مؤسسة مستشفى سرطان الأطفال-مصر Children's Cancer Hospital Foundation - Egypt 57357	**Policy Name**: Adverse Drug Reaction	
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1.0 Change of policy

1.1 No changes

2.0 Purpose

2.1 To establish a framework for the identification and review of adverse drug reactions (ADRs) within the institution to:

2.1.1 Inform healthcare providers about ADRs to improve patient care.
2.1.2 Identify trends to prevent future ADRs.
2.1.3 Define the role of physicians, nursing, pharmacy, and other healthcare personnel.
2.1.4 Report and evaluate ADRs occurring in the hospital.
2.1.5 Comply with JCI standards and GAHAR standards pertaining to ADR reporting.
2.1.6 Provide the national pharmacovigilance center and manufacturers with ADR reports when appropriate.

3.0 Policy

3.1 Policy statement:

3.1.1 Medication adverse drug reactions are monitored and documented in the time frame required.

3.2 Scope:

3.2.1 Any Adverse Drug Reaction occurs at any patient care areas in the CCHE.

3.3 Responsibilities

3.3.1 Medical director

3.3.2 Nursing director
3.3.3 Director of pharmaceutical services
3.3.4 Related healthcare staff

4.0 Definitions /abbreviations:

4.1 CCHE: Children Cancer Hospital – 57357 Egypt
4.2 CPID: Continuous Performance Improvement Department
4.3 MMU: Medication Management & Use
4.4 MMS: Medication Management & Safety
4.5 ADR: adverse drug reaction, it is a noxious and unintended response to a medicine that occurs at normal therapeutic doses used in humans for prophylaxis, diagnosis, or therapy of disease or occurred as a result of medication errors (including categories from E-I) and overdoses.

4.6 Serious adverse drug reaction:

4.6.1 Any untoward medical occurrence (unrelated to the original disease), that occurs at any dose and results in death, requires hospital admission or prolonged hospital stay, significant disability, or is life threatening, and may result from medication errors (categories F-I) or due to idiosyncratic effects.

5.0 Procedure:

5.1 Medical, nursing, and pharmacy personnel are responsible for reporting suspected ADRs that meet the above definition and if they result in any of the following:

5.1.1 Hospital admission
5.1.2 Adjustment or discontinuation of drug therapy
5.1.3 Requirement of systemic treatment
5.1.4 Prolongation of hospital stay
5.1.5 Complication of diagnosed disease state;
5.1.6 Patient death.

5.2 Upon discovery of a suspected ADR, the staff member should immediately notify the nursing staff and attending physician.
5.3 The staff member will report the ADR related to allergy by filling electronic Allergy Ad-hoc form.
5.4 Pharmacists will report suspected ADRs by submitting into drug monitor toxicity form or Pharmacy clinical Intervention Note on MISK.
5.5 First dose monitoring: Medical staff should report ADRs within 48hrs of occurrence.
5.6 Serious ADRs should be notified to primary physician and Patient Safety Committee Head, via incident report to discussed and provide appropriated recommendation.
5.7 Regular ADR Report analysis is done monthly by the pharmacy and analysis report is introduced to the patient safety committee and PNT committee for further Drug use evaluations and add or deletion of medications from formulary.

5.8 Adverse Drug Reaction Types:

5.8.1 **Type A —Exaggerated pharmacological response**

5.8.1.1 Pharmacodynamics (e.g., bronchospasm from beta-blockers) Toxic (e.g., deafness from aminoglycoside overdose)

5.8.2 **Type B—Non- pharmacological, often allergic, response**
- 5.8.2.1 Medicine-induced diseases (e.g., antibiotic-associated colitis)
- 5.8.2.2 Allergic reactions (e.g., penicillin anaphylaxis)
- 5.8.2.3 Idiosyncratic reactions (e.g., aplastic anemia with chloramphenicol)

5.8.3 **Type C—Continuous or long term (time related)**
- 5.8.3.1 Osteoporosis with oral steroids

5.8.4 **Type D—Delayed (lag time)**
- 5.8.4.1 Teratogenic effects with anticonvulsants or Lisinopril

5.8.5 **Type E—Ending of use (withdrawal)**
- 5.8.5.1 Withdrawal syndrome with benzodiazepines

5.8.6 **Type F—Failure of efficacy (no response)**
- 5.8.6.1 Resistance to antimicrobials

6.0 References:

6.1 University of Kentucky Hospital, Pharmacy Manual.

6.2 WHO Assessing and Managing Medicine Safety

7.0 Appendices:

7.1 Related Forms:
7.1.1 N/A

7.2 Related Policy(S):
7.2.1 Medication Management Program

7.3 Related Standards:
7.3.1 JCI standards 7th edition – MMU Chapter. (MMU.7)

7.3.2 GAHAR Standards name. MMS.17

7.4 Attachments
7.4.1 N/A