

### DEFINITIONS

Pharmacovigilance	science and activities relating to the detection, assessment, understanding, and prevention of adverse effects and other medicine-related problems
Adverse Drug Reaction	one which is noxious (cause discomfort), unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, and therapy of disease
Adverse Drug Events	any adverse event associated with the use of drug in humans, whether or not considered drug related
ADR - caused by drug at normal dose	
ADE - any event, may not be caused by drug	

### TYPES OF ADR

A - Augmented	"greater in size or value" <ol style="list-style-type: none"> <li>1. Extension effects - exaggeration of supposed indication</li> <li>2. Side effects - not related to indication</li> </ol>
B - Bizarre	<ol style="list-style-type: none"> <li>1. Idiosyncrasy - genetic factors</li> <li>2. Hypersensitivity - immune factors</li> </ol>
C - Continuous	cummulative dose of drug; effects require prolonged period of exposure to develop <ol style="list-style-type: none"> <li>1. Addiction - person takes drug COMPULSIVELY despite potential harm and DESIRE TO STOP</li> <li>2. Dependence - without the drug, the patient experiences WITHDRAWAL EFFECTS; can be Physical or Psychological</li> </ol> <p>Tolerance and Tachyphylaxis - less or no effect at normal dose (i.e. Nicotine)</p>
D - Delayed	<ol style="list-style-type: none"> <li>1. Carcinogenicity - ability to cause cance, neoplams, malignancy</li> <li>2. Teratogenicity - ability to cause fetal malformations</li> </ol> <p><i>Thalidomide tragedy that caused phocomelia</i></p>
E - End of Use	withdrawal symptoms

### Severity Reaction (ADR)

Mild	bothersome but requires no change in therapy
Moderate	requires change in therapy, additional, hospitalization
Severe	disabling or life-threatening

### MEDICATION ERRORS (ADE)

Category A	"ala pa"; potential harm but no error
Category B	"buti nalang"; did not reach the patient
Category C	"char lang" did not cause harm
Category D	need monitoring
Category E	need treatment or intervention
Category F	Prolonged hospitalization
Category G	"GG"; permanent patient harm
Category H	Hingalo; near death
Category I	Ililibing; caused death of patient

### DRUG INTERACTIONS

Alcohol + antihistamine	additive (CNS depression)
Antacid + fluoroquinolone	chelation (dec. absorption) -> delay
Antibiotic + estrogen	alter microbial flora (dec. estrogen effectiveness)
Barbiturates + other drugs	enzyme induction (dec. effectivity)
Erythromycin + other drugs	enzyme inhibition (inc. effectivity)
MAOI + tyramine	cheese effect/synergistic
Thiazide + digitalis	hypokalemia
Warfarin + green leafy vegetables	antagonistic
Aminoglycoside + loop diuretic	additive - both muscle relaxation
Aminoglycoside + curare	muscular relaxation

