CLINICAL POLICY

Medication Administration:
Adverse Drug Event (ADE) Reporting System

A. EFFECTIVE DATE :
April 7, 2021

B. PURPOSE :
To provide instructions and guidance on the reporting and review of Adverse Drug Events (ADEs) which includes Adverse Drug Reactions (ADRs), Medication Occurrences (MOs) and Medication Interventions (MIs).

C. POLICY :
All Medication Occurrences (MOs) and Adverse Drug Reactions (ADRs) shall be reported via the electronic Safety Intelligence (SI) software, which is a proactive, non-punitive collaborative effort to monitor medication events. The findings can be used to assist in studying, planning and implementing system changes that will minimize the frequency and severity of adverse patient outcomes and improve patient safety.

D. SCOPE :
This policy applies to all UConn Health staff who are involved with direct patient care.

E. DEFINITIONS :

1. **ADVERSE DRUG REACTION (ADR)** – As defined by ASHP (American Society of Health-System Pharmacists), an adverse drug reaction is any unexpected, unintended, undesired, or excessive response to a drug that requires any of the following:
    i. Discontinuing, changing or modifying the drug/dose
    ii. Admission, prolonged stay, or supportive care/treatment
    iii. Significantly complicates diagnosis, negatively affects prognosis, or results in temporary or permanent harm, disability, or death.
2. **MEDICATION OCCURRENCE (MO)** – A medication occurrence is an error in prescribing, verifying, dispensing, preparing, administering, documenting, or monitoring a medication. Medication occurrences include those that reach the patient and those that do not reach the patient.
    i. Types of medication occurrences include:
        - Dose omission, extra dose, wrong dose, wrong route, wrong drug, wrong patient, wrong dosage form;
        - Home medication list inaccurate, wrong infusion rate, monitoring error, inadequate pain management, unauthorized drug, or high risk drug.
3. **MEDICATION INTERVENTIONS (MI)** – A medication intervention occurs when a pharmacist or other health care provider helps to optimize medication therapy or minimizes medication cost. Interventions may be classified by rationale such as contraindications, non-formulary medication, incorrect dosing regimen, consults, IV to oral switches, inappropriate drug regimen, and renal dose adjustment.

F. MATERIAL(S) NEEDED :

None

G. PROCEDURE :

DATA COLLECTION PROCEDURE

1. Adverse Drug Reaction (ADR):
    a. The pharmacy department will accumulate ADR data in order to:
        i. Enhance patient safety by recognizing potential reactions and preventing further reactions and complications.
        ii. Gain a better understanding of drug effects.
        iii. Assist the FDA and pharmaceutical manufacturers in collection of ADR data for both currently available drugs and investigational drugs.
    b. Data will be presented at the Medication Safety Committee and Pharmacy & Therapeutics Committee for further review. The Pharmacy and Therapeutics Committee is responsible for reviewing ADRs on a regular basis and to discuss therapeutic and operational implications. These findings may result in recommendations to the Medical Staff for changes in prescribing to improve patient care.
2. Medication Occurrence (MO):
    a. The pharmacy department will accumulate MO data in order to:
        i. Enhance patient safety by reviewing gaps in the system that may have resulted in the occurrence and areas for improvement
        ii. Review any trends
    b. Data will be presented at the Medication Safety Committee and Pharmacy & Therapeutics Committee for further review. The Pharmacy and Therapeutics Committee is responsible for reviewing medication occurrences on a regular basis and to discuss therapeutic and operational implications. These findings may result in recommendations to the Medical Staff for changes in prescribing to improve patient care.
3. Medication Intervention (MI):
    a. The pharmacy department will accumulate MI data in order to:
        i. Demonstrate the benefit of pharmacist intervention
        ii. Broaden the pharmacist's clinical role
    b. Data after analyzed and trended by the pharmacy clinical coordinator will be presented at Pharmacy & Therapeutics Committee for further review. These findings may result in recommendations to the Medical Staff for changes in prescribing with the objective to improve formulary management and patient care.

REPORTING PROCEDURE

All Adverse Drug Events should be reported if they result in one of the following:

- A change and/or discontinuation of drug therapy
- Systemic treatment
- Prolongation of hospital stay
- Complication of diagnosed disease state
- Death

ADEs that result in an injury to the patient, that meet the criteria for reportability to the State of Connecticut Department of Public Health (DPH) as defined in Hospital Administrative Manual Policy # 11-008, must be reported to DPH within the proper timeframes. A Med Watch form may be completed for serious unexpected adverse reactions. These forms are mailed to the FDA.

