Allergy Status – Identification and Documentation

Basic Medication Safety (BMS) Certification Course
King Saud bin Abdulaziz University for Health Sciences
Ministry of National Guard – Health Affairs

Learning Objectives

- Identify the true drug allergic reactions
- Define the different types and classifications of ADR
- Identify the clinical presentation of drug allergy
- Recognize the treatment of drug hypersensitivity reactions
- Differentiate anaphylaxis from other allergic reaction presentations and its treatment

Case # 1

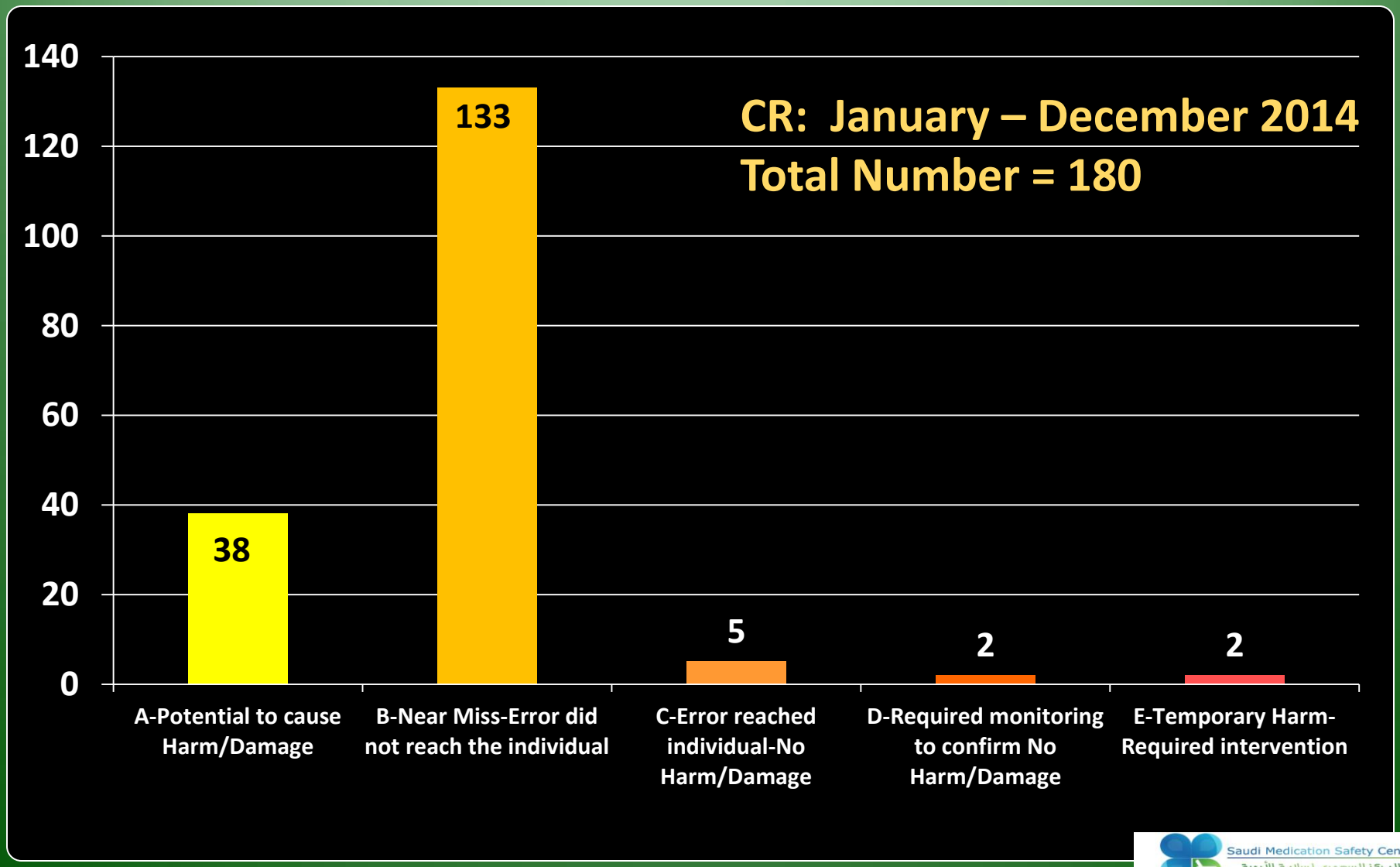
- 64 year old woman
- Hx anaphylaxis with cefuroxime

