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# A STUDY TO CARRY OUT SAFETY PROFILE AND RISK ASSESSMENT OF MRI CENTRE AT A TERTIARY CARE TEACHING HOSPITAL

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## ABSTRACT

**Background:**
Potential risks associated with Magnetic Resonance Imaging processes, and its adverse effects, with its damaging consequences for patients, healthcare professionals, and healthcare institutions, is a reason for concern in most health-related sectors. Failure Mode & Effect Analysis (FMEA) allows, the analysis of processes to take preventive tools for possible faults identification and the definition of improvement actions to optimize work and minimize the risk of errors for the patient.

**Aim:**
To evaluate the safety profile and carry out a risk assessment of the MRI Centre at a tertiary care teaching hospital.

**Settings & Design:**
A Cross-Sectional Descriptive prospective study of magnetic resonance imaging procedure was conducted over the period of 01 Nov 2021 to 30 Jan 2022.

**Methods & Material:**
Direct observations supplemented with semi-structured interviews were carried out to identify various hazards associated with MRI procedures and determine the various failure modes and evaluate their potential to cause patient harm. Two multidisciplinary teams were constituted and carried out their research independently, identifying common themes & thematic analysis was done. The FMEA approach also enabled each failure mode to be attributed accumulative numerical value, the Risk Priority Number (a numerical rating of the severity, probability, and detectability) of each failure mode. The hazard analysis was completed by plotting the RPNs of higher-risk failure modes in a Risk priority matrix divided into three coloured areas reflecting different levels of priority for action.

**Results & Conclusion:**
A total of 15 high-risk failures were identified and plotted in a graph allotting priorities and areas of improvement of processes. Improvements are suggested at both Organisational & Individual Levels.

## INTRODUCTION

Patient safety became an important issue in health care, particularly after the publication of the report "To Err is Human: Building a Safer Health System" by the Institute of Medicine in the United States in 1999. This report made the general public, healthcare policymakers, and healthcare providers aware that targeted actions are needed to increase patient safety. The report placed patient safety high on the healthcare agenda. In October 2004, the World Health Organization (WHO) launched the World Alliance for Patient Safety. Several interventions were started to improve the safety of patients.

Magnetic Resonance Imaging (MRI) is a widely used diagnostic modality. It is the preferred procedure for diagnosing a large number of potential problems or abnormal conditions that may affect different parts of the body. In general, MRI creates pictures that can show differences between healthy and unhealthy or abnormal tissues. Physicians use MRI to examine the brain, spine, joints (e.g., knee, shoulder, hip, wrist, and ankle), abdomen, pelvic region, breast, blood vessels, heart, and other body parts.

Potential risks associated with Magnetic Resonance Imaging processes, and its adverse effects, with its damaging consequences for patients, healthcare professionals, and healthcare institutions, is a reason for concern in most health-related sectors. October 18, 2021, a 60-year-old man at a South Korean hospital was killed in an MRI accident when an oxygen cylinder was carried into the scanning suite during his exam. [1]

On 18 October 2021, A 60-year-old man at a South Korean hospital was killed in an MRI accident when an oxygen cylinder was carried into the scanning suite during his examination. The oxygen cylinder was already on the pallet on which the patient was brought into the suite; during the scan, it was shifted about two meters and was sucked into the device, killing the patient. [2]

On 17 July 2021, an ambulance driver carrying an oxygen cylinder got stuck in a Magnetic Resonance Imaging (MRI) machine in Bhaindar, Mumbai while escorting a patient on Friday. Fortunately, the 40-year-old escaped with a fractured little finger on the right hand. The incident took place at Pratham MRI centre. [3]

