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What is an Adverse Drug Reaction?



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Pharm.D. Candidate 2014

Goals and Objectives

- Define what constitutes an adverse drug reaction (ADR)
- Determine the difference between an allergic and non-allergic ADR
- Provide examples of an allergic and non-allergic ADR
- Demonstrate understanding of internal and external ADR reporting
- Identify ways in which ADRs can be prevented

****ASHP (American Society of Health System Pharmacists) defines a significant ADR as any unexpected, unintended, undesired, or excessive response to a drug that.....**

- Requires discontinuing the drug
- Requires changing the drug therapy
- Requires modifying the dose
- Necessitates admission to a hospital
- Prolongs stay in a health care facility
- Necessitates supportive treatment
- Significantly complicates diagnosis
- Negatively affects prognosis
- Results in temporary or permanent harm, disability, or death

Two Types of Adverse Drug Reactions

- Allergic Drug Reactions
 - A drug hypersensitivity due to an immunologic response between the pharmacologic agent and the human immune system
 - Makes up 5-10% of ADRs
 - Most common with penicillins, sulfa, and local anesthetics
 - Repeatable, therefore, the offending drug should be avoided
- Non-Allergic Drug Reaction (idiosyncratic reaction)
 - Does not involve the immune system
 - Makes up 90-95% of ADRs

Signs and Symptoms Of An Allergic Reaction

- Urticaria (hives)
- Skin Rash (blisters, vesicles, raised lesions)
- Itching of skin or eyes
- Wheezing
- Swelling of lips, tongue, or face
- Nausea and Vomiting
- Anaphylaxis
 - Trouble Breathing
 - Fainting
 - Confusion
 - Rapid Pulse
 - Decreased Blood Pressure

Non-Allergic ADRs

- All medications have a therapeutic window, which means that receiving too little of a medication is not effective and too much may cause toxicity
- Factors that help contribute to these ADRs:
 - Age
 - Gender
 - Body Size
 - Specific Body Chemistry
 - Combination Of Drugs, especially if on 4 or more drugs concurrently
 - Pre-existing Conditions such as Asthma, HIV, Renal and Liver Dysfunction

Examples of Non-Allergic ADRs

- Sedatives
 - Over-sedation
- Opioids
 - Constipation
- Anticoagulants
 - Bleeding
- Insulin and some oral hypoglycemic agents
 - Hypoglycemia
- NSAIDs
 - GI bleeding
- Corticosteroids
 - Hyperglycemia
- Antihistamines
 - Dry mouth, drowsiness
- Antibiotics
 - Diarrhea
- ACE inhibitor
 - Cough
- Drug-drug, drug-food, drug-herbal interactions
 - Alcohol may interact with other drugs, such as sedatives to cause over-sedation
 - Grapefruit juice and St. John's Wort interactions may result in decreased effectiveness of some medications

Why is it so important to learn
about ADRs?

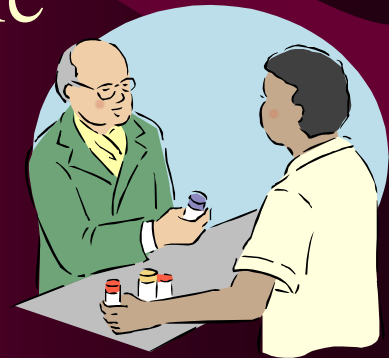


Important Points to Remember

- ADRs can occur in any patient and at any time
- The risk of ADRs may be increased by a patient's age, genetics, concurrent medications, and comorbid conditions
- ADRs may be involved with many commonly used medications, such as antibiotics, sedatives, NSAIDs, etc.
- There are other signs and symptoms of an ADR besides a rash, hives, or anaphylaxis

Important Points to Remember (Cont.)

- The population at the highest risk for ADRs are the elderly
 - 40% of individuals who are 65 years and older take **FIVE** or more medications!
- A recent one year study of Medicare outpatients revealed that out of the 1,523 identified ADRs, 421 were preventable



EXAMPLES?



External ADR Reporting

- Most new drugs are approved with an average of 1,500 patient exposures and the chance of some ADRs occurring is only one in 20,000 patient exposures
- Involves the teamwork of pharmacists, physicians, radiographers, nurses, and patients to report suspected ADRs

External ADR Reporting (Cont.)

- MedWatch is the U.S. Food and Drug Administration's adverse event reporting program for defective drugs and medical devices
- It was created to serve the public in ensuring safety of all marketed medical products
- It is important to report any unusual ADRs or ADRs involving newly marketed medications
 - ADRs should be reported to Pharmacy, who will then notify the FDA through MedWatch if the ADR is significant

Example One

- A recall has occurred for Duragesic 25 mcg/hr patches due to a manufacturer error. Some patches have a cut open edge, exposing patients or caregivers directly to fentanyl gel, which may lead to serious adverse reactions such as respiratory depression and possible overdose that could be fatal. *ADR reporting once again aided in making this problem known!*

Example Two

- Valproic Acid is an anticonvulsant utilized for controlling seizures. The antibiotic Doribax (doripenem) interacts with it when used concurrently.
 - This may lead to reduced levels of valproic acid in the bloodstream, which can result in loss of seizure control
- Valproic Acid also has a black box warning concerning hepatotoxicity, which is a potential adverse effect

