





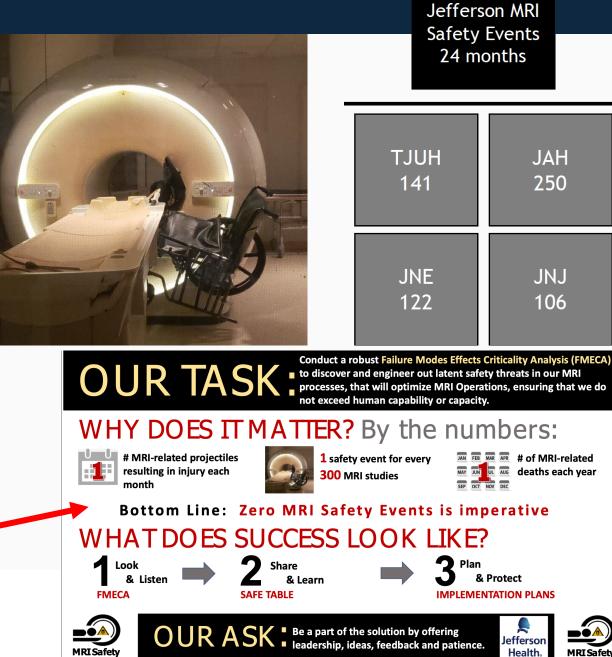
# MRI SAFETY FMECA: Engineering out Latent Safety Threats on an Enterprise Scale

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### The Problem...

- A wheelchair projectile incident in our MRI suite prompted an enterprise MRI safety incident review
- The last 2 years of enterprise MRI safety incident reports were reviewed, revealing:
  - Several projectile incidents including wheelchair, knives, firearms, ladders, and more
  - Thermal injuries
  - Multiple cardiac device near miss incidents
- Nationally, according to 10 years of data reported to the FDA, in the US:
  - 1 MRI-related projectile event resulting in injury every month,
  - 1 safety event for every 300 MRI studies and
  - 1 MRI-related death annually.
- We later created an infographic to communicate this to all relevant stakeholders

Delfino, J.G., et al., *MRI-related FDA adverse event reports: A 10-yr review*. Med Phys, 2019. **46**(12): p. 5562-5571.



### The Rationale

# **The FMECA Charter**

Timeline

#### These incidents resulted from numerous deviations • from established processes and system failures, indicating harm was imminent unless remediation was undertaken.

- Strong intervention was necessary because of the high-acuity, low-frequency nature of MRI safety events. Hence the need to engineer out system flaws and hardwire a better system.
- Decision to convene enterprise-wide Failure Modes • and Effects Criticality Analysis (FMECA).
  - Identify the top failure modes across the enterprise.
  - Propose and prioritize potential solutions and • implement top solutions.
- The FMECA process was mapped out over the course of a year to deliver solutions/action plans.
- Based on the 2-year MRI safety incident review, the • baseline enterprise annual serious safety incident rate was determined to be 4 with a goal of 0.

Summary Conduct FMECA and Safe Table events to identify MRI safety threats. Based on FMECA and results of Safe Table events, create implementation plans to eliminate safety threats posing risk to patients and staff.

#### Scope

In-Scope: Inpatient MRI operations across Jefferson Health Hospitals: Abington Hospital, Abington-Lansdale Hospital, Jefferson Bucks Hospital, Jefferson Cherry Hill Hospital, Jefferson Frankford Hospital, Jefferson Hospital for Neuroscience, Jefferson Stratford Hospital, Jefferson Torresdale Hospital, Jefferson Washington Township Hospital, Jefferson Methodist Hospital, Thomas Jefferson University Hospital

Out of Scope operations, Ma Surgical Hospita Orthopaedic Sp

KPI Outcome Me Number of times door to zone 4

Serious MRI Safet

Pilot the process

Weekly Project Mee

Planning: charter (what/why), stakeholder analysis/RACI (who), timeline/project plan (how/when), plan for Phase 1 (how), kickoff meeting

Phase 1 FMECA (~3 months): includes participatory ergonomics, process maps/swim lanes/work as performed/machines/systems. The Interdisciplinary teams will run an FMECA.

