

# Clinical Safety & Effectiveness Cohort 4-UTHSCSA

## MRI Contrast Mis-administrations

May 21, 2010

DO NOT  
DISTURB  
MRI STAFF  
WHILE  
PRESENTING!

# The Team

- UTHSCSA/UHS

- Ken Kist, MD (cohort member)
- Gilbert Cortez (cohort member)
- Kristi Hill-Herrera (cohort member)
- Ernest Prince (Patient Care Coordinator, UH Radiology)
- Abelardo Gonzalez (MRI Technologist, UH Radiology)
- Jacqueline Young (Customer Service Rep, UH Radiology)
- UH MRI Technologists and Nurses



- Sponsor Department

- Pam Otto, MD
- Michelle Ryerson, DNP, RN

# AIM Statement

**Reduce MRI contrast mis-administrations at University Hospital from 3 in 2009 to 0 (zero) by May 21, 2010, maintaining this goal into the future.**

# How is this Project Different?

- Some problems occur in on-going processes, and lend themselves to incremental improvements, to provide better outcomes, to save money or to allow better work flow.
- Other problems have consequences that are so severe that unique processes are required to prevent those problems from ever occurring.
- The goal is to design and implement a process that prevents the problem, i.e. makes it a
- NEVER EVENT.

# ROOT CAUSE ANALYSIS

- The Root Cause is the fundamental, underlying reason for a problem, which causes it to happen, repeatedly.
- If you don't identify the root cause, the problem will probably happen again, and again.
- Root cause analysis is especially appropriate when dealing with an event that is rare, but may have dire consequences.
- Our project focused on the root cause(s) of this type of problem.

# MRI

- MRI is an important tool in medicine's diagnostic repertoire.
- Last year we performed thousands of MRI's at this institution, for multiple indications.
- MRI has unique and powerful imaging capabilities, but the strong magnetic field that allows generation of it's images has well known dangers.



We know things can go wrong in the MRI suite.





# Gadolinium Based Contrast Agents

- We perform hundreds of MRI's every year, with contrast enhancement.
- In institutions like ours, many of these MRI's are performed on patients with multiple disease processes.
- The suitability and safety of MRI as a diagnostic test for one process can be effected by these co-morbidities.



# NSF

## (Nephrogenic Systemic Fibrosis)

- NSF is a rare (~5 cases/1000 patient-years) syndrome characterized by thickening and tightening of the skin and subcutaneous tissues, which can involve skeletal muscles, myocardium, lungs, liver and other solid organs.
- NSF is debilitating, frequently progressive and has no effective treatment. It does not spontaneously resolve and can contribute to or cause early patient demise.

A



B



# NSF

## (Nephrogenic Systemic Fibrosis)

- The syndrome was first described in 1997, and many trigger etiologies have been proposed (hypercoagulation syndromes, anti-phospholipid antibodies, deep vein thrombosis, metabolic acidosis, erythropoietin administration, and surgical or vascular interventions).
- But in the early and mid years of the last decade, one particular association became very clear.



# NSF

## (Nephrogenic Systemic Fibrosis)

- **NSF is associated with the administration of Gadolinium based contrast agents used for MRI.**
- **And**
- **The syndrome occurred in a select group of patients.**



# NSF

## (Nephrogenic Systemic Fibrosis)

- NSF is associated with the administration of gadolinium based contrast agents in patients with:
- Acute renal failure
- Severe, chronic renal failure
- Patients in the perioperative period of liver or renal transplant
- But it probably only occurs in 2%-4% of this population





- We thought gad was really safe and in fact often *used contrast enhanced MRI as an alternative* to iodine enhanced CT scans in patients with poor renal function.
- We thought: This shouldn't be too much of a problem. We'll just never give gadolinium to patients with low GFR or in the peritransplant period.
- But sometimes things can go wrong.



# Goal

- Our challenge was to develop a system that made the accidental administration of gadolinium based contrast agents to inappropriate candidates nearly impossible.
- We must prevent this from happening.....



