Thomas Jefferson University

JEFFERSON 200

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

Jefferson MRI Safety Events 24 months

TJUH 141	JAH 250
JNE 122	JNJ 106

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

- 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.

The FMECA Charter

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/Potential Phase 2: All Outpatient MRI operations, Magee Rehabilitation Hospital, Physicians Care Surgical Hospital, Radiation Oncology MRI-LINAC, Rothman Orthopaedic Specialty Hospital

Timeline

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

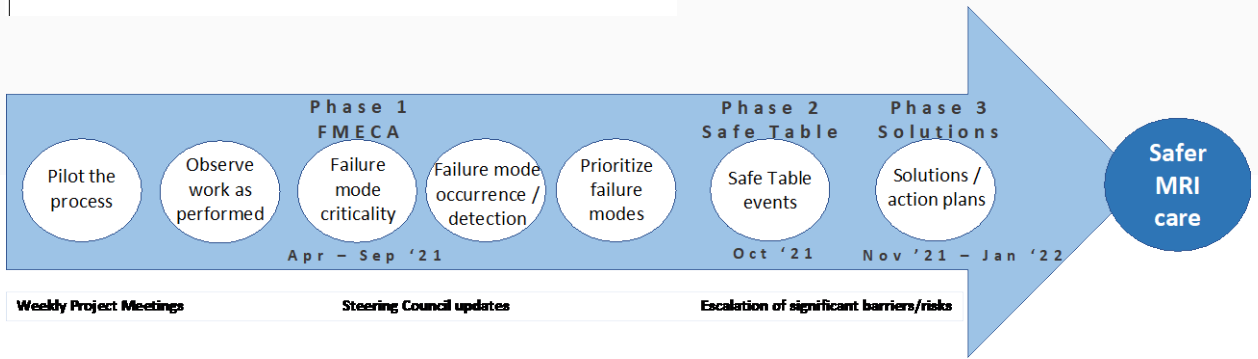
Phase 3 Implementation Plan (~2 months): includes developing implementation plan(s) to eliminate safety threats uncovered in FMECA and Safe Table events.

KPI Outcome Metric

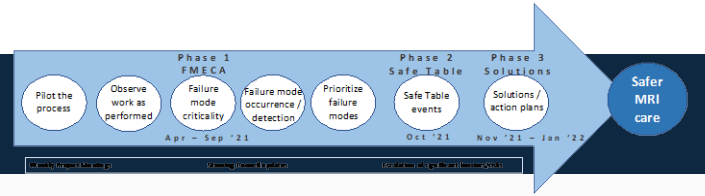
Number of times the metal detectors/wands are triggered by the patient at the door to zone 4
Serious MRI Safety event occurrences

KPI Process Metric

Number/rate of inpatient screenings prior to arriving in Radiology
Number of good catches/near misses reported
Number of quarterly ACA reviews



The Intervention



As part of the launch of the FMECA, additional necessary steps included:

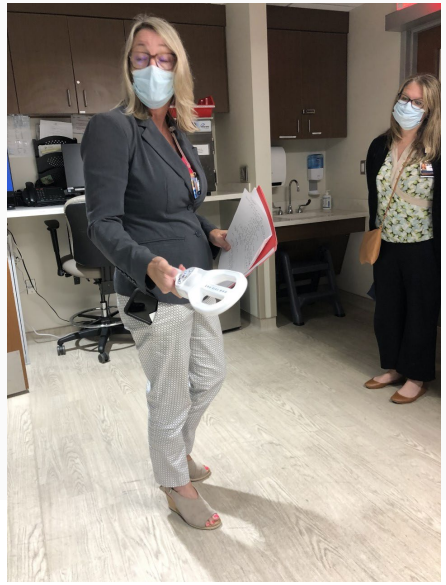
- Identifying all stakeholders involved in the lifecycle of the MRI process
- Devise messaging plan to the diverse, widespread group of stakeholders: create infographic
- Create systematic, proactive methods for evaluating a process
  - Identify where and how it might fail
  - Assess relative impact 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?)

