medication (usually the nurse) and from other members of the healthcare team involved in the patient's therapy. In some settings, a clinical pharmacist monitors medication therapy in the hospital and consults on medication therapy that requires special expertise to ensure safety and efficacy, for example total parenteral nutrition, anticoagulation, or treatment with aminoglycosides antibiotics. Monitoring prescribed medication starts from the moment prescription is received in the pharmacy. A qualified and trained pharmacist evaluates and monitors for drug indications, correct route of administration, administration time, and report drugs that may affect patient equilibrium and increase the risk of fall. Significant drug-drug and drug-food interactions are immediately reported to the treating physician and corrective measures are done accordingly.

When appropriate, the patient should be observed by the nurse after administration of the drug product to ensure that the doses were administered as prescribed and have the intended effect and observe if any adverse reactions occurred. Allergy to prescribed medication constitutes a major patient safety issue. It is the responsibility of admitting physician to take drug history for any known allergies and communicate it in writing to the pharmacy. Pharmacy should not dispense any medication without knowing and documenting drug allergy in the patient drug profile. The pharmacy is authorized to stop dispensing any medication the patient is allergic to until clarification is made with the prescriber.

MM.40 The hospital has a process for detecting, managing and reporting adverse drug reactions (ADRs).

MM.40.1 The hospital has a multidisciplinary policy and procedure on handling Adverse Drug Reaction (ADR) reports.

MM.40.2 The policy has a clear definition of ADR and its severity.

MM.40.3 The treating physician is notified at the appropriate time.

MM.40.4 The patient affected by ADR receives appropriate care at the appropriate time.

MM.40.5 The ADR report forms are readily available and in use.

MM.40.6 All ADRs are documented in the patient's medical record.

MM.40.7 The hospital conducts analysis of all significant and serious ADRs.

MM.40.8 The hospital has a system for improving ADR reporting.

MM.40.9 The hospital reports all serious or unexpected ADRs to the Saudi Food and Drug Authority.

Standard Intent:

Adverse drug reaction (ADR) is a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or

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.

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.