Phase 2 Safe Table event (~1 month): includes pulling teams together to share findings of FMECA, common cause mapping, affinity diagram

Phase 3 Implementation Plan (~2 months): includes developing implementation plan(s) to eliminate safety threats uncovered in FMECA and Safe Table events.

pital		
e/Potential Phase 2: All Outpatient MRI agee Rehabilitation Hospital, Physicians Care	KPI Process Metric	
tal, Radiation Oncology MRI-LINAC, Rothman pecialty Hospital	Number/rate of inpatient screenings prior	to arriving in
etric	Radiology	
s the metal detectors/wands are triggered by the pat	at the Number of good catches/near misses repo	orted
ety event occurrences	Number of quarterly ACA reviews	
Phase 1 FMECA Observe work as performed A pr - Sep '21	Phase 2 Safe Table Solutions Safe Table Solutions Safe Table events Solutions/ action plans Oct '21 Nov '21 - Jan '22	Safer MRI care
tings Steering Council updates	Escalation of significant barriers/risks	

# **The Intervention**

steps included:

As part of the launch of the FMECA, additional necessary • Recognition

- Identifying all stakeholders involved in the lifecycle of the MRI process
- Devise messaging plan to the diverse, widespread group of stakeholders: create infographic
- Create systematic, proactive methods for evaluating a process
  - Identify where and how it might fail
  - Assess relative impact of different failures
- Identify the process parts most in need of change
  - Failure modes (What could go wrong?)
  - Failure causes (Why would the failure happen?)
  - Failure effects (consequences of each failure?)

 Recognition that the problems exist due to "work as imagined" /= "work as performed"

Pilot the process Observe work as performed Safe<u>T</u>able

Safe Table

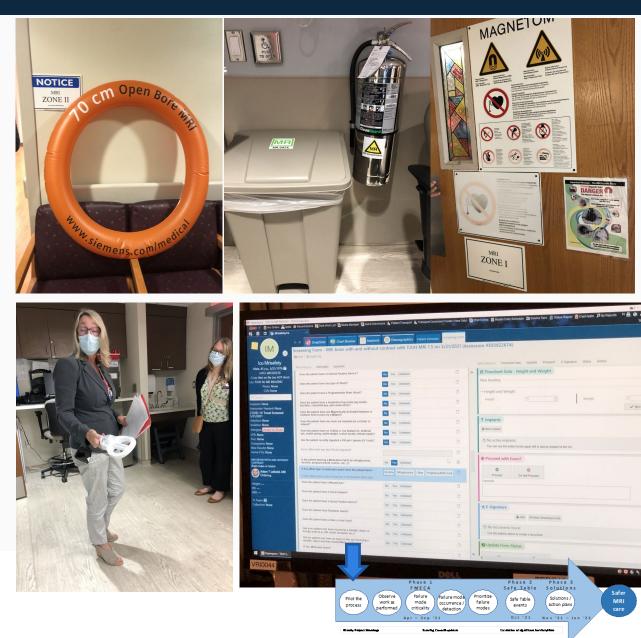
Failure mode mode criticality detection Prioritize failure mode detection modes

- Radiology physician/technologist leaders create swim lane diagrams of our local process.
- Swim lane diagram then grows to reflect the stakeholders across the life cycle of an inpatient MRI order. See below
  - Diagram reflects "work as imagined"
  - Then observe work "work as performed"
  - Contextual inquiry = ethnographic field study involving in-depth observation and interviews of small sample of users to gain robust understanding of work practices and behaviors