# Goal

- And as an additional incentive, we must avoid this consequence...





nephrogenic systemic fibrosis

Search

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Results 1 - 10 of about 726,000 for **nephrogenic systemic fibrosis**. (0.23 seconds)

**MRI Harm - Contrast Agent**

[www.LevinSimesKaiserGornick.com](http://www.LevinSimesKaiserGornick.com)

Have You Had a Contrast MRI? Free NSF NSD Legal Information

Sponsored Links

**MRI MRA Contrast Agent**

[AshcraftandGerel.com/NSF-NFD-MRI](http://AshcraftandGerel.com/NSF-NFD-MRI)

Lawsuits for NSF NFD Damage Millions in Med Prod Cases Settled!

**MRI/MRA Dye Law Firm**

[www.mri-contrast-lawsuit.com](http://www.mri-contrast-lawsuit.com)

Steinberg Law Firm is accepting NSF skin disease cases Nationwide

Tip: Save time by hitting the return key instead of clicking on "search"

**Official site of the Nephrogenic Systemic Fibrosis (NSF) Registry**

Oct 25, 2009 ... Nephrogenic Fibrosing Dermopathy/**Nephrogenic Systemic Fibrosis** is a recently described skin disorder characterized by thickened skin, ...

[What is NSF?](#) - [Links](#) - [Timeline](#) - [The "Center"](#)

[www.icnfd.org/](http://www.icnfd.org/) - [Cached](#) - [Similar](#)

**Nephrogenic systemic fibrosis - Wikipedia, the free encyclopedia**

**Nephrogenic systemic fibrosis** (NSF) or nephrogenic fibrosing dermopathy is a rare and serious syndrome that involves fibrosis of skin, joints, eyes, ...

[en.wikipedia.org/wiki/Nephrogenic\\_systemic\\_fibrosis](http://en.wikipedia.org/wiki/Nephrogenic_systemic_fibrosis) - [Cached](#) - [Similar](#)

**Nephrogenic systemic fibrosis: a serious late adverse reaction to ...**

by HS Thomsen - 2006 - [Cited by 143](#) - [Related articles](#)

Recently, it has been reported [1, 2] that a serious adverse reaction called **nephrogenic systemic fibrosis** (NSF) may occur after exposure to the ...

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**Nephrogenic Systemic Fibrosis - Gadolinium MRI Dye Lawsuit**

**Nephrogenic Systemic Fibrosis**, or **NSF**, is a relatively new disease has been linked to the use of Gadolinium-based dyes used in magnetic resonance imaging ...

[www.nephrogenicsystemicfibrosis.org/](http://www.nephrogenicsystemicfibrosis.org/) - [Cached](#) - [Similar](#)

**Nephrogenic Systemic Fibrosis Linked to Gadolinium Dyes**

**Nephrogenic Systemic Fibrosis**, a disease that affects the skin and body organs, has been linked to the use of Gadolinium-based MRI dyes.

Sponsored Links

**Systemic Fibrosis Lawsuit**

**Nephrogenic Systemic Fibrosis**

Lawsuit. Free consult NSF Attorney  
[www.nsflawsuitmrisideeffects.com/](http://www.nsflawsuitmrisideeffects.com/)

**MRI Dyes & NSF Disease**

Learn about the link. Free, prompt case review for injured patients.

[www.PersonalInjuryLawyerAmerica.com](http://www.PersonalInjuryLawyerAmerica.com)

**Nephrogenic Fibrosis**

Relax. Take a deep breath.

We have the answers you seek.