1. Adverse Drug Reaction (ADR):

a. When an ADR occurs or is suspected it is reported in the Safety Intelligence system by the staff member who discovered the reaction. The reporting is a collaborative effort among the health care team members. The following types of reactions are to be reported in the Safety Intelligence system:
    i. Serious side effect - an extension of a pharmacological effect for which the drug is used and which is dose-related and produces fatality, is life-threatening, or produces significant disability to the patient (e.g. beta-blocker induced CHF or severe bronchospasm).
    ii. Unexpected detrimental effects of a drug - a drug reaction that has not previously been reported in the literature (for example, mumps-like reaction to azathioprine).
    iii. Drug intolerance - lower threshold to the normal pharmacological effect of the drug.
    iv. Any side effect of experimental (investigational) drugs.
    v. Toxic effect of a drug due to accidental overdose resulting in an extension of all Pharmacological effects of the drug. This excludes poisoning due to self-administration.
b. The following types of reactions are not to be reported in the Safety Intelligence system:
    i. Reactions, which are extensions of the pharmacologic effect for which the drug is given, unless some other factors make the reaction significant (for example, insulin shock or bone marrow depression with alkylating agents).
    ii. Mild or trivial side effects, if these effects are well known. Trivial side effects are unwanted or unintended pharmacological effects of medication, often dose-related, which are not serious enough to discontinue the drug or requiring the use an antidote (for example, drowsiness from diphenhydramine or headache from nitroglycerine).
    iii. Disturbances that are totally dependent on the pathological state (for example, diarrhea from colon cancer and not from a laxative).
    iv. Toxic effects due to a purposeful and appropriate dosage.
c. MD/LIP/Nurse/Pharmacist will also document the ADR in the medical record noting the date, time, suspect medication and reaction. The health care team will communicate this information to others on the team when appropriate for the coordinated care of the patient.
d. Any newly diagnosed allergic reaction will be documented in the allergy section of the electronic patient record by noting drug, reaction type with additional comments, severity, management and outcome.
e. An allergy bracelet is placed on the patient and a sticker is placed on the cover of the chart if warranted by the type of ADR, in order to prevent recurrence.

2. Medication Occurrence (MO):
    a. Staff member who discovers the occurrence completes the report in the Safety Intelligence system.
    b. Report is reviewed by assigned department manager.
    c. Report is forwarded to other departments involved as appropriate.
    d. Report is forwarded to Quality Manager.
    e. Report is reviewed by the Medication Error Committee for improvements in the medication process.
3. Medication Intervention (MI):
    a. Pharmacist completes all information required in the electronic pharmacy system.
    b. Based on level of severity, select interventions are placed in the Safety Intelligence system.

H. <u>ATTACHMENTS :</u>

None

I. REFERENCES :

1. American Society of Health-System Pharmacists. ASHP guidelines on adverse drug reaction monitoring and reporting. Am J Health-Syst Pharm. 1995; 52:417–9

J. SEARCH WORDS :

Adverse Drug Reaction, Adverse Drug Event, ADR, ADE

K. ENFORCEMENT:

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

L. STAKEHOLDER APPROVALS :

One File

M. COMMITTEE APPROVALS :

Pharmacy and Therapeutics Committee, Medication Safety Subcommittee

N. FINAL APPROVAL :

1. Andrew Agwunobi, MD (Signed) 04/13/2021
Andrew Agwunobi, MD, MBA Date
UConn Health Chief Executive Officer

2. Anne Horbatuck (Signed) 04/07/2021
Anne D. Horbatuck, RN, BSN, MBA Date
Clinical Policy Committee Co-Chair

3. Scott Allen, MD (Signed) 04/09/2021
Scott Allen, MD Date
Clinical Policy Committee Co-Chair

4. Caryl Ryan (Signed) 04/08/2021
Caryl Ryan, MS, BSN, RN Date
VP Quality and Patient Services & Chief Nursing Officer

O. REVISION HISTORY :

Date Issued: 8/82 (Pharmacy Manual), 3/99 (Clinical Manual/Nursing Practice Manual)
Date Revised: 3/99, 3/03, 4/04, 10/08, 8/09, 8/16, 4/21
Date Reviewed: 7/03, 10/08, 8/13