I. PURPOSE

To provide guidelines for safe administration of contrast for Magnetic Resonance Imaging (MRI) for patients with impaired renal function who are at high risk for development of nephrogenic systemic fibrosis (NSF). To support the hospital mission of clinical, research and educational endeavors associated with Magnetic Resonance Imaging, and to provide high quality patient care and diagnostic services.

II. GUIDELINES

All high risk patients who are scheduled for contrast enhanced MRI scans must complete the UWHC Clinical NSF High Risk Screening Questionnaire before their procedure. The Questionnaire will be filled out by a nurse, physician or other healthcare provider.

OUTPATIENTS:
- We consider OUTPATIENTS at very low or no risk for NSF. In OUTPATIENTS, we use MultiHance® or Eovist® if the patient has a history of renal disease, per the screening sheet. The case does not need to be discussed with the ordering physician. We do not require eGFRs on OUTPATIENTS and they are not screened with the INPATIENT questionnaire.

SCREENING INPATIENTS:
- Case-based clinical screening guidelines minimize the risk of NSF while continuing to provide the option of contrast enhanced magnetic resonance (CE-MR) imaging to patients. Below are the UWHC Department of Radiology current guidelines, as reviewed at the yearly MR Safety Committee meeting.
- Currently we only consider INPATIENTS at high risk, and only if they fail the below screening questionnaire (see Section III).

III. UWHC CLINICAL NSF HIGH RISK SCREENING QUESTIONNAIRE

Patients are considered at high risk for NSF if they meet criteria from BOTH section 1 and section 2 of the following questionnaire:

1. Does the patient meet the following criteria:
   a. Inpatient with kidney or liver transplant (tx) with eGFR <60?
   b. Inpatient with native kidneys and eGFR <30?
   c. Inpatient with acute renal failure?
2. Does the patient have a recent (1 month) history of:
   a. Major infection (pneumonia/sepsis/osteomyelitis)?
   b. Vascular ischemia of the extremities (arterial thrombosis/gangrene/amputation)?
   c. Venous or arterial thrombosis (PE/hepatic artery thrombosis)?
   d. Major surgery or vascular procedure (Vascular/CABG/Amputation/Transplantation)?
   e. Multi-organ system failure?
IV. SCREENING PROCEDURE

1. All patients must have a UWHC Clinical NSF High Risk Screening Questionnaire completed prior to a scan in order to identify risk for NSF. Patients need to be screened prior to receiving any sedatives for a scan unless another person (e.g. child’s parent) is responsible for providing information.

2. The UWHC Clinical NSF High Risk Screening Questionnaire must be completed prior to the patient arriving for the MRI procedure. The MRI nurse will complete the screening form Monday through Friday from 7:30 AM to 11:00 PM. If a scan is needed after hours, on weekends or when the MRI nurse is not available, the nurse, physician or other healthcare provider caring for the patient will complete the screening form. The completed form will be faxed to 263-6014, or sent in the patient’s chart at the time of their study.

3. In some clinical settings, the benefits of a CE-MRI/A with MultiHance®/ Eovist® may outweigh the theoretical risk of NSF with MultiHance®/ Eovist® and the radiologist and patient’s physician may choose to proceed with the CE-MR examination in high risk INPATIENTS. In these cases, the ordering attending physician should discuss the theoretical risk of NSF with the patient and inform the patient that there are no reported cases of NSF with the exclusive use of MultiHance®/ Eovist®, here or elsewhere. Cases of NSF have been associated with other gadolinium based contrasts, including Omniscan®, which is not currently used at UWHC in patients with renal disease.

4. **IF the exam is deemed medically necessary by the physician and radiologist, and the patient is on hemodialysis, the patient should be dialyzed promptly post-MRI/A.** If the patient is not on hemodialysis, the patient should not have dialysis. The radiologist approving the MR exam should ask the referring service to notify the dialysis unit that the patient will need dialysis after the CE-MR exam and that MR staff will help coordinate the timing of the CE-MRI/A and dialysis.

5. The radiologist should document in the radiology report the discussion with the referring service as to the need for contrast and note the date and time of the discussion.

If there are any questions after speaking with the fellow or staff on MRI, please page Drs. Liz Sadowski (9036), Aji Djamali (5091), Scott Reeder (6713), Fred Kelcz (9693), Howard Rowley (2518) or Michael Tuite (4167).

V. DATA FROM UWHC

Data acquired from June 2005 to July 2006 at the UW found a 6.5% incidence of NSF in hospitalized patients meeting high risk criteria, who received Omniscan® for CE-MRI/A (Figure 1). All patients had concurrent pro-inflammatory conditions including infection, arterial/venous thrombosis and/or major surgery. Data acquired from November 2006 to April 2009 at the UW revealed a decreased incidence in NSF in the hospitalized patients receiving MultiHance® or Eovist® in place of Omniscan® for CE-MRI/A. There are no reported cases of NSF in this time period (Figure 2) and there have been no reported cases to date at the UW since switching to MultiHance®.

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**Figure 1:**

<table>
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<tr>
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<tbody>
<tr>
<td>91 inpatients</td>
<td></td>
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<tr>
<td>eGFR &lt; 30 or tx &lt; 60</td>
<td></td>
</tr>
<tr>
<td>ml/min/1.73m² AND</td>
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<tr>
<td>Pro-inflammatory condition</td>
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6.5% 6/91 w/NSF

**Figure 2:**

<table>
<thead>
<tr>
<th>November 2006 – April 2009</th>
<th>No Screening + MultiHance®</th>
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<tr>
<td>81 inpatients</td>
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<tr>
<td>eGFR &lt; 30 or tx &lt; 60</td>
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<tr>
<td>ml/min/1.73m² AND</td>
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<td>Pro-inflammatory condition</td>
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0% 0/81 w/NSF

NSF has exclusively occurred in patients who were hospitalized and very ill with co-existing pro-inflammatory
conditions, in addition to renal disease and exposure to Omniscan®. To date there are no documented cases of NSF at our institution in outpatients or inpatients without pro-inflammatory conditions receiving Omniscan®, MultiHance® or Eovist®.

VI. DATA FROM THE FDA
The FDA placed a BLACK BOX warning on all gadolinium containing contrast agents in May of 2007. They did not distinguish among the different agents in regard to relative incidence of NSF. Documented NSF cases have been seen after administration of Omniscan®, Magnevist® and OptiMARK®. No cases of NSF have been seen solely attributed to the administration of MultiHance®, ProHance® or Eovist®, to date.

FDA warning: NSF has only been identified in patients with acute or chronic renal insufficiency (eGFR<30 ml/min/1.73m²) or in acute renal dysfunction due to hepato-renal syndrome or in the perioperative liver transplantation period. Avoid using a GBCA in patients with known risks for developing NSF unless the diagnostic information is essential and can not be obtained with non-contrast enhanced MRI or other diagnostic procedures.

If only diminished renal function and gadolinium based contrast exposure are taken as risk factors (FDA warning), UWHC data acquired from November 2006 to April 2009 revealed no cases of NSF in 466 patient exams where MultiHance® was administered (Figure 3).

Figure 3:

Nov 2006-April 2009: 466 patient exams <30 ml/min/1.73m²

NO NSF CASES

VII. COORDINATOR
EA Sadowski, MD. Dept. of Radiology, Abdominal Imaging Section.
March 10, 2011