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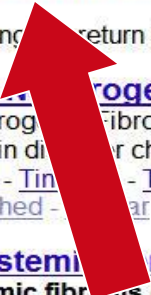
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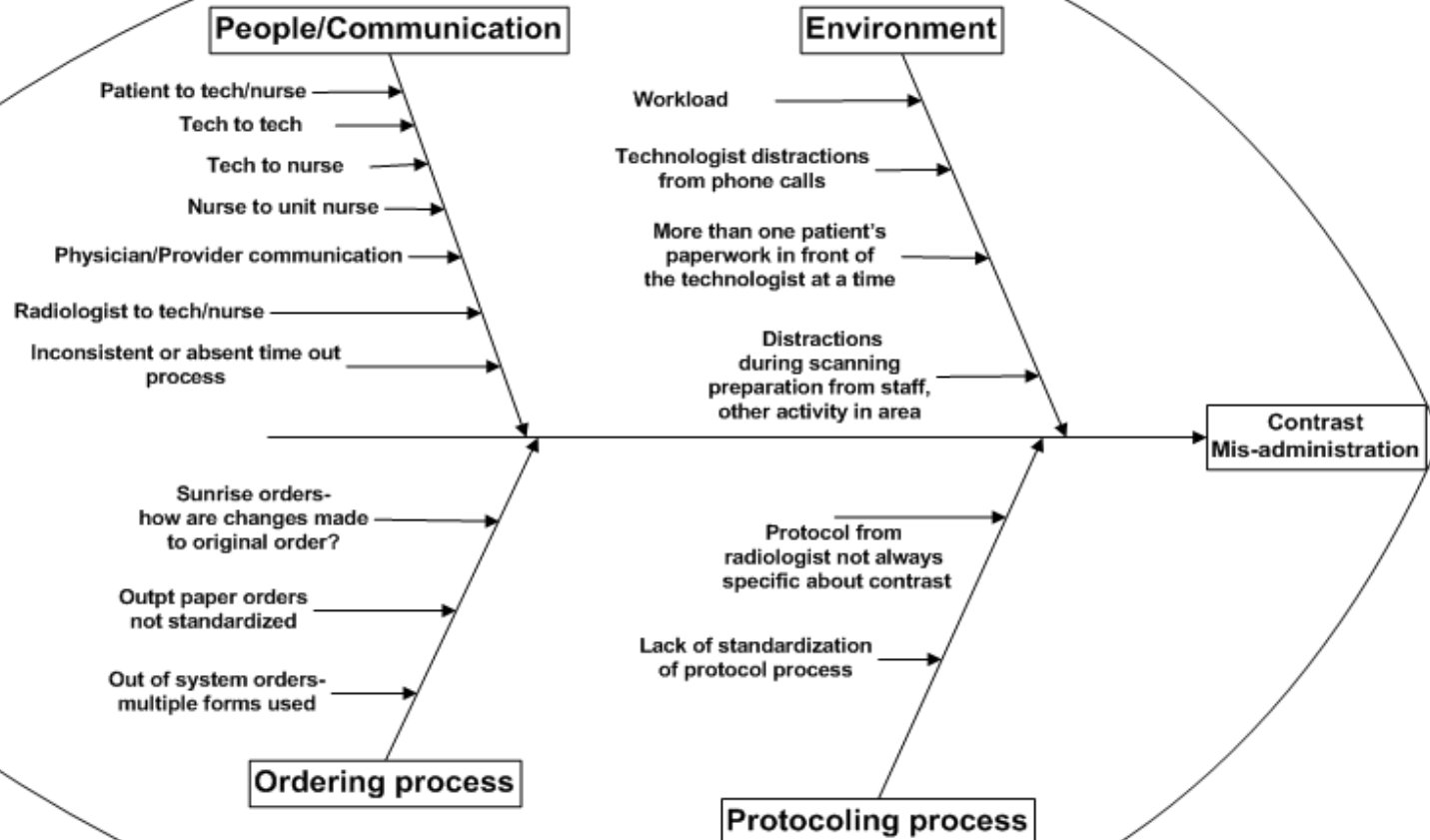
# Project Milestones

- **Team Created** December 2009
- **AIM statement created** January 2010
- **Weekly Team Meetings** January-April 2010
- **Background Data, Brainstorm Sessions,** January-February 2010
- **Workflow and Fishbone Analyses** January-February 2010
- **Interventions Implemented** January-March 2010
- **Data Analysis** March-May 2010
- **CS&E Presentation** May 2010