A	В	С	D	E	F	G	Н	1	J	К	L	M	Ν	0	Р	Q	R	S
Project: MRI Safety FMECA Project Sub-Teams	Radiologist	Radiology Technologist	Radiology Resident	Physicist	Patient Transport	N ursing (Floor)	Nursing ICU	Biomed	Anesthesia	Nursing ED	Ordering Resident (medicine)	Ordering Resident (Neuro-surg)	Ordering APP?	Informatics	Respiratory	Security	Environmental	Custoidal Servcies
2								P	roject Sub-Teams									
14 TJUH Center City																		
15 Jefferson Methodist Hospital	C Roth	P Natale	C Roth	Eric Gingold Ferose Mohammed	MarK Argenteri	Donna Di	Michelle McBride	Bill Bennett	Dean	Jacquelyn Gedraitis	Rebecca Jaffe	Aish?		Tod Simon	Laura Fantazzi	Kevin McGrorty	Mark Argentieri	x
16 Thomas Jefferson University Hospital	C Roth	P Natale	C Roth	Eric Gingold Ferose Mohammed	Jesus Sierra	Denise Shapiro	Marie Wilson (NICU)	Bill Bennett	Mike Mahla	Jason Smith	J Percopio			Tod Simon	Bridget Gekas	Joseph Byham	lman Bunton	x
17 Jefferson Hospital for Neuroscience	C Roth	P Natale	C Roth	Eric Gingold Ferose Mohammed	No transport at JHN	Maryann McCarrin	Maryann McCarrin	Bill Bennett	Coleen Vernick	Jason Smith				Tod Simon	Bridget Gekas	Joseph Byham	lman Bunton	x

#### The Intervention: Observing the Work as Performed

- Convene cross-functional teams and walkthrough process: pilot at one site then repeat at others
  - MRI physician and technologist leaders
  - Ethnography and human design experts
  - Referring physicians, nursing, transport
- Study order through study complete
- Contextual inquiry = ethnographic field study involving in-depth observation and interviews of small sample of users to gain robust understanding of work practices and behaviors
- Capture artifacts (see examples  $\rightarrow$ )
- Dummy patient created in the EMR to process the order and all IT elements of the process
- All observations documented and discussed immediately after each walkthrough



### The Intervention: Identifying/Analyzing Failure Modes

- The MRI life cycle was itemized by process step and participants listed potential failure modes for 6 critical steps, along with potential effects.
- Failure modes also analyzed based on the perceived criticality, or severity in terms of patient and/or staff harm, the frequency of occurrence and the detectability using a 10-point scale for each item.

RatingSeverityRatingOccurrenceRatingDetectability10Extemely dangerous Detath, total system breakdown no prior warning10Almost every time 1x/day10Undetectable or inspection not feasible, cannot readily be doneDetion to order VBMB ordered when CFUS shalls arise. Instance sergence to XB7Dangerous Moderate permanent injury, serious system disruption interrupting service without warning7Frequent failure 1x/week7Detection by chance no inspection process in place0Detecting data year arise. Undet terming patient port to order VBMB ordered when CFUS shalls arise. Undet terming patient port to order VBDetecting to order V							3			compromise diagnostic results
Extremely dangerous Death, total system breakdown no prior warning       10       Almost every time 1x/day       10       Undetectable or inspection not feasible, cannot readily be done       Design to risk method ut might is at bit model with inverse service       Undetectable or inspection not feasible, cannot readily be done         7       Dangerous Moderate permanent injury, serious system disruption interrupting service without warning       7       Frequent failure 1x/week       7       Detection by chance no inspection process in place       5       Screening patient pior to order MI       Ordering to rank MI is at the word ut might is at the model with cover might is at the might is at the model with cover might is at the might is at the might is at the model with cover might is at the might is at the might is at the model with cover might is at the model with cover might is at the model with cover might is at the might is at th	Ratino	severity	Ratina	Occurrence	Ratina	Detectability	4	Decision to order MRI		risks; unneccessary cost;
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Died/Rdd/With to pilot       TA/ddy       Ted side       Ted side       Constraints       Died/register       Died/register <thdied register<="" th="">       Died/register</thdied>	10	Death, total system	10	-	10	or inspection not	5	Decision to order MRI	period of time (pt had 3 MRIs in 3	risks; unnecessary cost, increase
7Moderate permanent injury, serious system disruption interrupting service without warning7Frequent failure laweek7Detection by chance no inspection process in placeScreening patient prot to ordering were warnScreening patient prot to ordering were warnDevice failure, burns, internal lightes, delays5Moderate Danger Minor injury, major system problem51 x/month5Manual double checks, sample inspections4Screening patient prot to ordering Mel examCoosing 'unable to determine' as a screening question choiceCauses ambjuity; the system does not instruct next step when this choice is selected3Low Danger very minor injury3Occasional fail 1 x/3 month3100% manual inspection process91No to Slight Danger1Rare Up to 1 x/yr1Certain detection n00% automated inspection process9				IX/ddy						
service without warning       service without warning       and the se	7	Moderate permanent injury, serious system	7	-	7	no inspection	5	01 1 0	screening patient prior to ordering	
Moderate Danger Minor injury, major system problem51x/month5Manual double checks, sample inspections8Image: Check of the choice is selected3Low Danger very minor injury3Occasional fail 1x/3 month3100% manual inspection process8Image: Check of the choice is selected1No to Slight Danger1Rare Up to 1x/yr1Certain detection 100% automated inspection process8Image: Check of the choice is selected								•••••••••••••••••••••••••••••••••••••••	5	does not instruct next step when
System problemImage: System problemImage: System problemImage: Streening patient prior to ordering MRI examPatient is not screened for anxiety and/or patient is not prepad for what to expectdelay in care; limiting diagnostic results; stop test before done; refuse to go in3Low Danger very minor injury3Occasional fail 1x/3 month3100% manual inspection process9Patient is not screened for anxiety and/or patient is not prepad for what to expectdelay in care; limiting diagnostic results; stop test before done; refuse to go in1No to Slight Danger1Rare Up to 1x/yr1Certain detection 100% automated inspection process9		Moderate Danger				Manual double	8			this choice is selected
3       Low Danger very minor injury       3       Occasional fail 1x/3 month       3       100% manual inspection process       9       Mid exam       What to expect       refuse to go in         1       No to Slight Danger       1       Rare Up to 1x/yr       1       Certain detection 100% automated inspection process       9       Image: Certain detection       9	5	• • •	5	1x/month	5	-		Screening patient prior to ordering		
No to Slight Danger     No to Slight Danger     Up to 1x/yr     1     Nor     Nor     No to Slight Danger     Safe Table Solutions	3		3		3		9	MRI exam	MPL exam and/or patient is not prepped for	
	1	No to Slight Danger	1		1	100% automated			the Observe Falure mode Prioritize falure mode or important falure	Safe Table Solutions Safer Safe Table Solutions MRI events action plans Care

