ALLERGY AND ADVERSE DRUG REACTIONS

Purpose:
The primary focus of LSUHSC electronic adverse drug event reporting and monitoring database is to improve adverse drug event (ADE) reporting and provide a standardized process for identifying, reporting, and monitoring adverse drug events. This database will monitor trends or areas of significant isolated ADE, create a feedback loop to practitioners, promote educational endeavors to prevent ADEs, and improve patient outcomes.

Scope:
All medication errors, actual adverse drug events, and potential adverse drug events shall be reported by health care personnel who are included in witnessing the event or first discovering the adverse drug event. This includes all actual or potential adverse drug events in a positive, proactive, and educational approach to information gathering and follow-up to facilitate improvement in all aspects of the medication process.

Definitions:
Actual Adverse Drug Event (ADE) - an event in the medication use process (prescribing, administering dispensing, monitoring) where the medication or IV fluid reached the patient and caused an undesirable clinical manifestation. For purposes of this policy, this definition includes harm caused by the drug as a result of adverse drug reactions, drug-drug interactions, product quality problems, or drug overdoses (accidental or intentional).

Potential Adverse Drug Event- an error in the medication use process that if it had reached the patient could have caused injury.

Adverse Drug Reaction (ADR) - a subset of ADEs that includes any unintended, undesired, or excessive clinical response that is consequent to and caused by the administration of medication or IV fluids at usual doses, and IV compatibilities.

Both the following are also considered ADRs:
Allergic reaction is an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug. Idiosyncratic reaction is an abnormal susceptibility to a drug that is peculiar to the individual.

For this policy, side effects, (which are expected, well known reactions resulting in little or no change in patient management) are not included in this definition. Additionally, drug withdrawal, drug-abuse syndrome, accidental poisoning, and drug-overdose complications should not be defined as ADRs.

ADE Severity Categorization
Level 1 - ADE occurred but required no change in treatment with suspected drug
Level 2 - Drug or IV fluid held, discontinued or changed, but no antidote or additional treatment needed.
Level 3 - Drug or IV fluid held discontinued or changed and/or antidote or other treatment needed.
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
Levels 5 and 6 are considered sentinel events by hospital policy

Allergy - an ADR mediated 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.

Causality Assessment - a determination of whether there is a likelihood that the drug caused or contributed to an adverse event. This includes assessing the time relationships between the drug use and the adverse event, response to dechallenge or rechallenge, or competing causes for the adverse event (underlying disease).

Grades of Severity that an event is linked to an ADE

<table>
<thead>
<tr>
<th>Level</th>
<th>Certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certain</td>
<td>A clinical event, including an abnormal laboratory test result, which occurs in a plausible time relationship to drug administration and cannot be explained by concurrent disease or other drugs or chemicals.</td>
</tr>
<tr>
<td>Probable/Likely</td>
<td>A clinical event, including an abnormal laboratory test result, which occurs within a reasonable time sequence to administration of the drug, is unlikely to be attributed to concurrent disease or other drugs or chemicals and follows a clinically reasonable response on withdrawal.</td>
</tr>
<tr>
<td>Possible</td>
<td>A clinical event, including abnormal laboratory test result, which occurs within a reasonable time sequence to administration of the drug but could also be explained by concurrent disease or other drugs or chemicals.</td>
</tr>
<tr>
<td>Unlikely</td>
<td>A clinical event or abnormal lab result, whose temporal relationship to drug administration makes a causal relationship improbable and in which other drugs or chemicals or underlying disease provides plausible explanations.</td>
</tr>
</tbody>
</table>


Reporter - the person who first alerts the primary person caring for the patient following identifying the ADE. This person can be the patient, family member, or health care personnel. The primary
person is considered to be the health care clinician (physician, nurse, nurse practitioner, pharmacist, etc) who is involved in the direct care of the patient and who observed the occurrence of the ADE.

Policy:
Louisiana State University Health Sciences Center (LSUHSC) encourages the reporting of adverse drug events and potential adverse drug events as a means to assess and improve the medication use process and provide a safe environment for patient care.

A. A history of any allergies/ADEs shall be obtained during the initial nursing assessment before any medications are administered, except in emergencies. This history is documented in the medical record. The electronic health record provides for this information to be available for all who prescribe, dispense and administer medications in the hospital and clinics.

B. For inpatients only, 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.

C. ADEs are reported by physicians, nurses, pharmacists, medical records (via e-codes), quality management personnel, or any LSUHSC staff member who is aware of ADEs. The electronic ADE form shall be completed as soon as the event is identified.

D. All severity level 1 through 6 reports will be forwarded to the Quality Management Department for peer review if the event has not been previously documented by the manufacturer via package insert as an expected ADE. Any ADE occurring prior to the patient entering the LSUHSC-system will not be subject to the Peer Review process unless the medication was prescribed by an LSUHSC physician.

E. Pharmacists will report the following ADEs to the Food and Drug Administration
   1. The ADE is classified as probable or possible and is a severe reaction
   2. The ADE is a level 5 or 6, is associated with a new drug, (released during the last 5 years), not listed in the drug’s /manufacture’s package insert, or if the event exhibits a temporal relationship to the administration of the new drug.

F. If Hospital Administration deems the event a Sentinel Event/Near Miss then a credible Root Cause Analysis is completed. LSUHSC staff members identifying an ADE in level 5 or 6, or classified as a sentinel event, should contact their supervisor, and follow the sentinel event policy.

Procedures
Reporting an ADE
A. Upon identifying the ADE, all levels 4 -5 shall be reported immediately to attending physician and have documented notification in the chart. Staff should navigate to the LSUHSC-Shreveport website “http: lsuhscshreveport.edu” then select “Inside myHSC”, select “Variances”, then select “Variance Reporting Form”. Complete the patient identification and scroll down to the “Medication Usage Variances” and select “MV01 Adverse Drug Reaction”. The ADE form is completed, where it is forwarded to pharmacy and quality management for processing and reviewing.
B. Clinical interventions and data are loaded into a secure database, where it is accessed via password by pharmacy and quality management.

Administrator

8/27/12
Date

Approved by Clinical Board: 1/16/01, 9/17/02, 2/17/04, 3/20/07, 9/21/10, 8/21/12
Written: 3/95
Revised: 11/97, 8/03, 8/03, 1/04, 1/07, 8/10, 8/12
Reviewed: 1/01, 9/02, 8/03, 8/03, 1/04, 1/07, 8/10, 8/12