# Selected Process Analysis Tools

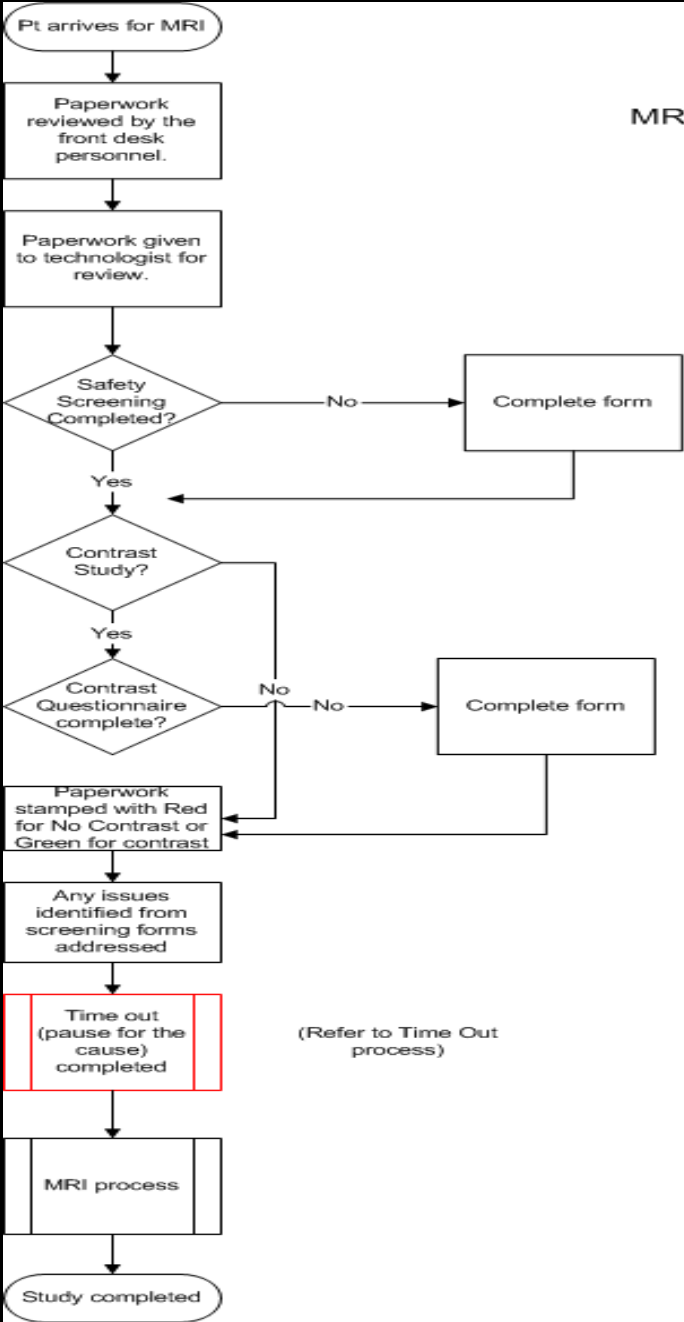
- Brainstorming
- Fish Bone
- Flow Chart

# MRI Contrast Mis-administrations Project





MRI contrast mis-administration project-January 2010



# How Will We Know That a Change is an Improvement?

- There will be no new events.
- There are no new problems created because of a change.
- G-Chart (time between rare events)

# What Changes Can We Make That Will Result in an Improvement?

- Establish a specific process based on established criteria for screening patients.
- Create a work-flow that allows for a double-check process between two technologists or a technologist and a nurse- the final stop/barrier.
- Reduce distractions for the technologists.
- Raise awareness level to a degree that all staff realize the importance and treat this a never-event.