October 25, 2019, a radiology nurse was seriously injured Oct. 23 at Sunderby Hospital in Luleå, located in northern Sweden, when caught in the strong magnetic field of the magnetic resonance imaging (MRI) scanner and pulled against it. The hospital said the nurse went to the patient and was apparently wearing a weight vest containing Ferrous metal. An MRI creates a very strong magnetic field, requiring everyone entering the examination room to leave all

magnetic metal objects outside the room. This includes jewellery, coins, keys, credit cards, mobile phones, watches and hearing aids. The magnetic field can destroy electronic devices and bank cards can be erased. [4]

The powerful magnetic field of the MR system can attract objects made from certain metals (i.e., metals known to be ferromagnetic, such as iron) and cause them to move suddenly and with great force. This can pose a possible risk to the patient or anyone in the object's "flight path." Improper safety screening for metal devices leads to potential hazards that include the following: dislodging medical or other metal implants, tissue heating, induced electrical currents, equipment or materials becoming dangerous missiles or projectiles, and potentially interrupting patient monitoring equipment. The development of a comprehensive and efficient screening procedure for potential contraindications is a critical component of patient safety. The powerful magnetic field of the MR system will pull on any ferromagnetic object in or on the patient's body such as a medical implant (e.g., certain aneurysm clips, implants, etc.). Therefore, all MRI facilities have comprehensive screening procedures and protocols they use to identify any potential hazards. [5]

Clinical risk management is a comprehensive program for the prevention of clinical risk. Clinical risk management or risk management in radiology regards the system of guidelines, protocols, routes, procedures, and organizational measures to reduce the likelihood of events and potential actions to produce adverse effects or unexpected effects on the health of professionals and/or patients. [6]

Failure Mode & Effect Analysis (FMEA) allows, the analysis of processes to take preventive tools for possible faults identification and the definition of improvement actions to optimize work and minimize the risk of errors for the patient. A careful analysis must aim to identify risks related to the management of all phases of a process of radiological diagnosis, for measuring and setting actions for prevention and control. FMEA is a strategy developed for identifying the potential errors of a product/process, evaluating the associated risk and assigning a value in terms of importance. [7]

The objective of the study is to apply the FMEA proactive analysis for risk management in "Magnetic Resonance Examination" process in order to identify the critical phases (activities) with higher Priority Risk Index (PRI) and to identify possible improvement projects. In order to determine the PRI, three characteristics are needed: probability (probability of the event occurring), severity (severity of the event), and detection (possibility of detecting critical aspects or identifying the failure through controls before the event has produced its negative effects). FMEA has been used in various areas of the hospital for proactive risk assessment and prevention. [8]

## AIM:

To evaluate the safety profile and carry out a risk assessment of the MRI Centre at a tertiary care teaching hospital.

## OBJECTIVES:

(a) To identify the various hazards associated with MRI Centre.
(b) To carry out the risk assessment of the identified hazards.
(c) To identify potential failure modes and recommend corrective actions.

## METHODOLOGY:

Failure mode and effect analysis (FMEA) is a method used in industry to assess complex processes according to a standardized approach with a view of identifying the elements that carry a risk of causing harm and, consequently, prioritizing remedial measures. It is based on the concept that risk is related not only to the likelihood of a failure occurring but also to the severity of the failure's consequences and the feasibility of detecting and intercepting a failure before it occurs.

Failure Mode: A failure mode is a way in which the component, subassembly, product, input, or process could fail to perform its intended function. Failure modes may be the result of upstream operations or may cause downstream operations to fail, that is, things that could go wrong.

Effect: The impact on the process or customer requirements as a result of the failure;
Severity: The impact of the effect on the customer or process;
Root cause: The initiating source of the failure mode;
Occurrence (or frequency): How often the failure is likely to occur;
Detection: The likelihood that the failure will be discovered in a timely manner, or before it can reach the customer.

Steps in Conducting FMEA (9)
(a) Step 1: Select a process to evaluate with FMEA
(b) Step 2: Recruit a multidisciplinary team. Be sure to include everyone who is involved at any point in the process.
(c) Step 3: Have the team meet together to list all of the steps in the process. Number every step of the process and be as specific as possible. It may take several meetings for the team to complete this part of the FMEA, depending on the number of steps and the complexity of the process. Flowcharting can be a helpful tool for outlining the steps.

