

### Adverse Drug Effects

Record severity of symptoms experienced over the last week as follows: **0=Not present; 1=Mild; 2=Moderate; 3=Severe**

### Common Drug Effects

- Bad taste in your mouth
- Blurred vision
- Constipation
- Delayed urination
- Diarrhea
- Difficulty having an erection
- Difficulty having an orgasm
- Dizziness
- Drowsiness
- Dry Mouth
- Forgetfulness
- Frequent urination
- Headaches
- Heart racing or Pounding
- Increased appetite
- Muscle twitching or clenching
- Nausea
- Nightmares
- Other stress problems
- Poor concentration
- Poor sleep
- Rash
- Ringing in your ears
- Spasms or drawing of muscles
- Sweating
- Swelling (hands, feet, face, etc.)
- Thirst
- Tingling or numbness
- Trembling
- Uncomfortable urge to move about
- Unsteadiness
- Weight gain

### ADE

#### Simply ...

- **Adverse:** Untoward, unintended, possibly causing harm (noxious)
- **AE:** Adverse Event, Effect or Experience
- **ADE (Adverse Drug Event):** An AE which happens in a patient taking a drug
- **ADR (Adverse Drug Reaction):** An ADE in which a causal association is suspected between the drug and the event

### ADE vs ADR

#### 1. What is an adverse drug event (ADE)?

An adverse drug event is "an injury resulting from the use of a drug. Under this definition, the term ADE includes harm caused by the drug (adverse drug reactions and overdoses) and harm from the use of the drug (including dose reductions and discontinuations of drug therapy)." Adverse Drug Events may result from medication errors but most do not.

#### 2. What is an adverse drug reaction (ADR)?

An adverse drug reaction is a "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 physiologic function." Note that there is a causal link between a drug and an adverse drug reaction. In sum, an adverse drug reaction is harm directly caused by the drug at normal doses, during normal use.

#### 3. How does an ADR differ from a side effect or allergy?

An allergy is an adverse drug reaction mediated by an immune response (e.g., rash, hives). A side effect is an expected and known effect of a drug that is not the intended therapeutic outcome. The term "side effect" tends to normalize the concept of injury from drugs. It has been recommended that this term should generally be avoided in favor of adverse drug reaction.

#### 4. What is a medication error?

Medication errors are mishaps that occur during prescribing, transcribing, dispensing, administering, adherence, or monitoring a drug. Examples of medication errors include misreading or miswriting a prescription. Medication errors that are stopped before harm can occur are sometimes called "near misses" or "close calls" or more formally, a potential adverse drug event. Not all prescribing errors lead to adverse outcomes. Some do not cause harm, while others are caught before harm can occur ("near-misses").