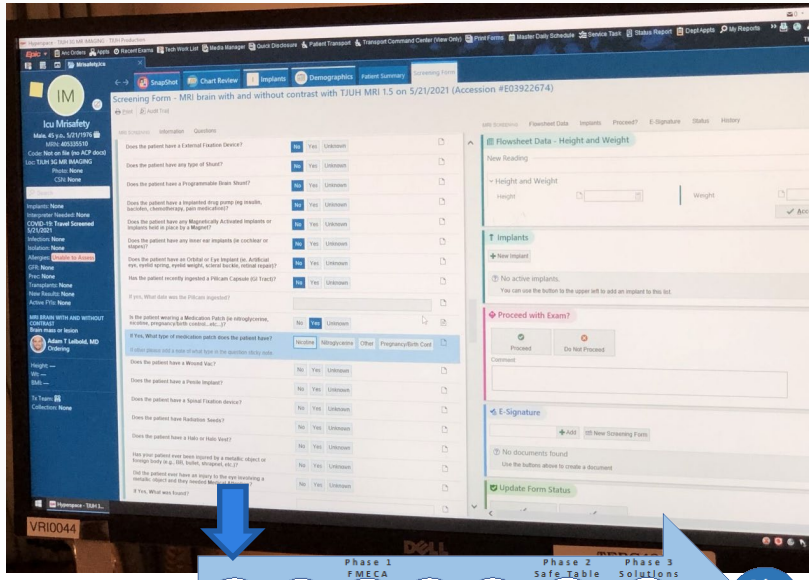
- Recognition that the problems exist due to "work as imagined" /= "work as performed"
- Radiology physician/technologist leaders create swim lane diagrams of our local process.
- Swim lane diagram then grows to reflect the stakeholders across the life cycle of an inpatient MRI order. See below
  - Diagram 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

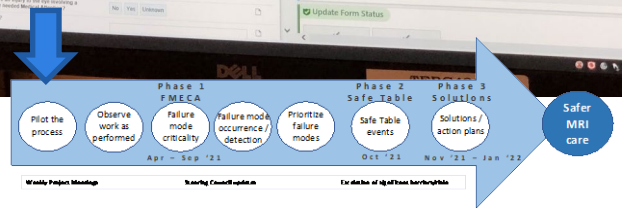
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1	Project: MRI Safety FMECA **Project Sub-Teams**	Radiologist	Radiology Technologist	Radiology Resident	Physicist	Patient Transport	Nursing (Floor)	Nursing ICU	Biomed	Anesthesia	Nursing ED	Ordering Resident (medicine)	Ordering Resident (Neuro-surg)	Ordering APP?	Informatics	Respiratory	Security	Environmental	Custoidal Servcies
2		Project 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	Iman 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	Iman 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 ➔)
- 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





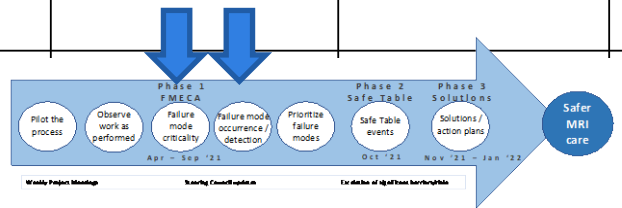


The Intervention: Identifying/Analyzing Failure Modes

- 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.

Rating	Severity	Rating	Occurrence	Rating	Detectability
10	**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
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	**Moderate Danger** Minor injury, major system problem	5	**1x/month**	5	**Manual double checks, sample inspections**
3	**Low Danger** very minor injury	3	**Occasional fail** 1x/3 month	3	**100% manual inspection** process
1	**No to Slight Danger**	1	**Rare** Up to 1x/yr	1	**Certain detection** 100% automated inspection process

	A	B	C
1	**Process step**	**Potential failure mode**	**Potential failure effects**
2	**What is the step?**	**In what ways can the step go wrong?**	**What is the impact if the failure mode is not prevented or corrected?**
3	Decision to order MRI	patient clinical accuity is not appropriate for the MRI exam	Missing implants; unnecessary exam exposing patient to unnecessary risk; delay other patients; putting critically ill patient in further harm way; compromise diagnostic results
4	Decision to order MRI	MRI ordered when CT/US should be ordered first	Unnecessary exposure to MRI risks; unneccessary cost; increase length of stay
5	Decision to order MRI	Ordering too many MRIs in a short period of time (pt had 3 MRIs in 3 months)	Unnecessary exposure to MRI risks; unnecessary cost, increase length of stay
6	Screening patient prior to ordering MRI exam	Ordering patients with known implants and/or devices	Device failure, burns, internal injuries, delays
7	Screening patient prior to ordering MRI exam	Screening form not being utilized/not screening patient prior to ordering exam	Device failure, burns, internal injuries, delays
8	Screening patient prior to ordering MRI exam	Choosing "unable to determine" as a screening question choice	causes ambiguity; the system does not instruct next step when this choice is selected
9	Screening patient prior to ordering MRI exam	Patient is not screened for anxiety and/or patient is not prepped for what to expect	delay in care; limiting diagnostic results; stop test before done; refuse to go in