More Examples

- Liver disease due to excessive dosages of acetaminophen
- 41,000 hospitalizations a year due to NSAID induced ulcers
- Drug Induced Parkinson's from drugs such as antipsychotics and anticonvulsants
- 32,000 hip fractures per year leading to 1,500 deaths due to drugs that cause severe dizziness, lightheadedness, or drowsiness in the elderly

Internal ADR Reporting

- Completion of an adverse drug reaction report should be completed whenever an ADR is suspected by going to the
 - Jameson Portal Page
 - CHART
 - Adverse Drug Reaction
- You do not need to wait for the physician or pharmacy to sign off on a suspected ADR before reporting
- There are 28 mandatory fields that must be completed, which are indicated by a green asterisk

CHART – Main Screen

Icon Wall - Windows Internet Explorer provided by Jameson Health System

https://r16.rlsolutions.com/CHART_Prod/Homecenter/Client/Home.aspx

File Edit View Favorites Tools Help

ADR tab

Logged in as Ronald Shollenberger

Icon Wall

Find a form

Please use the search above to narrow down your event results by using keywords to describe the event that you're looking for.

Rx
Medication Error

ADR
Adverse Drug Reaction

Equipment/Supplies/Devices
Equipment/Supplies/Devices

Fall
Fall

Error Related to Procedure/Treatment/Test
Error Related to Procedure/Treatment/Test

Complication of Procedure/Treatment/Test
Complication of Procedure/Treatment/Test

Transfusion
Transfusion

Skin Integrity
Skin Integrity

Done

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New File
tab →

ADR tab

When and Where Event Occurred

Adverse Drug Reaction Submission Form - Windows Internet Explorer provided by Jameson Health System

https://rl6.rlsolutions.com/CHART_Prod/submission.aspx?form=ADR&icon=1&file=0

File Edit View Favorites Tools Help

Adverse Drug Reaction Submission Form

Logged In as Ronald Stollenberger

Adverse Drug Reaction Submission Form

Table of Contents

- Form Instructions
- Person Affected
- When and Where Event Occurred
- Event Details

File Status

1 of 51 total fields completed.

1 of 28 mandatory fields completed.

When and Where Event Occurred

When

Event Date *

Event Time (00:00)

Event Shift

Where

Site *

Care Area Name *

Care Area Type *

How was the event discovered? *
[Add/Modify](#)

Individual preparing report: *

Reporting Department:

Delete More Actions Submit

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Event Details

Adverse Drug Reaction Submission Form - Windows Internet Explorer provided by Jameson Health System

https://rl6.rlsolutions.com/CHART_Prod/submission.aspx?form=ADR&icon=1&file=0

File Edit View Favorites Tools Help

Adverse Drug Reaction Submission Form

rlsolutions

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Adverse Drug Reaction Submission Form

Table of Contents

- Form Instructions
- Person Affected
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- File Status

1 of 51 total fields completed.

1 of 28 mandatory fields completed.

Event Details

Harm Score Definitions

Unsafe Conditions

- A- Circumstances that could cause adverse events (e.g. look-alike medications, confusing equipment, etc.).

Event, No Harm

- B1- An event occurred but did not reach the individual (near miss/close call) because of chance alone.
- B2- An event occurred but did not reach the individual (near miss/close call) because of active recovery efforts by caregivers.
- C- An event occurred that reached the individual but did not cause harm and did not require increased monitoring.
- D- An event occurred that req'd monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm.

Event, Harm

- E- An event occurred that contributed to/resulted in temporary harm and required treatment or intervention.
- F- An event occurred that contributed to/resulted in temporary harm and required initial/prolonged hospitalization.
- G- An event occurred that contributed to/resulted in permanent harm.
- H- An event occurred that resulted in a near-death event (e.g. required ICU care/other intervention to sustain life).

Event, Death

- I- An event occurred that contributed to/resulted in death.

Specific Event Type *

Harm Score *

Type of Outcome/Injury Not Specified [Add/Modify](#)

Describe the Event *

Delete More Actions Submit

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Event Details (Cont.)

Adverse Drug Reaction Submission Form - Windows Internet Explorer provided by Jameson Health System

https://rl6.rlsolutions.com/CHART_Prod/submission.aspx?form=ADR&icon=1&file=0

File Edit View Favorites Tools Help

Adverse Drug Reaction Submission Form

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Adverse Drug Reaction Submission Form

Table of Contents

- Form Instructions
- Person Affected
- When and Where Event Occurred
- Event Details
- File Status**

1 of 51 total fields completed.

1 of 28 mandatory fields completed.

Suspect Medication

Name of Medication Administered *

Medication Class Administered

Dose *

Frequency *

Strength/Concentration

Route *

Start Date (mm/dd/yyyy)

Stop Date (mm/dd/yyyy)

ADR Specific Information

ADR abated after use stopped or reduced? *

ADR reappeared after reintroduction? *

Was drug involved in ADR appropriate for condition? *

Delete More Actions Submit

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Event Details (Cont.)