(d) Step 4: Have the team list failure modes and causes for each step in the process, and list all possible "failure modes"—that is, anything that could go wrong, including minor and rare problems. Then, for each failure mode listed, identify all possible causes.

For every failure mode identified, the team should answer the following questions and assign the appropriate score (the team should do this as a group and have consensus on all values assigned):

- Likelihood of occurrence: How likely is it that this failure mode will occur? Assign a score between 1 and 10, with 1 meaning "very unlikely to occur" and 10 meaning "very likely to occur."
- Likelihood of detection: If this failure mode occurs, how likely is it that the failure will be detected? Assign a score between 1 and 10, with 1 meaning "very likely to be detected" and 10 meaning "very unlikely to be detected."
- Severity: If this failure mode occurs, how likely is it that harm will occur? Assign a score between 1 and 10, with 1 meaning "very unlikely that harm will occur" and 10 meaning "very likely that severe harm will occur." In patient care examples, a score of 10 for harm often denotes death.

Following Rating scales were used to assign values to the occurrence (O), severity (S), and detection (D) scores while carrying out Risk Assessment of MRI Centre by FMEA tool (Table 1 – 3):

**Table 1: Rating Scale for assigning values to occurrence (O)**

| Occurrence | Score |
|---|---|
| Remote | 1 |
| Uncommon | 2 |
| Occasional | 3 |
| Frequent | 4 |
| Very Frequent | 5 |

**Table 2: Rating Scale for assigning values to severity (S)**

| Severity of Event | Score |
|---|---|
| Minor injury; abrasions / contusions | 1 |
| Minor injuries; cuts / burns | 2 |
| Major injuries; fractures / cuts / burns / damage to internal organs | 3 |
| Severe injury; amputation / eye loss / permanent disability | 4 |
| Death | 5 |

**Table 3: Rating Scale for assigning values to detection (D)**

| Detection | Score |
|---|---|
| Very High | 1 |
| Moderate | 2 |
| Low | 3 |
| Very Low | 4 |
| Nothing | 5 |

(e) Step 5: For each failure mode, have the team assign a numeric value (known as the RPN) for the likelihood of occurrence, the likelihood of detection, and severity. Assigning RPNs helps the team prioritize the areas to focus on and can also help in assessing opportunities for improvement.

Risk Priority Number (RPN) = O x S x D
O - Occurrence of event S - Severity of event
D - Detection of event

(f) Step 6: Evaluate the Results, calculate the RPN for each failure mode, multiply the three scores obtained (each of likelihood of occurrence, detection, and severity). Identify the failure modes with the top 10 highest RPNs. These are the ones the team should consider first as improvement opportunities. To calculate the RPN for the entire process, simply add up all of the individual RPNs for each failure mode. Use RPNs to plan improvement efforts. Failure modes with high RPNs are probably the most important parts of the process on which to focus improvement efforts. Failure modes with very low RPNs are not likely to affect the overall process very much, even if eliminated completely, and they should therefore be at the bottom of the list of priorities (Table 4).

**Table 4: RPN Scoring & Corrective Actions to be taken**

| RPN Scoring | Corrective actions | |
|---|---|---|
| RPN of > or = 5 | High Risk | Abandon the task |
| RPN of 2-4 | Moderate Risk | Improve existing control & take remedial action |
| RPN of < 2 | Low Risk | |
| RPN of 1 | Very Low Risk | Monitoring required |

