

Policy: Adverse Drug Reaction Reporting and Intensive Review of Serious or Lethal Adverse Drug Reaction

ADVERSE DRUG REACTION REPORT

Identification (Name, Unit, Visit ID)

1. **Description of Suspected ADR** (by discovering practitioner (nurse, pharmacist or physician) or practitioner to whom reaction is reported).

A. Date and time when the reaction was first observed: _____

B. Describe the suspected ADR:

C. Describe intervention(s) made immediately before medical, pharmaceutical and nursing staff intervention(s):

D. Describe intervention(s) made by medical, pharmaceutical and nursing staff:

E. List medication(s) suspected of causing the reaction (attach separate sheet if needed)

Medication 1: _____ Medication 2: _____ Medication 3: _____

F. Complete Section F if the discoverer is not a physician/APRN, (physician/APRN must be notified of any suspected adverse drug reaction):

Name of Physician/APRN Notified: _____ Date and Time of Notification: _____

G. Section 1 Completed By: (may type in data if this is an electronic form)

Signature	Printed Name/Title	Date
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2. **Physician/APRN Investigation of Reaction** (To be completed by physician) (attach separate sheet if needed).

A. Summarize symptoms of the reaction:

B. Describe facts or circumstances surrounding the reaction:

C. Describe additional information such as possible drug-drug or food-drug interactions, or pre-existing conditions that could have led to the ADR.

D. Describe associated treatment(s) ordered:

E. Using the **Individual's MAR**, review all medications the individual was receiving at the time of the reaction. (Attach a copy of the MAR to this form)

MAR reviewed

F. Is a medication suspected of causing the reaction? Yes No Unsure

i. If "no", proceed directly to section 2M, sign and date, and forward to the Clinical Director.

G. List Suspected Medication(s) and Rate the ADR probability for each medication

List suspected Medication(s) →												
Question	Yes	No	Don't Know/NA	Score	Yes	No	Don't Know/NA	Score	Yes	No	Don't Know/NA	Score
Are there previous conclusive reports on this reaction?	+1	0	0		+1	0	0		+1	0	0	
Did the adverse reaction occur after suspected drug was administered?	+2	-1	0		+2	-1	0		+2	-1	0	
Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0		+1	0	0		+1	0	0	
Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0		+2	-1	0		+2	-1	0	
Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0		-1	+2	0		-1	+2	0	
Did the reaction appear when placebo was given?	-1	+1	0		-1	+1	0		-1	+1	0	
Was the drug detected in the blood (or other bodily fluids) in concentrations known to be toxic?	+1	0	0		+1	0	0		+1	0	0	
Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0		+1	0	0		+1	0	0	
Did the patient have similar reaction to the same or similar drugs in any previous exposure?	+1	0	0		+1	0	0		+1	0	0	
Was the adverse event confirmed by any objective evidence?	+1	0	0		+1	0	0		+1	0	0	
Total Score:												
Write ADR Probability Rating → "Definite" (Total Score ≥ 9) "Probable" (Total Score = 5, 6, 7, or 8) "Possible" (Total Score = 1, 2, 3, or 4) "Doubtful" (Total Score = 0)												

- H. Is ADR still expected? (circle one) YES NO UNSURE
 i. If "No" skip to section 2N signatures and forward form to Clinical Director.
 ii. If "Unsure" please explain _____
- I. Based on the ratings in Item H and on clinical judgment, which medication most likely caused the ADR? _____
 i. Medication classification: **Medical** (non-psychotropic) **Anticonvulsant** (non-psychotropic)
 Psychotropic: Antidepressant Antiparkinson Antipsychotic Benzodiazepine Mood Stabilizer Other: _____
 ii. Route: P.O. Per Tube Topical Rectal Subcutaneous I.M. Vaginal Other
- J. Type of reaction:
 i. Allergy Dose-Related Drug-drug interaction Drug-food interaction Withdrawal Idiosyncratic Unknown
 Other (explain): _____
- K. Does the drug need to be added to individual's allergy list? Yes No (If "Yes", submit an order to pharmacy stating "individual is allergic to (drug)")
- L. Outcome of the reaction
 Not yet known
 Minor: An ADR that is insignificant or is secondary to a coexisting condition or reaction
 Moderate: An ADR that is non life-threatening but requires non-emergent intervention
 Serious: An ADR that presents a life-threatening circumstance, results in temporary or permanent harm, requires medical intervention to prevent or minimize harm, or results in hospitalization
 Lethal: An ADR that results in death
- M. Part 2 Completed By: (may type in data if this is an electronic form)

Signature	Printed Name/Title	Date
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Part 3. Clinical Review: To be completed by the Clinical Director.

- No further action Additional information requested Hold until outcome is known Determined that no ADR occurred
 Add to individual's allergies list Incident/injury report completed Intensive Review indicated (required for all serious/lethal ADRs)
 Report to FDA (required for all serious/lethal ADRs) Additional Comments _____

Signature of Clinical Director	Clinical Director Printed Name/Title	Date
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