Adverse Drug Events

Purpose and Scope

To outline a process for reporting adverse drug reactions by Licensed Respiratory Care Practitioners.

Account-ability

Licensed Respiratory Care Practitioners, Licensed nurses, including Utilization Review Nurses, Case Managers, Clinic Nurses, Emergency Room Nurses, Physicians, Pharmacists, Quality Management personnel,. Admissions personnel, Laboratory Personnel and Drug Information Center Personnel.

Definition

An Adverse drug reaction (ADR) can be defined as one that necessitates any of the following:

- Discontinuation of a drug after the first few doses because of adverse effects.
- Any decrease in the dose due to adverse effects, excluding titration of doses.
- Any anaphylactic/anaphylactoid reaction that requires administration of an antihistamine (diphenhydramine - Benadryl), epinephrine, corticosteroid or atropine.
- Malignant hyperthermia or neuroleptic malignant syndrome resulting from the use of medication.
- Any suspected Type-1 allergic reaction, for example, appearance of a rash.
- Urgent reversal of medication using an antidote such as digoxin immune fab (Digibind), naloxone (Narcan), flumazenil (Romazicon), phytonadione (Vitamin K), and protamine sulfate, exclusive of Anesthesiology and Recovery Room.
- Physician documentation that a noxious or unintended adverse symptom of a drug has occurred.
- Increased length of stay and/or urgent admission to an intensive care/telemetry unit as a result of an adverse drug reaction.
- Unexpected metabolic or organ system failure/toxicity resulting from the use of medication.
- Requires reporting to the FDA.

Procedure

Relative to Inpatient Nursing Personnel/Respiratory Care Practitioner:

Step	Action
1	All suspected adverse drug reactions will be reported to the physician and documented in EPIC.

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Procedure Continued

Step	Action
2	An "Adverse Drug Reaction Reporting" form shall be completed for a call made to the ADR hotline (7-4ADR or 74237) by the licensed respiratory care practitioner with information which includes the following: • Patient addressograph or patient name and unit history number • Person reporting, including position title • Date of the report • Suspected drug(s) • Type of reaction • Patient outcome
3	Call the Respiratory Care Services Supervisor. Report the above information.
4	If the report is via the adverse drug reaction reporting form, the completed form shall be placed in the Pharmacy "pick-up" bin or sent to the Drug Information Center in the Pharmacy via mailing route 0701.

References

AARC Clinical Practice Guidelines, Respiratory Care; 1995; 40 (12): 1300-1307: Assessing Response to Bronchodilator Therapy at Point of Care

UTMB Handbook of Operating Procedures; Section 9, Clinical Affairs Policies; Subject 9.13, General Procedures. Policy 9.13.14 Adverse Drug Reactions http://www.utmb.edu/policy/ihop/search/09-13-14.pdf

Attachments

Adverse Drug Reaction Reporting Form