|  |  |
| --- | --- |
| [Facility Logo] | Resident Label |

**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):**

[ ]  **No change-therapy continued** [ ]  **Therapy changed to another agent** [ ]  **Therapy discontinued**

[ ]  **Increased monitoring** [ ]  **Symptomatic medical treatment** [ ]  **Corrective surgical procedure** [ ]  **Disability** [ ]  **Permanent Damage** [ ]  **Delayed discharge**

[ ]  **Hospitalization** [ ]  **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?*Answer yes if 2 or more well-described case reports can be found in the literature***
 | **+ 1** | **0** | **0** |  |
| 1. **Did the adverse reaction appear after the suspected drug was administered?*Answer yes if reaction occurs in close temporal relation (e.g., within 1-2 days) after drug administration***
 | **+ 2** | **– 1** | **0** |  |
| 1. **Did the adverse reaction improve when the drug was discontinued or a specific antagonist given?*Answer yes if reaction lessens or disappears after the suspect drug stops or a pharmacologic antagonist given***
 | **+ 1** | **0** | **0** |  |
| 1. **Did the adverse reaction reappear when the drug was readministered?*Answer yes if reaction disappears after drug discontinuation but reappear when the drug was restarted***
 | **+ 2** | **– 1** | **0** |  |
| 1. **Are there alternative causes (other than the suspect drug) that could have caused the reaction?*Answer yes if the reaction can be explained by causes or medications other than the suspect drug***
 | **– 1** | **+ 2** | **0** |  |
| 1. **Did the reaction reappear when a placebo was given?*Answer yes if the reaction reappears after administration a placebo***
 | **– 1** | **+ 1** | **0** |  |
| 1. **Was the drug detected in blood or other fluids in concentrations known to be toxic?*Answer yes if drug concentration is in the toxic or supratherapeutic range***
 | **+ 1** | **0** | **0** |  |
| 1. **Was the reaction more severe when dose was increased or less severe when dose was decreased?*Answer yes if the intensity of the reaction is stronger with higher dose or weaker with lower dose***
 | **+ 1** | **0** | **0** |  |
| 1. **Did the patient have a similar reaction to the same or similar drugs in any previous exposure?*Answer yes if patient has a similar documented reaction when exposed to the suspect drug or related medication in the past***
 | **+ 1** | **0** | **0** |  |
| 1. **Was the adverse reaction confirmed by any objective evidence?*Answer yes if the reaction can be confirmed by abnormal lab values, imaging, or physical examination***
 | **+ 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, *C difficile* 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, Ceftaroline, Ceftazidime, Ceftazidime-Avibactam, Ceftibuten, Ceftolozane-Tazobactam, Ceftriaxone, Cefuroxime, Cephadroxil, Cephalexin** | **Nausea, vomiting diarrhea, *C difficile* infection, allergic reactions (including rash, serum sickness), altered mental status** |
| **Carbapenems** | **Doripenem, Ertapenem, Imipenem-Cilastatin, Meropenem** | **Nausea, vomiting, diarrhea, *C difficile* infection, seizure**  |
| **Fluoroquinolones** | **Ciprofloxacin, Delafloxacin Levofloxacin, Moxifloxacin**  | **Disorientation, delirium, agitation, seizure, hypo- or hyper-glycemia, peripheral neuropathy, tendon rupture, QT prolongation, nausea, vomiting, *C difficile* 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 sulfonylureas)** |
| **Glycopeptides** | **Telavancin, Vancomycin IV** | **Redman syndrome (flushing, itching, hypotension), worsened renal functions** |
| **Others** | **Clindamycin, Metronidazole, Nitrofurantoin** | **All: Nausea, vomiting; Clindamycin: diarrhea, *C difficile* 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.**