

**INFORMATION SHEET REGARDING  
THE USE OF GADOLINIUM-BASED MR CONTRAST AGENTS AND  
NEPHROGENIC SYSTEMIC FIBROSIS (NFS)**

- 1. Summary of currently known facts regarding the use of a Gadolinium-based MR contrast agent and Nephrogenic systemic fibrosis (NFS)**
  - a.** NFS is a condition that results in fibrosis of the skin and connective tissues throughout the body. NFS results in skin thickening and may result in loss of normal ability to flex and extend the joints resulting in contractures. In addition, some patients develop widespread fibrosis (scarring) of the skin, muscles and other organs. This condition may be debilitating or result in death. Its cause is unknown and there is no consistently successful treatment.
  - b.** NFS has been reported following the use of all five FDA approved gadolinium-based contrast agents (Magnevist, MultiHance, Omniscan, OptiMARK, Prohance), but most predominately following the use of Omniscan, Magnevist, and OptiMARK.
  - c.** Among patients with known renal function, all patients with reported NSF after exposure to gadolinium-based contrast agents have had acute or chronic severe renal insufficiency, renal dysfunction due to the hepato-renal syndrome or renal dysfunction in the setting of perioperative liver transplant period. The vast majority of patients were receiving dialysis.
  - d.** To date, there is no report of a patient developing NFS, with normal or mild to moderate renal dysfunction.
  
- 2. Recommendations regarding the use of Gadolinium-based MR contrast agents**
  - a.** Avoid the use of Gadolinium-based contrast agents unless the diagnostic information is deemed essential and is unavailable with non-contrast enhanced magnetic resonance imaging (MRI).
  - b.** It is not currently required to screen all patients with laboratory tests prior to administering a gadolinium-based contrast agent.
  - c.** However, it is recommended that prior to the administration of a gadolinium-based contrast agent all patients should be screened by history. The following is a list of sample questions that should be asked:
    - i.** Do you have a history of renal (kidney) disease?
    - ii.** Do you have a history of diabetes?
    - iii.** Do you have a history of liver disease?
    - iv.** Have you ever had a kidney or liver transplant?
    - v.** Have you ever had a serious injury or trauma to the kidneys?
    - vi.** Have you ever been on dialysis?

- vii. Have you been on chemotherapy during the past 60 days?
  - d. Any patient who answers in the affirmative to any of these questions should be screened with laboratory tests (serum creatinine level and glomerular filtration rate) for renal dysfunction, prior to the administration of gadolinium-based contrast.
  - e. Individuals are at risk for NSF if they have a glomerular filtration rate  $<30\text{mL}/\text{min}/1.73\text{m}^2$ .
  - f. Laboratory tests are not required for individuals with no history of kidney or liver disease.
  - g. When using gadolinium-based contrast agents, do not exceed the dose recommended in the product labeling and allow adequate time for elimination of the contrast prior to readministration.
  - h. Avoid using gadolinium-based contrast agent in any patient with known risk factors for NSF unless the diagnostic information is deemed essential and cannot be obtained with non-contrast enhanced MRI or other diagnostic procedures.
  - i. **All patients receiving gadolinium-based contrast agents should be screened with a questionnaire for a history of possible kidney or liver disease. Any patient with a potential history of liver or kidney disease should undergo laboratory analysis. Any patient with documented renal disease in whom it is deemed essential that they receive gadolinium-based contrast should sign an informed consent document (sample questionnaire and informed consent document are attached).**
3. **For additional and more in depth information regarding gadolinium-based contrast agents and their association with NFS, please refer to the accompanying background documents**
- a. FDA document “Gadolinium-Based Contrast Agents for Magnetic Resonance Imaging (marketed as Magnevist, MultiHance, Omniscan, OptiMARK, Prohance), 5 page document.
  - b. Renal Disease, Gadolinium-based MR contrast agents, and nephrogenic systemic fibrosis (NSF) extracted from the American Roentgen Ray Society Publication Kanal E, Barkovich AJ, Bell C, et al. ACR Guidance Document for Safe MR Practices: 2007 *AJR* 2007; DOI: 10.2214/AJR.06.1616.
  - c. Letter entitled “Gadolinium-containing MRI contrast agents and Nephrogenic Systemic Fibrosis (NSF) – Update