A Cross-Sectional Descriptive prospective study of magnetic resonance imaging procedure was conducted over the period of 01 Nov 2021 to 30 Jan 2022. Direct observations were carried out to identify various hazards associated with MRI procedures and determine the various failure modes and evaluate their potential to cause patient harm. The observations were supplemented with semi-structured interviews with stakeholders. Two multidisciplinary teams were constituted involving Radiologists, Clinical Risk Assessment Specialists, Residents, and Paramedical staff (MRI technicians) of the MRI Centre were formulated for the tasks. The two teams carried out their research independently of each other. Later on, common themes were identified and thematic analysis was done. The FMEA approach also enabled each of the elements comprising the process under investigation to be attributed accumulative numerical value, the Risk Priority Number, which can be used to prioritize the action to be taken because it is a numerical rating of the severity, probability, and detectability of each failure mode. The hazard analysis was completed by plotting the RPNs of higher-risk failure modes in a Risk priority matrix (Fig. 2), which is a graph divided into three coloured areas reflecting different levels of priority for action:
Area 1 (Red) - Urgent action required (abandon the task)
Area 2 (Yellow) - Remedial actions required (Improve existing control)
Area 3 (Green) - Scheduled actions or monitoring required

The priority matrix gave graphical evidence of which steps, in the complex process of MRI, more urgently needed corrective action to reduce the risk of failures.

## OBSERVATIONS

During a prospective study of MRI Centre to evaluate safety profile following hazards and associated failure modes were identified and risk assessment was carried out as by calculating RPN as follows:

**Table 5: Various hazards and the high-risk failure modes that were identified in multiple FMEAs with the RPNs count.**

| Hazards | Risk No | Failure Modes | Causes | Effects | Occurrence of Event (O) | Severity of Event (S) | Detection of event (D) | P = O x D | RPN |
|---|---|---|---|---|---|---|---|---|---|
| Magnetic Missile Hazards | R1 | A MR unsafe wheel chair is brought into the entrance of the MR scan room | Wheel chair was not labelled or colour coded as MR safe or non-availability of MR safe wheel chair | Minor injuries/abrasion/fracture to patient | 1 | 3 | 1 | 1 | 3 |
| | R2 | A MR unsafe cylinders is brought into the entrance of the MR scan room | Cylinder was not labelled or colour coded as MR safe or non-availability of MR safe cylinders | Minor injuries/contusion/ fractures/damage to internal organs to patient | 2 | 3 | 1 | 2 | 6 |
| | R3 | The patient, who had a pacemaker, is taken into the MR scan room | Lack of thorough checks or screening of medical records before planning MRI Scan | The powerful magnets can trigger changes in a pacemaker's settings, and this may pose a life-threatening risk for patients | 1 | 5 | 1 | 1 | 5 |