В

**Potential failure** 

mode

In what ways can the step go

wrong?

patient clinical accuity is not

appropriate for the MRI exam

Α

**Process step** 

What is the step?

Decision to order MRI

С

**Potential failure** 

effects

What is the impact if the

failure mode is not prevented

or corrected?

Missing implants; unnecessary exam exposing patient to

unnecessary risk; delay other

patients; putting critically ill patient in further harm way;

# The Intervention: Prioritizing the Failure Modes/Safe Table Ideation

- Failure modes prioritized based on risk priority number (RPN = severity x occurrence x detectability) failure and radiology leaders were assigned failure modes to propose solutions
- Failure modes grouped to 3 domains:
  - 1. Ordering MRI exams

nts with unsafe implants

ngton, 2019-2020)

- 2. Prepping patients for MRI exams
- 3. Screening patients, staff and objects

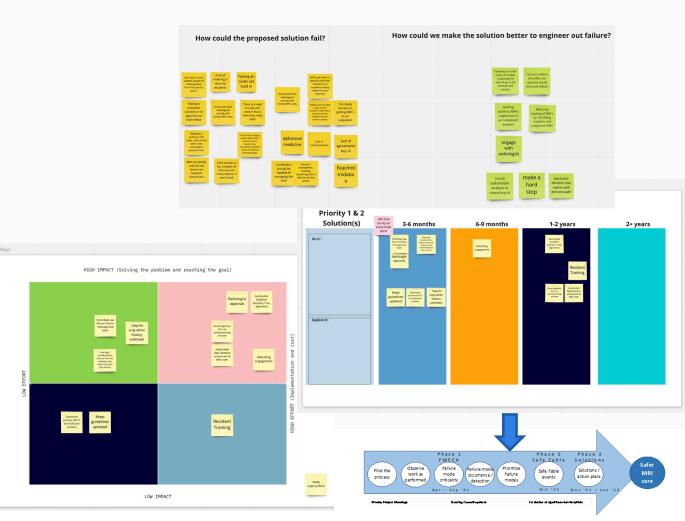
Observations	Causes	Effects	
Orders for MRI exams and multi-part MRI exams that are not clinically necessary	Knowledge of what is involved in an MRI exam and safety risks is lacking	Unnecessary exposure for patients and staff to MRI safety risks	
Orders for MRI exams for patient who are not clinically suitable for an	Lack of institutional/departmental utilization guidelines for MRI exams	Increase safety risk and stress for Radiology Technologists	
MRI	No patient suitability assessment guidelines exist	Delays and limited access to MRI for patients for whom MRI is clinically	
20% MRI inpatient order are multi-part and the majority not clinically indicated.	Ordering Providers do not know the patients	appropriate	
II. Prepp	oing Patients for MRI	Exams	
Observations	Causes	Effects	
		Unidentified implants, attachments,	
Incomplete MRI Patient Screening Forms	Nurse are unclear of their role and expectations for MRI screening	ferrous materials can cause thermal injuries, projectile injuries, or death	
		ferrous materials can cause thermal	

