

Adverse Drug Reaction Worksheet

Evaluation Date: _____ Evaluated By: _____ Date of Adverse Reaction: _____

Suspect Medication: _____ Dosing Regimen: _____ Is medication new? Yes No

Adverse Reaction: _____
(Refer to a list of common adverse antimicrobial reactions in Table 1 on the next page)

Probability Reaction Related to Medication (from the Naranjo Probability Scale below):

- Definite (≥ 9) Probable (5-8) Possible (1-4) Doubtful (0)

Consequence of Adverse Reaction (check all that apply):

- | | | |
|--|---|--|
| <input type="checkbox"/> No change-therapy continued | <input type="checkbox"/> Therapy changed to another agent | <input type="checkbox"/> Therapy discontinued |
| <input type="checkbox"/> Increased monitoring | <input type="checkbox"/> Symptomatic medical treatment | <input type="checkbox"/> Corrective surgical procedure |
| <input type="checkbox"/> Disability | <input type="checkbox"/> Permanent Damage | <input type="checkbox"/> Delayed discharge |
| <input type="checkbox"/> Hospitalization | <input type="checkbox"/> Other (specify): _____ | |

Reviewer: _____ Date: _____

Naranjo Adverse Drug Reaction Probability Scale (with modifications)

The following scale is used to assess the likelihood a particular adverse reaction is related to a medication. Answer each of the 10 questions, calculate total score, and determine if an adverse drug reaction is Definitely, Probably, Possibly, or unlikely related to the drug in question. *(Interpretation of the probability classification can be found in Table 2 on the next page)*

Question	Yes	No	Do Not Know	Score
1. Are there previous CONCLUSIVE reports on this reaction? <i>Answer yes if 2 or more well-described case reports can be found in the literature</i>	+ 1	0	0	
2. Did the adverse reaction appear after the suspected drug was administered? <i>Answer yes if reaction occurs in close temporal relation (e.g., within 1-2 days) after drug administration</i>	+ 2	- 1	0	
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist given? <i>Answer yes if reaction lessens or disappears after the suspect drug stops or a pharmacologic antagonist given</i>	+ 1	0	0	
4. Did the adverse reaction reappear when the drug was readministered? <i>Answer yes if reaction disappears after drug discontinuation but reappear when the drug was restarted</i>	+ 2	- 1	0	
5. Are there alternative causes (other than the suspect drug) that could have caused the reaction? <i>Answer yes if the reaction can be explained by causes or medications other than the suspect drug</i>	- 1	+ 2	0	
6. Did the reaction reappear when a placebo was given? <i>Answer yes if the reaction reappears after administration a placebo</i>	- 1	+ 1	0	
7. Was the drug detected in blood or other fluids in concentrations known to be toxic? <i>Answer yes if drug concentration is in the toxic or supratherapeutic range</i>	+ 1	0	0	
8. Was the reaction more severe when dose was increased or less severe when dose was decreased? <i>Answer yes if the intensity of the reaction is stronger with higher dose or weaker with lower dose</i>	+ 1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure? <i>Answer yes if patient has a similar documented reaction when exposed to the suspect drug or related medication in the past</i>	+ 1	0	0	
10. Was the adverse reaction confirmed by any objective evidence? <i>Answer yes if the reaction can be confirmed by abnormal lab values, imaging, or physical examination</i>	+ 1	0	0	
Total Score				



Table 1. List of Common Adverse Antimicrobial Reactions*

Drug Class	Class Member	Common Adverse Reaction
Penicillins +/- Beta-Lactamase inhibitors	Ampicillin, Ampicillin-Sulbactam, Amoxicillin, Amoxicillin-Clavulanate, Cloxacillin, Dicloxacillin, Nafcillin, Oxacillin, Penicillin, Piperacillin-Tazobactam	Nausea, vomiting, diarrhea, <i>C difficile</i> infection, allergic reactions (including rash, hemolytic anemia), elevated serum creatinine, bone marrow suppression with long-term use, phlebitis with IV therapy
Cephalosporins +/- Beta-Lactamase Inhibitors	Cefaclor, Cefazolin, Cefdinir, Cefditoren, Cefepime, Cefixime, Cefotetan, Cefoxitin, Cefpodoxime, Cefprozil, Ceftriaxone, Ceftazidime, Ceftazidime-Avibactam, Ceftibuten, Ceftolozane-Tazobactam, Cefuroxime, Cephalexin, Cephadroxil	Nausea, vomiting, diarrhea, <i>C difficile</i> infection, allergic reactions (including rash, serum sickness), altered mental status
Carbapenems	Doripenem, Ertapenem, Imipenem-Cilastatin, Meropenem	Nausea, vomiting, diarrhea, <i>C difficile</i> infection, seizure
Fluoroquinolones	Ciprofloxacin, Delafloxacin, Levofloxacin, Moxifloxacin	Disorientation, delirium, agitation, seizure, hypo- or hyper-glycemia, peripheral neuropathy, tendon rupture, QT prolongation, nausea, vomiting, <i>C difficile</i> infection, increased in liver function tests, aortic dissection
Macrolides	Azithromycin, Clarithromycin, Erythromycin	Nausea, vomiting, elevation in liver function tests, reversible tinnitus or deafness, taste alteration, phlebitis with IV therapy
Tetracyclines	Doxycycline, Minocycline, Tetracycline	Nausea, vomiting, sunburn, esophageal ulcer, phlebitis with IV therapy, teeth discoloration
Sulfonamides	Sulfamethoxazole-Trimethoprim	Allergic reactions (rash, hives, drug fever, Steven Johnson Syndrome), headache, sunburn, hyperkalemia, worsen renal functions, bone marrow suppression, hemolytic anemia, hypoglycemia (especially with sulfonamides)
Glycopeptides	Telavancin, Vancomycin IV	Redman syndrome (flushing, itching, hypotension), worsened renal functions
Others	Clindamycin, Metronidazole, Nitrofurantoin	All: Nausea, vomiting; Clindamycin: diarrhea, <i>C difficile</i> infection, taste alteration; Metronidazole: disulfiram reaction after alcohol (flushing, dyspnea), taste alteration, peripheral neuropathy, confusion; Nitrofurantoin: interstitial pneumonitis especially with chronic use, hemolytic anemia

* The above list does not include all antimicrobials or all adverse drug reactions. Consult drug references and published literature for additional information if an adverse drug reaction not listed above is suspected.

Table 2. Interpretation of Probability Categories

Category	Score Range	Interpretation
Definite	≥ 9	Reaction 1) followed a reasonable temporal sequence after a drug or in which a toxic drug level had been established in body fluids or tissues; 2) followed a recognized response to the suspected drug; and 3) was confirmed by withdrawal but not by exposure to the drug
Probably	5 – 8	Reaction 1) followed a reasonable temporal sequence after a drug; 2) followed a recognized response to the suspected drug; 3) was confirmed by withdrawal but not by exposure to the drug; 4) could not be reasonably explained by the known characteristics of the patient's clinical state
Possible	1 – 4	Reaction 1) followed a temporal sequence after a drug; 2) possibly followed a recognized pattern to the suspected drug; 3) could be explained by characteristics of the patient's disease
Doubtful	0	Reaction was likely related to factors other than a drug

Reference

Naranjo CA, *et al.* A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981;30:239-45.