| | R4 | MRI scan of patient with aneurysmal clip / prosthesis | Failure in taking detailed medical history regarding implants/ clips/prosthesis by referring physician or patient didn't recall about any surgery | The powerful magnets can dislodge or displace aneurysmal clip / prosthesis, and this may pose a life-threatening risk for patients | 2 | 5 | 1 | 2 | 10 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | R5 | A radiographer getting an injection tray with metallic scissors into the MR scan room | Radiographer in hurry or stress didn't check about metallic instrument in injection tray | Minor injuries/lacerations/eye loss or permanent disability to patient | 1 | 4 | 1 | 1 | 4 |
| Acoustic hazards | R6 | Patients are exposed to sound pressure levels above 95dB for more than 15 min time | Acoustic exposure more than 95 dB without hearing protection during scanning | Temporary or permanent damage to auditory system | 2 | 3 | 2 | 4 | 12 |
| RF Burns | R7 | Scanning of patients with clothing containing metallic materials/threads such as athletic wear (e.g., yoga pants, shirts, etc.), socks, braces | Staff and patients are unaware of metallic threads in clothing and they are even undetected during screening | These metallic threads can heat up and burn the patient during an MRI | 2 | 2 | 3 | 6 | 12 |
| | R8 | Improper positioning of patient in scanner with hands/thighs/calves touching together creating conductive pathway | Exposure to radiofrequency (RF) electromagnetic fields (EMF) can induce heating in biological tissue due to creation of | Heating of biological tissue causing burns | 1 | 2 | 2 | 2 | 4 |
| | R9 | Patient with impaired thermoregulatory ability (infants/pregnant women) taken to MRI | inability to ascertain the effect of increased heat load | Heating of biological tissue causing burns | 1 | 2 | 1 | 1 | 2 |
| Contrast Related Hazards | R10 | Patient vomits after oral contrast material is administered | Allergic/ hypersensitivity reaction after contrast injection | Physiological effects like nausea, vomiting, headache, metallic taste | 1 | 1 | 1 | 1 | 1 |
| | R11 | Patient with kidney failure, kidney transplant, liver disease injected with gadolinium contrast | Allergic/ hypersensitivity reaction after contrast injection due to impaired organ function | further impairment of kidney/ liver function | 1 | 3 | 1 | 1 | 3 |
| | R12 | Breast feeding mother taken for MRI scanning | It usually takes about 24 hours for the contrast agent to clear the body. | Infants may get exposed to contrast agent and may get allergic reaction or physiological effects like nausea, vomiting | 1 | 1 | 1 | 1 | 1 |
| Screening Related Hazards | R13 | Screening form incorrectly filled out | Radiographer in hurry or stress misses out in filling complete form | Physiological effects, allergic reaction or life-threatening damage to patient | 1 | 3 | 1 | 1 | 3 |
| | R14 | Nurse filling out form unsure of MR compatibility of devices | Incomplete knowledge about MR compatible devices | Minor injuries/abrasion/burns to patient | 1 | 2 | 1 | 1 | 2 |
| Helium Leaks | R15 | An emergency quench or a liquid helium leak | The release of helium into scan room due to an emergency quench or the leaking of helium from the MR scanner. | Danger of asphyxiation or frost-bite from the very cold helium gas exhaust for MR users and participants within or entering magnet room during the release of the helium | 1 | 5 | 2 | 2 | 10 |