#### III. Screening Patients, Staff, and Objects Entering MRI

MRI screening form is long

Observations	Causes	Effects
Staff who plan to accompany the patient or might enter the MRI scanner in an emergency, are not	High volume creates through-put pressure	Unidentified implants, attachments, ferrous materials can cause thermal injuries, projectile injuries, or death
MRI screened	Ancillary staff are not compliant and/ or can bypass metal detection	Increase stress for Radiology Technologists
Ferro and non-ferro-magnetic wands are not consistently used to detect metal on/in patients, staff, and	Inadequate Radiology Technologist staffing	Nurse accompanying patient has unscreened pacemaker
equipment going into Zone 3	a La constante e a constante com se constante e a constan	Respiratory therapist pushes
Clinicians entering Zone 3 without screening	Most MRI areas do not have minimum standard of metal detection devices	through to Zone 4 without being screened.

 Causes and effects were outlined all in preparation for the upcoming Safe Table Event to share experience, findings and observations with all enterprise stakeholders



#### The Intervention: Prioritizing Solutions

- Radiologist and technologist FMECA leaders chose top 3 action items for the 3 FMECA problems identified (38 actions considered)
- Participants then organized their 9 top action items into most to least impactful based on perceptions of how effective the actions would be to engineer out the problems identified
  - 1 = the most effective action
  - 9 = the least effective action

- Staff then had the opportunity to provide feedback for why they had chosen the actions they had
- To obtain a rank order of Action Item Priority
  - Percentage of agreement across 8 participants was used

Observe work as Failure mode

Pilot the process Prioritize failure modes Safe Table

Safer MRI care

Solutions / action plans

- The 38 Action Items Ranked into 24 priority bins
- 12 Actions not selected by the 8 participants

Rank	Action	Count	Percent Agreement (8)	Average Score (SD)
1	Purchase wands/FMDs (1 per scanner for all locations) with 2 types of detection	7	87.5%	2.79 (SD= 1.78)
2	Radiology ready (standardized screening process in use in 1 hospital division)	6	75.0%	4.17 (SD= 2.64)
3	Automated Ordering Guideline (decision tree, algorithm)	6	75.0%	5.17 (SD= 2.41)
4	Radiologist approval	5	62.5%	7.00 (SD= 1.88)
5	Attending engagement	4	50.0%	4.50 (SD= 3.52)
6	Improve staffing to adequate levels	4	50.0%	4.50 (SD= 2.39)
7	Mandatory, annual Staff Education on MRI	4	50.0%	4.75 (SD= 2.76)
8	Screening/entry form at admission/triage/intake	4	50.0%	4.75 (SD= 1.26)
9	Purchase Wall systems	4	50.0%	5.00 (SD= 2.00)
10	Radiology screen at bedside	3	37.5%	3.00 (SD= 1.00)
11	Education on radiology ready	3	37.5%	4.34 (SD= 3.22)
12	Restructure screening form	3	37.5%	5.00 (SD= 3.61)
13	Standard Screening process	3	37.5%	5.00 (SD= 3.47)
14	Enterprise screening & metal detection policy & procedure	2	25.0%	2.50 (SD= 2.13)
15	Auto-populate form (at least it does in JNJ)	2	25.0%	6.50 (SD= 3.54)
16	Automated flags between assessment & MRI order	2	25.0%	7.50 (SD= 2.13)
17	Resident Training	2	25.0%	9.00 (SD= 0.00)
10				