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

I. Ordering MRI Exams

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 MRI	Lack of institutional/departmental utilization guidelines for MRI exams	Increase safety risk and stress for Radiology Technologists
20% MRI inpatient order are multi-part and the majority not clinically indicated.	No patient suitability assessment guidelines exist	Delays and limited access to MRI for patients for whom MRI is clinically appropriate
	Ordering Providers do not know the patients	

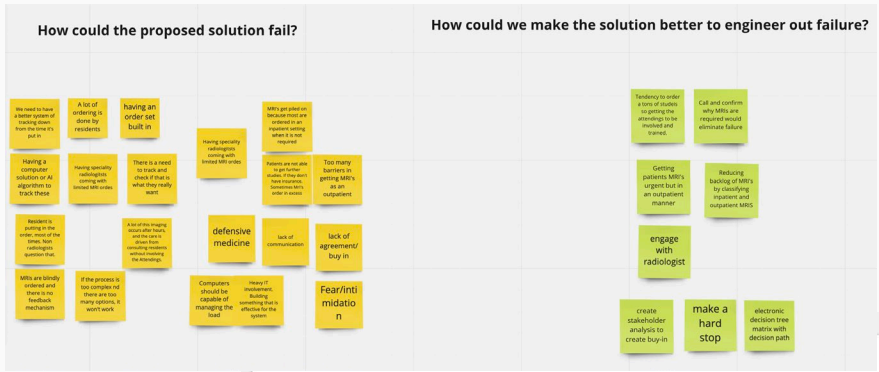
II. Prepping Patients for MRI Exams

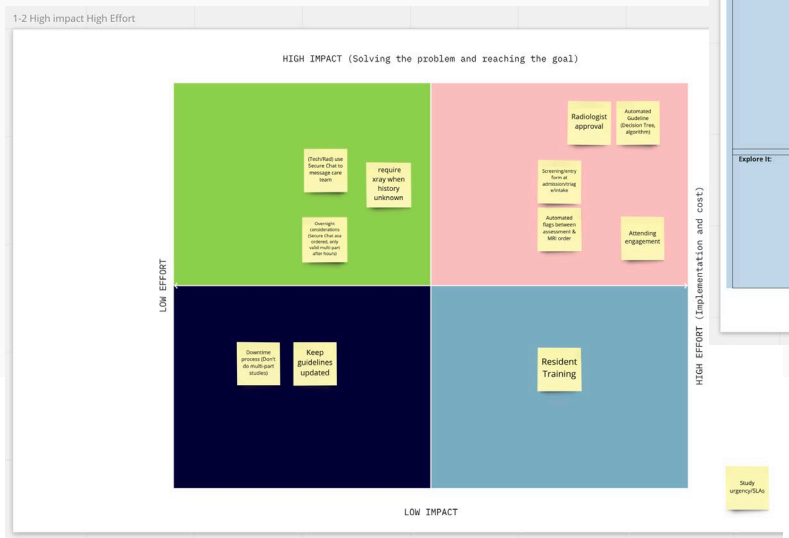
Observations	Causes	Effects
Incomplete MRI Patient Screening Forms	Nurse are unclear of their role and expectations for MRI screening	Unidentified implants, attachments, ferrous materials can cause thermal injuries, projectile injuries, or death
Foreign objects not removed from patients at the bedside/in the ED	Inadequate education for nurses on MRI screening	Increase stress for Radiology Technologists
Upwards of 55 MRI orders for patients with unsafe implants (Abington, 2019-2020)	No MRI screening checklist for nurses	Delays and limited access to MRI
	MRI screening form is long	

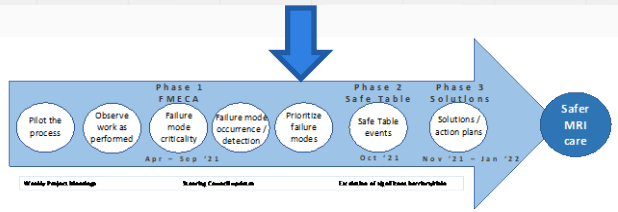
III. Screening Patients, Staff, and Objects Entering MRI