**RESULTS**

The study identified various hazards and potential failure modes possible in the process of magnetic resonance imaging at each step starting from the screening of the patient up to imaging. RPNs is an important tool to identify the failure modes that pose the greatest risk of harm and prioritize the actions.

Table No. 5 displays various hazards and the high-risk failure modes that were identified in multiple FMEAs with the RPNs count.

**Failure Modes**

A total of 15 high-risk failures were identified, plotted in areas 1 (red), 2 (yellow), and 3 (green) of the priority matrix (Figure 1), with associated causes and effects (Table 6).

- Urgent action required (Abandon the task)

-Remedial action required (Improve existing control)

- Scheduled action or monitoring required

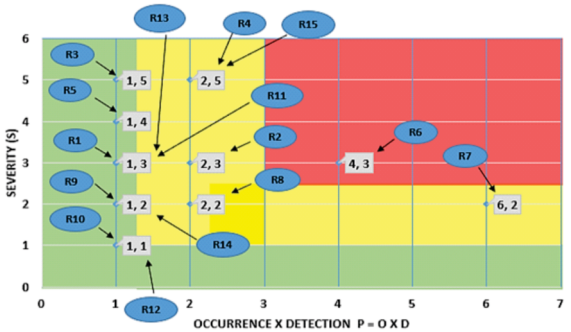


**Figure 1: Risk Priority Matrix**

**Table 6: Classifications of Failure Modes**

| Risk No | Failure Mode | Action |
|---|---|---|
| Red Area | | |
| R6 | Patients are exposed to sound pressure levels above 95dB for more than 15 min time | Urgent action required (Abandon the task) |
| R7 | Scanning of patients with clothing containing metallic materials/threads such as athletic wear (e.g., yoga pants, shirts, etc.), socks, braces | |
| **Yellow Area:** | | |
| R2 | A MR unsafe cylinders is brought into the entrance of the MR scan room | Remedial action required (Improve existing control) |
| R4 | MRI scan of patient with aneurysmal clip / prosthesis | |
| R8 | Improper positioning of patient in scanner with hands/thighs/calves touching together creating conductive pathway | |
| R15 | An emergency quench or a liquid helium leak | |
| **Green Area:** | | |
| R1 | An MR unsafe wheelchair is brought into the entrance of the MR scan room | Scheduled action or monitoring required |
| R3 | The patient, who had a pacemaker, is taken into the MR scan room | |
| R5 | A radiographer getting an injection tray with metallic scissors into the MR scan room | |
| R9 | Patient with an impaired thermoregulatory ability (infants/pregnant women) taken to MRI | |
| R10 | The patient vomits after oral contrast material is administered | |
| R12 | Breastfeeding mother was taken for MRI scanning | |
| R13 | Screening form was incorrectly filled out | |
| R14 | Nurse filling out form unsure of MR compatibility of devices | |

## Recommendations

Based on detailed study of various hazards and potential failure modes associated with Magnetic Resonance Imaging process by using Failure Mode Effects Analysis (FMEA) a qualitative risk management tool, which helped to proactively identify failure modes, following are recommendation for the good practices to be followed to ensure patient safety while carrying out MR Imaging in a tertiary care teaching hospital:

### Actions at Organisation level

- √ Use of labelled & colour coded MR safe equipment
- √ Appointing of qualified staff in MRI Centre
- √ Training and awareness of staff on effective communication techniques

### Actions at Individual level

- √ Use of Safety checklist while giving appointment
- √ Implementation of 'pause & check' process before entering scan room
- √ Patient must change to suitable MRI safe clothing before scan
- √ Proper positioning of patient's limbs while scanning

### Other Recommendations

- √ Ear protection (noise cancelling headphones, earplugs) should always be provided for everyone within the magnet room.
- √ Filling of Safety Screening form by referring doctor.
- √ MR Technician should advise and monitor the patient to ensure that they do not position their limbs in a way that will create conductive body loops or insulation shall be placed between the patient's skin and these types of items.
- √ Patients with impaired thermoregulatory mechanisms (pregnant women, infants) should be handled with caution, or insulation shall be placed between the individual's skin and these types of items, and scanning times will be kept as short as practicable.
- √ Pump breast milk before the MRI scan, which can be used to feed the infant until the contrast agent has been cleared from the body.
- √ Use of steroid medication before the scan to avoid an allergic reaction to contrast or doing test dose of intended contrast.
- √ Induction and periodic training of staff handling MRI machines.
- √ A quench pipe should be installed in such a way as to vent cryogenic helium gases into the atmosphere rather than into the magnet room. In the event of a system quench, all staff and participants shall be evacuated from the MR examination room as quickly as safely feasible, an oxygen monitor should be installed in the magnet room to detect oxygen depletion, with an alarm panel in the console of the MRI control room.

## CONCLUSION

In today's healthcare world, patient-safety issues are of major concern. MRI Safety is paramount while working within the MR Environment due to the potential hazards it presents to both staff and patients. Three major forces can pose a risk to both patients and staff. First, the magnetic field of the MRI is always on, and any ferromagnetic objects or equipment exposed to the static magnetic field can act as projectiles. Second, the dynamic magnetic field can potentially generate a current in implants or pacemakers. Finally, the excitement of protons by the radiofrequency magnetic field can produce enough heat to generate burns. Medical providers should be aware of these forces and their consequences, and should maintain a high level of vigilance to ensure patient safety.

Implementation of the FMEA will lead to identification of key areas of focus for risk mitigation in MRI Centre. It also stimulates the most urgent improvement efforts in clinical practice to prevent errors before they occur and to identify opportunities to improve safety in healthcare delivery. Hence, FMEA is an effective and reliable tool to proactively examine complex processes in the MRI Centre to minimize the future occurrence of failures, thus improving patient safety and streamlining the efficiency.

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