σ

#### Interventions

	Apr - 548 /21 Oct /21 Nov /21 - Jan /22		_		
Rank	Weekly Project Meetings Detering Council updates Escalation of nightfant burriers/risks		Count	Percent Agreement (8)	Average Score (SD)
1	Purchase wands/FMDs (1 per scanner for all locations) with 2 types of detection		7	87.5%	2.79 (SD= 1.78)
2	Radiology ready (standardized screening process in use in 1 hospital division)	6	75.0%	4.17 (SD= 2.64)	
3	Automated Ordering Guideline (decision tree, algorithm)		6	75.0%	5.17 (SD= 2.41)
	MAGNET IS ALKEVED.				

Solutions

Solutions /

action plan

Safer MRI

Phase 2

Safe Table

Safe Table

events

#### Top 3 solutions implemented:

1. FMDs

Phase 1 FMECA

Failure mode

Failure mode Prioritize occurrence / Failure

Observe work as

Pilot the process

- Enterprise FMD deployment 1.
- Standardized screening form/process 2.
- Spine imaging algorithm 3.

3-	6 Months	6-9 Months	1-2 Years	2+ Years	4 18		
		1. Purchase FMD wands (1 per scanner for all locations) with 2	3. Automated Guideline (Decision tree,			nal Imaging	Guidelines
	2. Radiology ready	types of detection	algorithm )		Non Trauma Myelopathy Pathway	Non Trauma Back Pain Pathway	Spinal Trauma Pathway
-	7. Mandatory,	5. Attending engagement	<ol> <li>4. Radiologist approval</li> <li>6. Improve</li> </ol>	<b>10.</b> Radiology screen at bedside			
	annual Staff Education on		staffing to adequate		Traumatic Focal Spinal	Traumatic Focal Neurological Deficit	Unexaminable Trauma Patient
-	MRI	9. Purchase FMD wall systems	8. Screening/ entry form at admission/ triage/intake	Impact	Tendemess Pathway		With Suspicion of Spine Injury
					Report	Pagent (Pagent)	-Secol - Composition - Academic

#### A. MRI Suitability **Screening form** 8. Additional Invaluence/N C. Special Needs D. Monitoring and/or Removable Device Guiding Principles for design: Answers will 1) prepopulate if available, from the implant Tab and/or patient chart; 2) Create a checklist for the provider, 3) Guide ordering provider to order set, 4) Prepopulate to the MRI Screening Form OP **Current Screening Question** Proposed Screening Question **Action Required** patient able to reli is your patient able to reliably If no, provider order arrays, then answ puestions/silent & oriented x37 remaining questions to the best of nedical questions knowledge. At JNJ only - order with MRI CLEARANCE PROTOCOL What is the contact name and telephone number of who filled out the screening form? Has your patient ever experienced any s your patient require sedar If patient meets any of these criteri problems related to a previous MRI because they have experienced problems provider order sedation meds. Allow an mamination or MRI procedure? with a previews MRI manipation or MRI extra 30 minutes before the exam for rocedure, are uncomfortable in is your patient claustrophobic o whereable in enclosed spaces losed spaces, unable to lay flat, or are

MRI Screening Process

2. Standardizing the

#### un Br. Additional Implants / Nan-removable External Devices - As part of the MRI Screening process, Nurse (or outpatient) will answer the followin and manufacts and take the resulted actions

OP	Current Screening Question		Proposed Screening Question	Action Required
64	Does the patient have any cardiac stents?	12	Does your patient have any stents, filters,	If yes, input make, model, implant date (or
45	Does the patient have any abdominal stents?	1	valves, or grafts?	scan documentation of such)
46	Does the patient have billary stents?	1	<ul> <li>cardiac stexts</li> </ul>	
67.	Does the patient have any vascular stents?	1	<ul> <li>abdominal stents</li> </ul>	"Implant will be cleaned by Radiology"
12	Does the patient have any carotid stents?	1	<ul> <li>biliary stents</li> </ul>	
8	Does the patient have any renal stents?	-	<ul> <li>vascular stents</li> <li>carotid stents</li> </ul>	
ē.	Does the patient have any ureteral stents?			
1	Does the patient have an WC filter?	1	<ul> <li>nenal stents</li> </ul>	
	Does the patient have any heart value reglacements?		uneteral stents     NC fibers     Heart valve reglacement     Vascular graft     Other (please explain)	

