ALLERGY AND ADVERSE DRUG REACTIONS

Purpose:

To readily identify patients with known food, drug and environmental allergies/adverse drug reactions and to provide for documentation of such on the Patient Assessment, in order to prevent the possibility of reactions.

Definitions:

Allergy - a reaction caused by an immune response to a drug, resulting in tissue inflammation and/or organ dysfunction usually, but not always, characterized by angioedema, rash or anaphylaxis.

Adverse Drug Event (ADE) - any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

Severity Scale
Level 1 – ADE occurred but required no change in treatment with suspected drug
Level 2 – Drug held, DC’ed or changed but no antidote or additional treatment needed.
Level 3 – Drug held, DC’ed or changed AND/OR antidote or other treatment required.
Level 4 – ADE required patient transfer to an intensive care setting
Level 5 – ADE caused permanent harm to the patient
Level 6 – ADE either directly or indirectly led to the patient’s death

Policy:

1. A history of any allergies/ADEs shall be obtained during the admission nursing assessment before any medications are administered, except in emergencies. This history is documented in the space provided on the Patient History and Discharge Record.
2. An orange allergy/ADE bracelet shall be placed on any patient who has admitted by history to a specific allergy/ADE, or who has demonstrated allergic clinical manifestations.

3. An allergy alert sticker shall always be placed on the front of the patient's chart, and allergies/ADEs shall be documented on each unit dose Medication Administration Record (MAR), the first physician order sheet and electronically in the HIS (Invision). If the patient has no known allergies/ADEs, NKDA shall be documented in these areas.

4. Suspected Adverse Drug Reactions shall be identified and reported on the Hospital Variance Reporting website. The physician must also document the ADE in the Progress Notes of the patient's medical record.

5. If upon investigation a physician deems the patient does not have the noted allergy/ADE, the physician shall write an order to remove the noted allergy and document such in the progress notes of the medical record.

6. The Pharmacy Department will be responsible for monitoring and grading of reported adverse reactions:
   a) All suspected ADEs shall be reported to the pharmacy for investigation and entered into the pharmacy department's intervention database.
   b) All severity level 5 and 6 reports shall be forwarded to the Quality Management Department for Peer Review.
   c) All severity level 2, 3, and 4 reports will be forwarded to the Quality Management Department for Peer Review if the reaction has not been previously reported by the manufacturer as a side effect or adverse effect.
   d) Any ADE occurring prior to the patient entering the LSUHSC-S system will not be subject to the Peer Review process unless the medication was prescribed by an LSUHSC-S physician.

The reaction will be reported to the manufacturer or the Food and Drug Administration if:

1. The ADE is classified probable or definite and is a severe reaction.
2. The ADE is probable or definite and is not listed in the manufacturer's package insert.

3. The ADE involved is a new drug (released in the last three years) and exhibits a temporal relationship to the administration of the new drug.

Administrator

2/18/04

Date

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