



# Validation and Benchmarking of Patient Reported Experience Measures (PREM) tool for the safety of patients undergoing MRI investigations

**Authors:** Jawahar SK Pillai<sup>1</sup>, Lallu Joseph<sup>2</sup>, Biswajeewan Sahoo<sup>1</sup>

<sup>1</sup> Department of Hospital Administration, All India Institute of Medical Sciences, Bhubaneswar, Odisha, India

<sup>2</sup> Quality Department, CMC Vellore, India, and Secretary General, Consortium of Accredited Healthcare Organizations (CAHO), India.

**Proposal # 12**

## INTRODUCTION

Magnetic Resonance Imaging (MRI) is an essential medical diagnostic test. MRI is perceived as safe, but incidents can be fatal due to the failure of safety measures. Accidents reported in the past have resulted in loss of life, infrastructure, and legal consequences to the hospitals. MRI-related adverse events are preventable. A patient, in general, is not aware of the Magnetic field used in the MRI process. Hospitals often neglect pre-diagnostic counselling, considering high patient volumes and workload. Patients with in situ metallic implants, pacemakers, jewellery, or ferromagnetic objects like metallic clips or stents are the most vulnerable to accidents and adverse events inside the MRI unit. Patient Reported Experience Measures (PREM) are questionnaire-based tools that patients respond to based on their perceptions of the medical intervention.

## AIM & OBJECTIVES

The study's primary objective was to develop a context-specific PREM tool for MRI safety by co-producing with the patients and other stakeholders through constructive feedback. This tool is expected to help assess whether the healthcare worker performs the intended actions to ensure patient safety. The secondary objective is validating and benchmarking the MRI safety PREM tool.

## METHOD

A multiphase study was conducted in fifteen hospitals in India using purposive sampling. Phase 1 included forming an expert group for focused group discussions to develop a Standard Operating Procedure (SOP) and the PREM Questionnaire. Phase 2 consisted of a pilot study with a sample size of 213 participants (Patients), and phase 3 consisted of a field study with 719 participants (Patients). Informed consent was obtained from the participants.

The Institution Ethics Committee (IEC) approved the study, AIIMS Bhubaneswar (T/EMF/Hosadm/2023-24/209).

### Phase 1:

A core group was formed with experts from hospital administration, radiology, nurses, quality managers, statisticians, and support staff from a group of private and public medical institutions and hospitals in the country.

### Phase 2: Pilot Study

A pilot study was done across fifteen hospitals in the country with a sample size of 213.

### Phase 3: Field Study

To ensure a national-level survey, a total of fifteen hospitals, with three hospitals from each of the five geographical regions of India (east, west, north, south, and central), were selected and the survey was conducted with sample size of 719.

## RESULTS

The PREM tool was developed with 21 questions based on the SOP, findings of FGDs, and patient feedback. The Kuder-Richardson Formula 20 (KR-20) internal consistency value for the PREM tool was 0.94, which was interpreted as excellent and indicated high reliability. The mean Content Validity Index (CVI = 0.99) of the PREM tool indicated higher content validity, and the Content Validity Ratio (CVR=0.952) showed that the expert group considered the questions essential. 95% of the patients in the pilot study answered most of the questions affirmatively. Concerning removing metallic devices before the scan, 100% of participants said yes in the pilot study, whereas in the main study, 99% replied affirmatively.

S. No.	PREM Tool for MRI Safety	Patient Response
1	Did the doctor inform you about the need for the MRI Scan in the plan of treatment?	Yes/ No
2	Did the hospital staff/ doctor explain you about the cost of MRI scan?	Yes/ No
3	Did the doctor inform you about the type of MRI scan needed and the part of the body involved?	Yes/ No
4	Did the staff inform you about the appointment (time & date) and estimated time duration of the MRI scan?	Yes/ No
5	Did the doctor take your permission (consent) for the MRI scan?	Yes/ No
6	Did the staff verify your name/ hospital registration number with the file or MRI request slip?	Yes/ No
7	Did the staff ask you about any history of allergies? (for Contrast Enhanced MRI)	Yes/ No/ Not Applicable
8	Did the staff/doctor explain about side-effects of contrast?	Yes/ No/ Not Applicable
9	Did the doctor advise for blood tests, which is required before the contrast-enhanced MRI? (S. Creatinine & S. Urea)	Yes/ No/ Not Applicable
10	Have you observed the staff performing hand wash/hand rub during the procedure?	Yes/ No
11	Did the staff ask you about past history of surgery with any metal devices like implants or pacemakers placed inside your body (in situ) ?	Yes/ No
12	Did the staff inform you about removing all metallic wearable items like jewellery, coins, pen, watch, safety pins, belts etc. before MRI scan?	Yes/ No
13	Did the staff screen you with a metal detector device before entering the MRI Room?	Yes/ No
14	Did you notice the caution signage's in the MRI unit or room?	Yes/ No
15	Did the staff ask you to change to hospital clothes in the changing room?	Yes/ No
16	Did you have privacy in the changing room?	Yes/ No
17	Did the staff inform you not to move or lie still during the MRI scan?	Yes/ No
18	Did the staff inform you about constraints of space where you lie down inside the MRI machine?	Yes/ No/ Not Applicable
19	Did the staff inform you about how to respond if you feel uncomfortable or scared during the MRI scan?	Yes/ No
20	Did the staff inform you about the occurrence of loud noise when the MRI scan is in the process?	Yes/ No/ Not Applicable
21	Did the staff tell you when and where the result/ report of MRI scan will be available?	Yes/ No

## CONCLUSIONS

The MRI Safety PREM tool was developed and validated. It is a zero-cost patient Safety tool that any organization can quickly adopt. It was accepted by patients and healthcare workers as the selected questions were vital for obtaining patients' perceptions while undergoing MRI, thereby ensuring patient safety and improved quality of care. The study recommends using the MRI Safety PREM in all healthcare settings globally.

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## CONTACT INFORMATION

Dr Jawahar S K Pillai, Department of Hospital Administration  
AIIMS Bhubaneswar, Odisha, India, Email: [jawahardr@yahoo.com](mailto:jawahardr@yahoo.com),