

therapy of disease, or for the modification of physiological function. An unexpected adverse reaction refers to a reaction, the nature or severity of which is not consistent with domestic labelling or market authorization, or expected from characteristics of the drug. A serious adverse reaction is any medical occurrence that at any dose normally used in humans: results in death, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is life-threatening.

All new medicines undergo a significant amount of testing and evaluation before marketing to ensure the product is not only effective, but also safe. There are no drugs that are free of side-effects or adverse reactions. One large meta-analysis estimated that ADRs cause 3–4% of all hospital admissions in the USA. Adverse drug reactions may be due to the unknown effects of new (or older) drugs, unknown drug combinations and interactions, or poor drug quality.

Monitoring medication effects includes observing and documenting any adverse effects. The healthcare institution established a mechanism for documenting in patient's medical record, reporting adverse events and the time frame for reporting. Hospitals are responsible for ensuring that patients are treated as safely as possible. Prevention of ADRs is possible, and indeed necessary. Studies have shown that over 50% of adverse drug reactions may be preventable. Most ADRs are related to the prescribing of an incorrect dose or the administration of a drug to a patient with a known allergy. Many ADRs could be avoided if the relevant health worker asked specific questions before prescribing and/or dispensing a drug. Pharmacy and therapeutics committee regularly review reported ADR reports and inform professional staff of the incidence and impact of ADRs.

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**MM.41 The hospital has a process for monitoring, identifying, and reporting significant medication errors, including near misses, hazardous conditions, and at-risk behaviors that have the potential to cause patient harm.**

- MM.41.1 There is a multidisciplinary policy and procedure on handling medication errors, near misses, and hazardous situations (e.g., confusion over look-alike/sound-alike drugs or similar packaging).
- MM.41.2 The policy has a clear and acceptable definition of significant medication error, near misses, and hazardous situations.
- MM.41.3 The treating physician is notified of the medication error at the appropriate time.
- MM.41.4 Medication error reporting is completed within the specified time frame after discovery of the error.
- MM.41.5 The hospital has a standard format for reporting medication errors.
- MM.41.6 Staff are educated on the process and importance of medication error reporting.

- MM.41.7 There is active reporting of medication errors, near misses, and hazardous situations.
  - MM.41.8 The hospital conducts intensive root-cause analysis for all significant or potentially significant medication errors.
  - MM.41.9 Medication errors, near misses, and hazardous situations are documented in the patient's medical record.
  - MM.41.10 The hospital utilizes reported data to improve the medication use process, prevent medication errors, and improve patient safety.
  - MM.41.11 Healthcare professionals are provided with feedback on reported medication errors, near misses, and hazardous situations.
  - MM.41.12 The hospital reports sentinel events related to serious medication errors to the relevant authorities.
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**Standard Intent:**

In its 1999 landmark paper, "To Err is Human," the U.S. Institute of Medicine stressed the fact that medical errors are the eighth most frequent cause of death in the United States, more frequent than car accidents, breast cancer, or AIDS. On average, every hospital patient is probably subjected to at least one medication error every day. Fortunately, many of these errors do not cause harm. Regardless of numbers, medication errors are common and that they can happen to all of us. We all—from patients to providers to policymakers—need to take this issue more seriously so that we can make medication use as safe as we would like it to be and as safe as it deserves to be. Also, medication errors compromise patient confidence in the health-care system and increase health-care costs. Risk managers are taking a more proactive approach to preventing medication incidents in hospitals.

Medication errors may be committed by both experienced and inexperienced staff. The outcome(s) or clinical significance of many medication errors may be minimal, with few or no consequences that adversely affect a patient. Tragically, however, some medication errors result in serious patient morbidity or mortality. Determination of the causes of medication errors should be coupled with assessment of the severity of the error. Medication error reporting has been shown to improve medication-use systems and aid in conducting a cause analysis of a medication error.

The fundamental purpose of medication error reporting system is to learn how to improve the medication use and prevent errors recurrence. Reporting of medication errors must become culturally accepted throughout health care. A major investment of resources will be required in the health care system to apply the lessons derived from the reporting of medication errors. Medication error reporting system should include near misses, hazardous conditions, and at-risk behaviors.

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