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

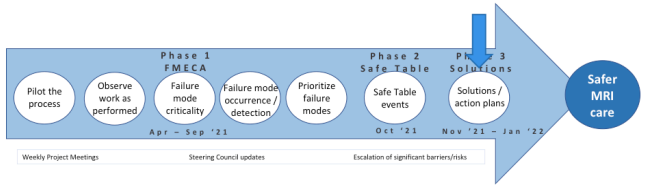
- Causes and effects were outlined all in preparation for the upcoming Safe Table Event to share experience, findings and observations with all enterprise stakeholders







The Intervention: Prioritizing Solutions

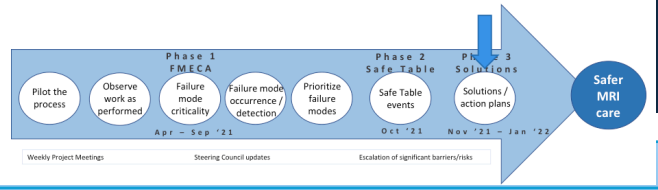


- Radiologist and technologist FMECA leaders chose top 3 action items for the 3 FMECA problems identified (38 actions considered)
- Participants then organized their 9 top action items into most to least impactful based on perceptions of how effective the actions would be to engineer out the problems 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
  - The 38 Action Items Ranked into 24 priority bins
  - 12 Actions not selected by the 8 participants

Top 10 prioritized on a 2-year time line.

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)

Interventions



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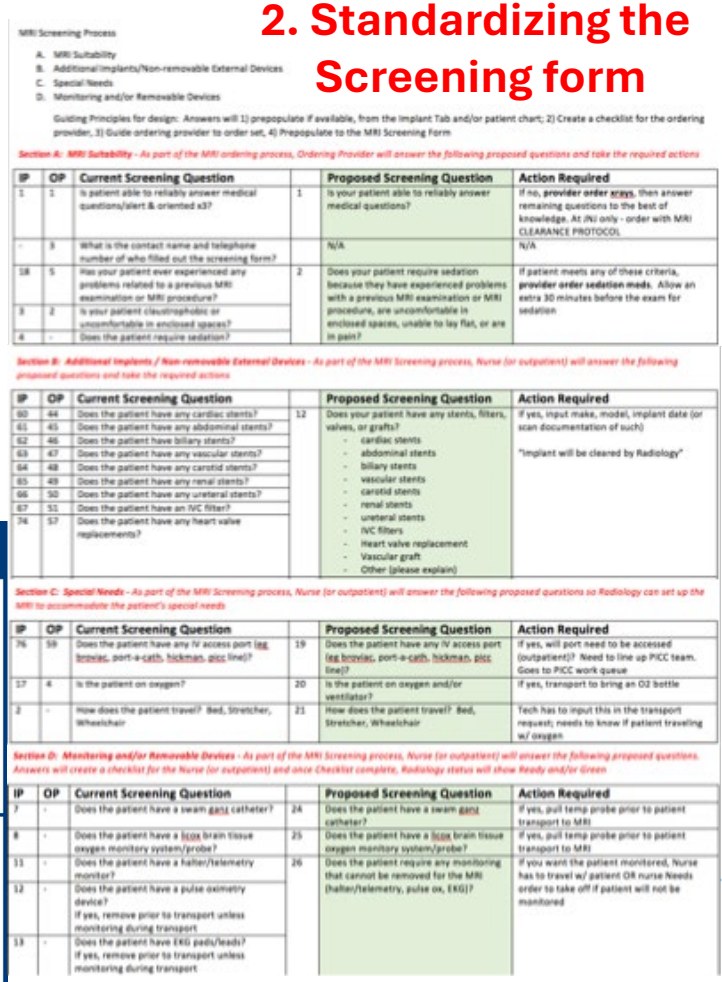
2	Radiology ready (standardized screening process in use in 1 hospital division)	6	75.0%	4.17 (SD= 2.64)
3	Automated Ordering Guideline (decision tree, algorithm)	6	75.0%	5.17 (SD= 2.41)

