1.0 Purpose:

To ensure patient safety by establishing a standardized system for **identifying, reporting, managing, and preventing adverse drug reactions (ADRs) and adverse drug events (ADEs)** in the hospital.

2. Scope

This policy applies to:

- All inpatients, outpatients, and emergency patients receiving medications at Inodaya Hospital
- All healthcare professionals, including physicians, nurses, and pharmacists
- Pharmacy and hospital safety/quality committees

3. Definitions

- **Adverse Drug Reaction (ADR):** A harmful or unintended response to a drug administered at normal doses for prophylaxis, diagnosis, or therapy.
- **Adverse Drug Event (ADE):** Any injury resulting from the use of a drug, including medication errors, overdoses, and ADRs.
- **Serious ADR/ADE:** An event that results in death, is life-threatening, requires hospitalization or prolongs existing hospitalization, or causes significant disability.

4. Policy Statement

Inodaya Hospital is committed to:

- Ensuring **early detection** of ADRs/ADEs

- Ensuring **prompt management** of ADRs/ADEs
- Maintaining a **robust reporting and documentation system**
- Using data to **prevent recurrence and improve medication safety**

5. Procedure:

5.1.1 Orientation for all medical, nursing staff and pharmacists describing the importance of ADR reporting and the role of the healthcare provider in the ADR reporting program

5.1.2 Adverse drug reactions meeting at least one of the criteria stated in definition shall be reported by raising an incident report within 24 hours from the time of occurrence.

5.2 Medical / nursing / pharmacist shall be responsible for reporting suspected ADRs that meet the above definition and reporting criteria. ADRs are reported by completing the Patient Incident Report form.

5.3 The patient's primary physician shall be responsible for confirming or ruling out any suspected adverse reaction reported to them or identified by them.

5.4 The patient's primary physician shall document the reaction in the patient's medical record when an adverse drug reaction has been confirmed.

5.5 All reported ADRs shall be reviewed monthly by the Drug & Therapeutics committee

5.6 A summary *of* reported ADRs shall be forwarded to the Quality Team on a Monthly basis.

Immediate Management

Upon identification of ADR/ADE:

1. **Stop the suspected medication** immediately (if appropriate).
2. **Provide emergency care** including airway, breathing, circulation support.
3. **Notify the treating physician** immediately.
4. **Activate Code Blue** if patient's condition deteriorates.
5. **Document the event** in the patient's medical record.

6 ADR (Hartwig's) Severity Assessment Scale.

Level 1 An ADR occurred but required no change in treatment with the suspected drug

Level 2 The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. No antidote or other treatment requirement was required. No increase in length of stay (LOS)

Level 3 The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. AND/OR An Antidote or other treatment was required. No increase in LOS

Level 4 Any Level 3 ADR which increases length of stay by at least 1 day. OR The ADR was the reason for the admission

Level 5 Any Level 4 ADR which requires intensive medical care

Level 6 The adverse reaction caused permanent harm to the patient

Level 7 The adverse reaction either directly or indirectly led to the death of the patient

ADR: adverse drug reaction.

Mild = Levels 1 and 2; moderate = Levels 3 and 4; severe = Levels 5, 6 and 7

- Adverse drug reactions are reactions to the drugs that could have occurred due to the inherent conditions of the patient or the inherent properties of the concerned drug
    - Adverse drug reactions are captured through the ADR form and a registry of concerns is maintained by the pharmacy team
    - The ADR is presented to the Deputy Medical superintendent for further action & discussion in the Drugs & Pharmaco-Therapeutic Committee for further directions with regards to the process

5.0 Responsibilities:

5.1 Drug & Pharmaco Therapeutic Committee members
5.2 All physicians

6.0 Applicability: Medical, Nursing and Pharmacy personnel