

Medical Device–Associated Adverse Events in Intensive Care Units of a Tertiary Care Hospital: A Prospective Observational Study under the Materiovigilance Programme of India

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Abstract:

Medical device–associated adverse events (MDAEs) can compromise patient safety, particularly in intensive care settings where multiple critical devices are used continuously. The Materiovigilance Programme of India (MvPI) provides a structured framework for monitoring and evaluating such events. This study characterized MDAEs reported from intensive care units in a tertiary care hospital. A hospital-based prospective observational study was conducted at MGM Medical College and Hospital, Kamothe, Navi Mumbai. ICU-associated MDAEs reported from October 2025 to March 2026 were analyzed using materiovigilance forms, biomedical engineering records, incident logs and device-use records. Events were assessed according to implicated device, MvPI/CDSCO risk classification, root cause, causality and corrective action. A total of 95 ICU-associated MDAEs were analyzed. Patient monitors were the most frequently implicated devices (38; 40.00%), followed by ventilators (22; 23.16%) and infusion pumps (14; 14.74%). Class B devices accounted for 48 (50.53%) events, followed by Class C devices (45; 47.37%). Software defects were the most frequent root cause (27; 28.42%), followed by mechanical (22; 23.16%) and electrical defects (20; 21.05%). Causality was predominantly classified as possible (45; 47.37%) and probable (41; 43.16%). Repair was the most common corrective action (44; 46.32%), followed by replacement (20; 21.05%) and notification to manufacturer (19; 20.00%). ICU-associated MDAEs predominantly involved monitoring and life-support devices, highlighting the need for systematic reporting, preventive maintenance and timely corrective action to strengthen medical device safety in intensive care settings.

Keywords:

Materiovigilance, Medical device–associated adverse events, Intensive care unit, Medical device safety, MvPI.