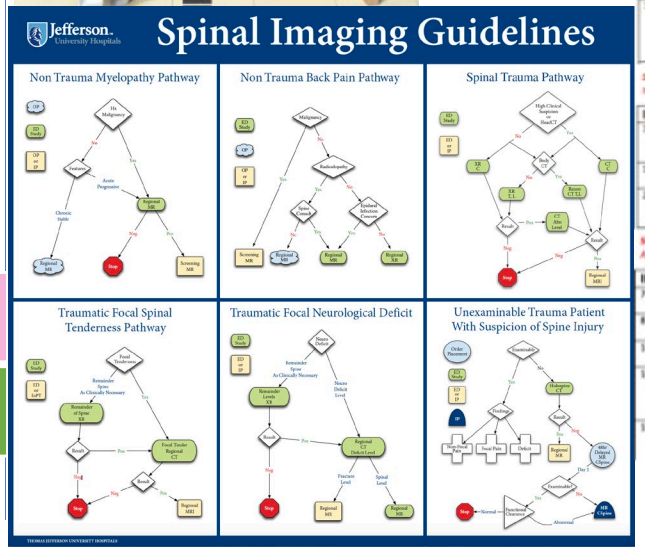
Top 3 solutions implemented:

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

1. FMDs

2. Standardizing the Screening form





3. Multipart study ordering

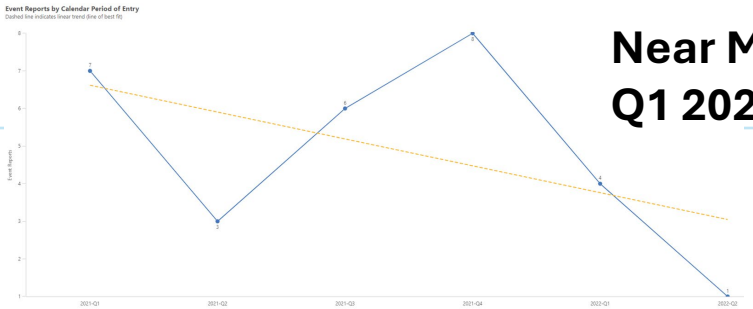
3-6 Months	6-9 Months	1-2 Years	2+ Years
2. Radiology ready	1. Purchase FMD wands (1 per scanner for all locations) with 2 types of detection	3. Automated Guideline (Decision tree, algorithm)	10. Radiology screen at bedside
7. Mandatory, annual Staff Education on MRI	5. Attending engagement	4. Radiologist approval	
	9. Purchase FMD wall systems	6. Improve staffing to adequate levels	
		8. Screening/ entry form at admission/ triage/intake	

Effort

Impact

Study of the Intervention(s), Results and Conclusion

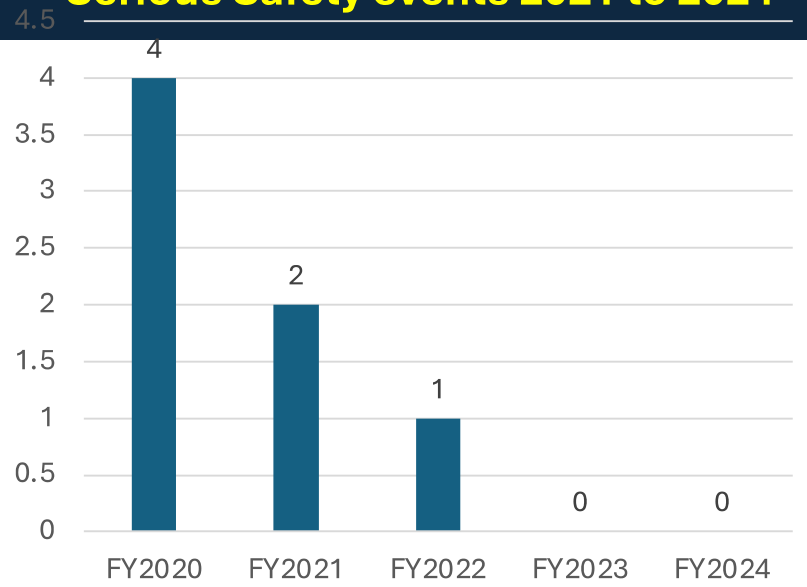
- MRI serious safety event rate is an outcome measure where the **lack of harm** in a potentially dangerous environment **is a positive outcome**.
- The acceptable rate of harm is zero, the starting point of any given measurement time period, and any reported incident confers poor performance.
- Other 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 had a positive impact on MRI safety across the enterprise.
- Many initiatives are still in progress and it is worth considering whether the Hawthorne Effect had any potential impact on performance.

Serious Safety events 2021 to 2024



- 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.**