Adverse Drug Reaction Submission Form - Windows Internet Explorer provided by Jameson Health System

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File Edit View Favorites Tools Help

Adverse Drug Reaction Submission Form

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Adverse Drug Reaction Submission Form

Table of Contents

- Form Instructions
- Person Affected
- When and Where Event Oc...
- Event Details
- File Status**

1 of 51 total fields completed.
1 of 28 mandatory fields completed.

Start Date (mm/dd/yyyy)

Stop Date (mm/dd/yyyy)

ADR Specific Information

ADR abated after use stopped or reduced?

ADR reappeared after reintroduction?

Was drug involved in ADR appropriate for condition?

Approp drug monitoring, other lab tests done and used?

Toxic serum drug level documented?

Previously documented history of allergy or reaction to drug?

Drug-drug, drug-food, or drug-lab interaction involved in ADR?

Poor compliance involved in ADR?

Potential Contributing Factors

Delete More Actions Submit

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Potential Contributing Factors and Notification

Adverse Drug Reaction Submission Form - Windows Internet Explorer provided by Jameson Health System

https://rl6.rlsolutions.com/CHART_Prod/submission.aspx?form=ADR&icon=1&file=0

File Edit View Favorites Tools Help

★ Favorites Adverse Drug Reaction Submission Form

Logged In as Ronald Shollenberger

Adverse Drug Reaction Submission Form

Table of Contents

- Form Instructions
- Person Affected
- When and Where Event Oc...
- Event Details
- File Status

1 of 51 total fields completed.

1 of 28 mandatory fields completed.

These sections are not mandatory, but very useful

Poor compliance involved in ADR? *

Potential Contributing Factors

Team Factors	Not Specified	Add/Modify
Work Environment	Not Specified	Add/Modify
Task Factors	Not Specified	Add/Modify
Staff Factors	Not Specified	Add/Modify
Patient Characteristics	Not Specified	Add/Modify
Organizational Management	Not Specified	Add/Modify

Other Potential Contributing Factor

Who Was Notified?

Date	Name	Type of Person Notified
Not Specified		

[Add](#) | [Modify](#) | [Delete](#)

Delete More Actions Submit

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How Can ADRs Be Prevented?



- Obtain A Medication History including
 - Past allergies or ADRs
 - Current medications (Rx, OTC, vitamins, herbals)
 - Recently discontinued medications (if ADR suspected)
 - Disease states
 - **MAKE EVERY ATTEMPT TO OBTAIN AS DETAILED A HISTORY AS YOU CAN!!**

How Can ADRs Be Prevented?

- Be aware of high risk patients
 - Multiple medications (2 or more)
 - Age \geq 65 years old
 - Existing drug allergies
 - Patients taking certain medications (anticonvulsants, antibiotics, digoxin, warfarin, and amiodarone)
- Consult a pocket reference to verify unusual dosages
- Consult with pharmacists/drug info specialists
- Review appropriate IV push and infusion rates
- Check available and up-to-date computer programs
 - Micromedex
 - DynaMed

Notification to patient regarding
new allergy identified during
patient stay/visit to hospital.

Inpatient

- Section added under “other” on electronic discharge instructions
 - New Drug Allergy
 - During your hospital stay, your physician has determined that you may have experienced an allergic reaction to _____. Be sure to tell doctors, dentists and other caregivers about your allergies. Record this allergy information and carry it on your person or wear a medical alert bracelet that lists allergies.
 - **See screen shot next slide**

Other Instructions:

Cool mist humidifier (vaporizer) to increase air moisture

Education Forms Given To Patient

Disease Management Awareness
Pneumococcal Vaccine Teaching Sheet
Influenza Vaccine Teaching Sheet

New Drug Allergy

lasix

New Drug Allergy Explanation

During your hospital stay your physician has determined that you may have experienced an allergic reaction to lasix. Be sure to tell doctors, dentists and other caregivers about your allergies. Record this allergy information and carry it on your person or wear a medical alert bracelet that lists allergies.

Instructions Status INPROGRS
Discharge Medication List

Adult Low Dose Aspirin (Aspirin) [81 mg tablet, delayed release (DR/EC)]: By Mouth

LAST DOSE GIVEN DATE: _____ TIME: _____

Stop taking the following Medication

No Medications qualify for this section.

Discharge Instructions/Orders were overseen by: ABRAHAM, WILLIAM

Emergency Department

- Information provided to patient via Med Host printed discharge instructions.

Summary

- Non-allergic ADRs make up the majority of ADRs
- There are more signs and symptoms of an ADR besides a rash, hives, or anaphylaxis
- ADRs may occur with many commonly used medications, such as antibiotics, sedatives, and NSAIDs
- ADRs may be reported externally through MedWatch and internally through CHART
- ADRs may be prevented by obtaining a complete medical history as well as consulting with references or other health care professionals for verification

References

- Riedl MA, Casillas AM, Geffen D. Adverse Drug Reactions: Types and Treatment Options. *Am Fam Physician*. 2003;68(9):1781-1791. Available at <http://www.aafp.org/afp/2003/1101/p1781.html>.
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Questions?



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