- Dx bowel obstruction, s/p laparotomy / mesh repair
- Post-op: metroNIDAZOLE and ciprofloxacin
- ASO – day before anticipated discharge

- Cefuroxime 750 mg IV every 8 hour prescribed via CPOE
- Allergy alert fired, overridden by physician with ‘OK’
- Allergy alert fired, overridden by pharmacist with ‘*’
- Administered by a nurse without verifying the allergy
- ADT form over the bed transcribed “NKA”

- Anaphylactic shock / Coded / Transfer to ICU / Expired

Medication Errors / Near Misses: Patients with Known Allergy Harm Category



Definitions

- **Adverse Drug Reaction:** Is a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function. (Saudi FDA)

- **Drug hypersensitivity:** an immune-mediated response to a drug agent in a sensitized patient; includes both allergic and pseudo allergic drug reactions

- **Drug allergy:** is restricted specifically to a reaction mediated by IgE

Classifications of ADRs

1. Type A Reactions

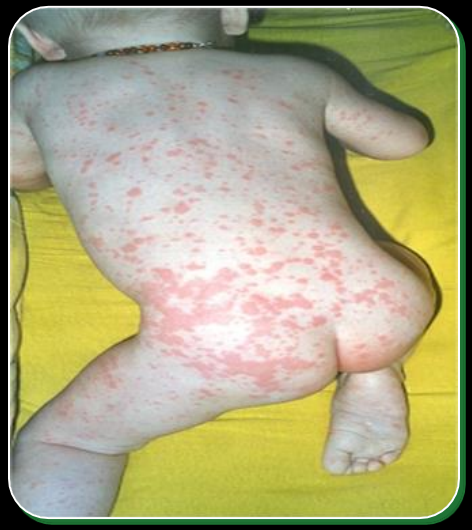
- **Predictable**
- **Common**
- **Relate to the pharmacologic actions of the drug**
- **May occur in any individual**
- **Examples:**
  - **Toxicity** – hepatic failure with high dose acetaminophen
  - **Side effect** – sedation with antihistamines
  - **Secondary effect** – development of diarrhea with antibiotic treatment
  - **Drug interaction** – theophylline toxicity in the presence of erythromycin tx