# Intervention Plan

- **Implement a final time out process**
- **Reduce distractions**
- **Continue to identify failure points in the process**

# Implementing the Change

## Do

- **January 25, 2010-Implemented the time-out process with two staff members- nurse and technologist or two technologists.**
- **By day 3, we had 100% compliance from all shifts**

TIME OUT (PAUSE FOR THE CAUSE) CHECKLIST

- | Yes                      | No                       |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Correct Patient/Double Identifier?  |
| <input type="checkbox"/> | <input type="checkbox"/> | Correct Exam?   |
| <input type="checkbox"/> | <input type="checkbox"/> | MRI Safety Form Reviewed? Any contraindications have been investigated?   |
| <input type="checkbox"/> | <input type="checkbox"/> | Laterality: Correct Site Confirmed?   |
| <input type="checkbox"/> | <input type="checkbox"/> | Exam Protocolled By Radiologist? Is the protocol clear to you? <b>If not, exam MUST be sent back to Radiologist for protocol or clarification before the exam is performed.</b> |
| <input type="checkbox"/> | <input type="checkbox"/> | Ask the patient, "Is there anything else you feel I need to know before we begin?"  |

\*\*\*\*\*STOP HERE IF EXAM TO BE DONE WITHOUT CONTRAST\*\*\*\*\*

For all contrast exams, the following have been verified:

- | Yes                      | No                       |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Older than 55?  |
| <input type="checkbox"/> | <input type="checkbox"/> | Kidney or Liver Transplant? Single Kidney?  |
| <input type="checkbox"/> | <input type="checkbox"/> | Renal Disease? <b>If patient is on dialysis, MUST be consented by Radiologist.</b> When is patient scheduled for next dialysis? |
| <input type="checkbox"/> | <input type="checkbox"/> | Diabetic?   |
| <input type="checkbox"/> | <input type="checkbox"/> | Hypertension?   |

If YES to any of the above questions, the following must be completed:

- What is the patient's creatinine from the last 30 days?
- Calculated GFR? Form attached? **If GFR is 30 and below, patient MUST be consented by Radiologist.**

Initials \_\_\_\_\_  Tech  RN Initials \_\_\_\_\_  Tech  RN

DO NOT PLACE IN THE MEDICAL RECORD-FOR RADIOLOGY AUDIT PURPOSES ONLY 1/22/10

# Implementing the Change

## Do

**January –February:**

- **Raised the awareness level of all staff on the distractions in the environment.**

**Worked to reduce these with verbal and visual queues.**

NO FOOD

The final step before  
the procedure.

QUARTET *Ultimate*

CAUTION

MRI  
LEVEL III

Personnel Only

DO NOT  
DISTURB  
MRI STAFF  
WHILE SCAN  
IN PROGRESS!