#### 1000 AND IN ACCOUNTS

IP.	OP	Current Screening Question		Proposed Screening Question	Action Required
76	59	Does the patient have any N access port leg. brokiac, port-a-cath, hickman, picc line)?	19	Does the patient have any IV access port (ag browled, port-a-cath, hickman, picc line()	If yes, will port need to be accessed (outpatient)? Need to line up PICC team. Goes to PICC work queue
17	4	Is the patient on oxygan?	20	is the patient on oxygen and/or ventilator?	If yes, transport to bring an O2 bottle
2		Now does the patient travel? Bed, Stretcher, Wheelchair	11	How does the patient travel? Bed, Stretcher, Wheelchair	Tech has to input this in the transport request; needs to know if patient travelin w/ oxygen
		tentering and/or Removable Devices - As part a create a checklist for the Nurse for outpetient) as Current Screening Question			
	+	Does the patient have a swam gass catheter?	24	Does the patient have a swam gant catheter?	If yes, pull temp probe prior to patient transport to MRI
•	4	Opes the patient have a loop brain tissue oxygen monitory system/probe?	25	Opes the patient have a loop brain tissue organ monitory system/probe?	If yes, pull temp probe prior to patient transport to MRI
	۰.	Does the patient have a halter/telemetry monitor?	26	Does the patient require any monitoring that cannot be removed for the MRI	If you want the patient monitored, Nurse has to travel w/ patient OR nurse Needs
11	+	Does the patient have a halter/telemetry	26	Does the patient require any monitoring	

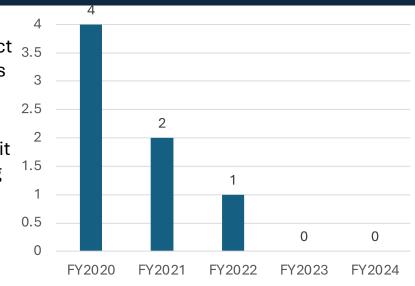
#### 3. Multipart study ordering

# Study of the Intervention(s), Results and Conclusion

- MRI serious safety event rate is an outcome measure where the <u>lack of harm</u> in a potentially dangerous environment <u>is a</u> <u>positive outcome</u>.
- The acceptable rate of harm is zero, the starting point of any given measurement time period, and any reported incident confers poor performance.
- Other metrics are needed to assess performance regularly to find trends and process performance before the zero turns into a one, two, etc. Potential metrics =
  - Adherence to redundant MRI screening practices
  - Adherence to standardized use of FMDs
  - Reporting of less serious incidents, such as near misses
  - FMD output: frequency of detection of inadvertent potentially unsafe objects
- Near misses and serious safety events trending downward.
- No harm events flat ranging between 4 and 9 per quarter since the FMECA.
- Enterprise FMD deployment approved for this fiscal year.

#### Near Miss events Q1 2021 to Q2 2022

- The FMECA clearly 4 had a positive impact 3.5 on MRI safety across 3 the enterprise.
- Many initiatives are still in progress and it is worth considering whether the Hawthorne Effect had any potential impact on performance.



- Strategic trade-offs and costs were not adequately assessed
  - Extra time for technologists to conduct meaningful FMD patient assessment
  - Impact of new screening process on ordering clinicians and nursing (i.e., time and effort)
  - Reduction in cost from optimizing IP/ED MRI utilization
- Time and effort of FMECA stakeholders was not accounted for and balanced with expected positive impact on MRI safety
- This work identified the greatest MRI safety threats in a large enterprise in the domains of: ordering, screening and FMDs.
- Engineering out system safety threats leads to a reduction in serious MRI safety events and near miss events in the inpatient and emergency department settings.

#### Serious Safety events 2021 to 2024