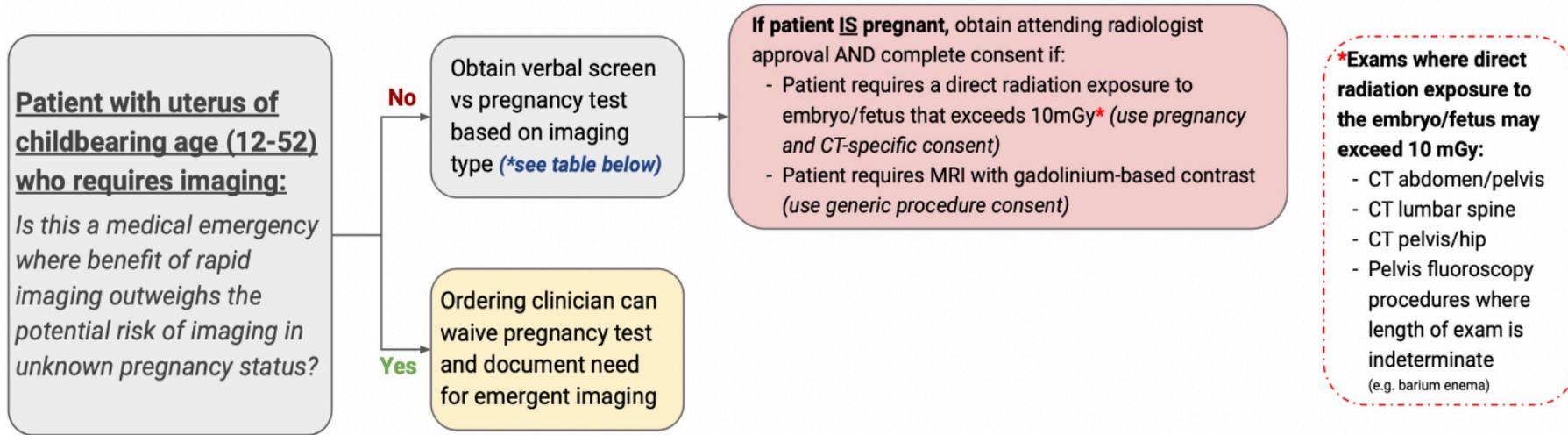
- Inform and REASSURE patient.
- Reference for clinicians about fetal exposure dose and its significance.
- Encourages risk benefit discussion.
- Uses universal “risk” language.
- Risk estimate is based on most conservative data available to date.

BOTH FORMS THEN TRANSLATED INTO SPANISH AND CHINESE (our two most common patient languages in the ER)

FOR GADOLINIUM – Use the generic hospital written informed consent form as imaging of a pregnant patient with gadolinium is likely to be a rare scenario.

After all our efforts, the emergency department embraced our new policy, which will be electronically available for all ED trainees and staff. This was mirrored by the radiology department for our trainees and staff. This quality improvement initiative and the improved process for pregnancy screening has added more clarity for both departments.

Imaging In Pregnancy



EXAM ORDERED	TYPE OF PREGNANCY TEST NEEDED
CT abdomen, pelvis, hip, or lumbar spine	SERUM/URINE REQUIRED
All MRI studies	SERUM/URINE REQUIRED
Fluoroscopy studies involving pelvis (IR, Fluoro)	SERUM/URINE REQUIRED
All other CT scans	VERBAL ONLY*
All X-rays	VERBAL ONLY*

**If verbal screening (e.g. "are you pregnant?") is not possible, then serum/urine pregnancy needed for all exams except extremity x-rays*

Courtesy: Malini Singh, MD

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KEY STAKEHOLDERS:

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- CT and MRI technologists
- Emergency medicine physicians
- Obstetricians
- Risk management
- Radiation safety officer

DATA COLLECTION:

- Extensive literature review
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IMPACT & FOLLOW-UP:

- Continued monthly assessment at radiology quality and safety committee and ED-radiology council meetings
- Educational sessions for radiology and other departments with pre- and post-session knowledge surveys
- Monitor for deviations from clinical algorithm and discuss any new issues which may warrant modification of guidelines.

ROLLOUT:

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