WHILE SCAN IN PROGRESS  
MRI STAFF ONLY

RELATIONSHIP



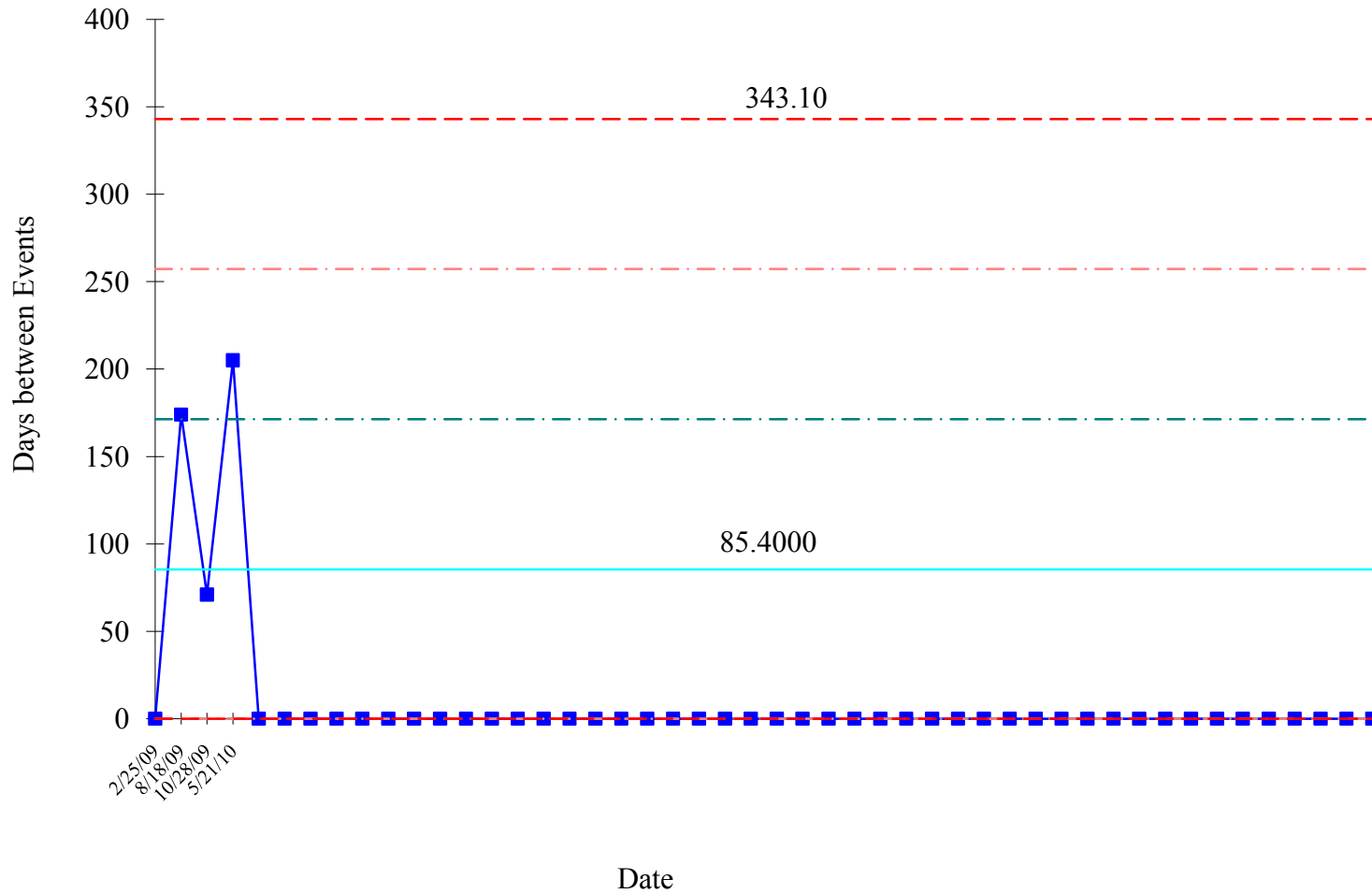
# Results/Impact

## Check

- Time out forms were audited for continued compliance.
- Held meetings with staff for input on the new process.
- G chart selected as the tool most appropriate to measure time between rare events. As of May 21, 2010, we are at 205 days since the last event!

# Results/Impact

## Days between Events



# Expansion of Our Implementation

## Act

- Changes showed positive progress and were continued with input from the staff.
- The time-out steps have become a natural part of the workflow.
- Distractions have been reduced as seen by observations and staff input. Will continue to be monitored by all.
- The work-flow process continues to be monitored.

# Applicability

- This same process can be applied to iodinated contrast in CT.
- Distractions are an issue in all modalities. Efforts toward reducing these and empowering staff to limit unnecessary interruptions will be broadened.



# Umar Farouk Abdulmuttalab

- On Christmas, 2009, in spite of world-wide efforts to prevent airplane bombings, this 23 year old got on a plane, with plastic explosives in his underpants, and tried to blow up the plane over Detroit.
- No system of prevention is perfect.
- Our current protocols are always being re-evaluated to detect flaws and deficiencies that could let a mis-administration get by.

# Conclusion/What's Next

- Staff have learned the time-out process and it appears to have become a part of the culture. Will continue to spot check and make observations.
- Reducing distractions is difficult unless staff is willing to intervene with others at crucial points. Will monitor by making observations and asking all staff to participate in this monitoring- “have each other’s backs”.
- Evaluate the new work environment as the MRI suite moves in 2010.

# References

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**Thank you!**