

Revised March 24, 2016

RE: MRI and Gadolinium Use in Pregnant Patients

MEMO TO: Department of Radiology

FROM: Howard Rowley (Chair, MRI Safety Committee), Scott Reeder (Chief, MRI)

The following memo provides an interval update on the UW-Madison Department of Radiology policy for scanning pregnant patients, including the use of gadolinium contrast agents, approved on 3/16/16 by the UW MRI Safety Committee.

Non-contrast MRI in Pregnant Patients:

There are no known deleterious effects of MR imaging on the fetus, and we consider MRI to be a safe imaging modality for pregnant patients. As part of the screening process, patients are screened for pregnancy, and if a patient is found to be pregnant, according to the ACR Safety Guidelines (Kanal, JMRI 2013; 37:501-530), "consideration should be given to reassessing the potential risks versus benefits of the pending study in determining whether performance of the requested MR examination could safely wait until the end of pregnancy". We share this philosophy. As such, when an MRI is ordered on a pregnant patient, consideration for alternative diagnostic strategies should take place. If it is determined that the MRI should proceed, it should be documented in the medical record that:

- 1. The information needed cannot be obtained from ultrasound or other diagnostic test that does not require ionizing radiation.
- 2. The information that is needed affects the care of the patient and/or the fetus during pregnancy.
- 3. The attending referring physician feels that the scan cannot wait until after the pregnancy and is needed to obtain the necessary information.

Informed consent is no longer required for non-contrast MRI exams in pregnant patients. However an information sheet (or similar electronic version) should be provided to the patient. This can be done by the MRI assistant, MRI technologist, or MRI safety nurse. If the patient has any questions or concerns, an attending radiologist is available 24/7 for consultation by phone if needed.

There are no data to suggest any differences in risk from MRI exposure at different trimesters, and therefore all safety considerations for non-contrast MRI in pregnancy apply equally at all stages of pregnancy. Other standard MRI screening continues to apply for pregnant patients.

Finally, as 3T clinical scanners are increasingly common, the question of 1.5T vs. 3T arises. Although there are no known risks of non-contrast MRI in pregnancy at either 1.5T or 3T, some experts recommend patients be scanned at 1.5T given increases in RF energy deposition (Specific Absorption Rate (SAR)) at 3T. We also make this recommendation. However, depending on scanner availability and other considerations that could delay or prevent a medically necessary MRI exam, non-contrast MRI at 3T in pregnant patients is permissible and should not be considered a contraindication.



Gadolinium Based Contrast Agents in Pregnant Patients:

Historically, gadolinium based contrast agents have been absolutely contraindicated in pregnant patients at UW-Madison. It is well known that free gadolinium (which is highly toxic) accumulates in the amniotic fluid in low concentrations of uncertain significance, after intravenous injection of gadolinium based contrast agents. There are also animal data that demonstrate teratogenic effects of gadolinium in the developing animal fetus. There is a paucity of safety data in humans, with no large-scale safety studies and only a few studies with small numbers of patients that demonstrated no deleterious effects of gadolinium based contrast agent exposure in pregnancy. Given the lack of human safety data and the theoretical risks of teratogenicity, gadolinium has historically been an absolute contraindication.

However, unusual and extenuating circumstances may arise where the care of the mother and/or fetus would be significantly compromised without a contrast enhanced MRI during pregnancy, and no other diagnostic test would answer the clinical question. In these rare situations, the UW-Madison Department of Radiology policy allows for the use of gadolinium based contrast agents, but only with a well documented risk benefit analysis demonstrating the need for an MRI with gadolinium. This analysis must involve the attending radiologist and attending referring physician (not a fellow or resident). In addition to the same documentation required for non-contrast MRI, it should be documented that:

- 1. Alternative imaging tests, including ultrasound and those using ionizing radiation (CT with or without iodinated contrast, nuclear scintigraphy, fluoroscopy, etc) could not provide the necessary information. Only if such tests will not provide the needed information should MRI with a gadolinium based contrast agent be considered.
- 2. If an MRI is needed, consideration to non-contrast techniques should be strongly considered. Reasons why a non-contrast MRI could not provide the necessary information must be provided.

Informed consent from the pregnant patient must be obtained by the attending Radiologist when contrast is to be given, and should document that the patient is aware of the potential risks. The consent form must be signed by the attending radiologist.

Questions can be directed to Howard Rowley, Ed Jackson, Scott Reeder, Liz Sadowski, Fred Kelcz, Mike Tuite or Tom Grist.