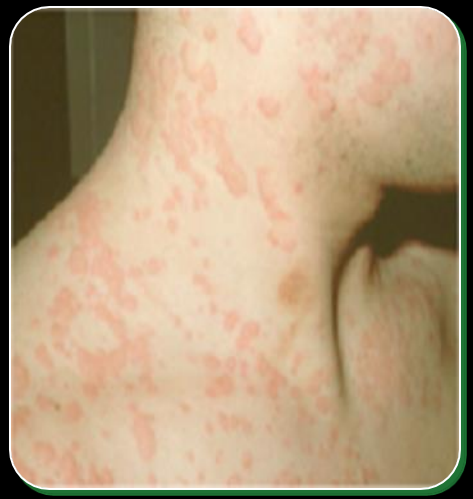
2. Type B Reactions

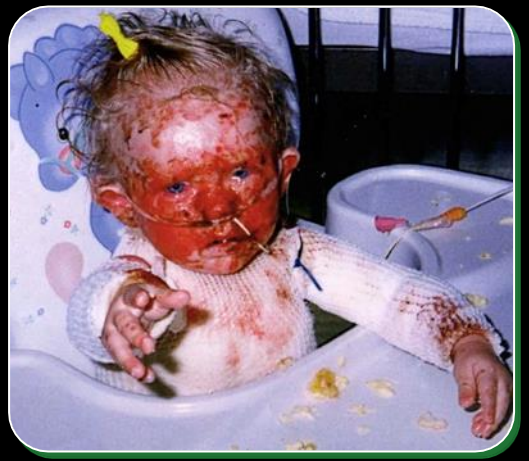
- **Unpredictable**
- **Uncommon**
- **Usually not related to the pharmacologic actions of the drug**
- **Occur only in susceptible individuals**

- **Example:**
  - **Hypersensitivity (immunologic) reaction**
    - anaphylaxis with penicillin administration

Skin Manifestations







Anaphylaxis (Type I Reactions)

- **Timing**
- IgE-mediated reactions occur rapidly after the last administered dose
- The time to onset is influenced by the route of administration:
  - IV: seconds to minutes
  - Orally: 3 - 30 minutes (empty stomach)
  - Orally: 10 - 60 minutes (with food)
- IgE-mediated anaphylactic reactions should NOT begin several days into a course of therapy

History.....!

- Are you allergic to any drugs / food?
- What happened when you took this medication / food?
- When was this reaction?
- Have you taken that medication / food since?
- Do you have any other allergies?

Common Medicines: Drug Allergy

- Anticonvulsants
- Anti-infectious agents
- Neuromuscular blocking agents (NMBA)
- NSAID (phenylbutazone, diclofenac,..)
- Radiocontrast media

Case # 2

- 58 year old woman
- Hx allergy to Celecoxib and Penicillin, which was on pre-printed prescription form
- Prescribed Celecoxib and filled the same day
- Patient took first dose 13 days after filling prescription
  - "Mild" Anaphylaxis
  - ECC – EPINEPHrine, IV steroids and IV DiphenhydrAMINE
- Discharged home after three (3) hours

Therapy and Management (Non-Anaphylaxis)

- Discontinuation of the offending medication
- Call the prescriber
- Symptoms will resolve within two (2) weeks if the diagnosis of drug hypersensitivity is correct
- Additional therapy for drug hypersensitivity reactions is largely supportive and symptomatic
- Systemic corticosteroids may speed recovery in severe cases of drug hypersensitivity
- Topical corticosteroids and oral antihistamines may improve dermatologic symptoms

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APPENDIX F

PENICILLIN (BETA-LACTAM) ALLERGY CROSS-REACTIVITY ALGORITHM

Always check for any drug allergy before prescribing, dispensing and administering drugs

Does the patient have any known allergies?

YES

NO → Confirm with the patient and document "NKA" = No Known Allergy

Allergic to a Penicillin Antibiotic (See list below)

DO NOT GIVE

Penicillin-Containing Antibiotics:
- Amoxicillin
- Ampicillin
- Ampicillin/Sulbactam
- AUGMENTIN (contains Amoxicillin and Clavulanic acid; CO-amoxiclav)
- Cloxacillin
- Flucloxacillin
- Penicillin G (Benzylpenicillin)
- Penicillin V (Phenoxymethylpenicillin)
- TAZOCIN (Piperacillin + Tazobactam)

USE WITH CAUTION

Cephalosporins:
- Cefaclor
- CeFAZolin
- Cefepime
- Cefotaxime
- Cefprozil
- Cefradine
- CefTAZidime
- CefTRIAXone
- Cefuroxime
- Cephalexin

Other beta-lactam antibiotics:
- Imipenem
- Meropenem

Avoid if history of **anaphylaxis** to penicillin.

Use may be considered in other penicillin allergic patients. If treatment is prescribed or recommended, **check** that the penicillin allergy has been considered, discussed fully with the patient and documented in HIS-CPR and in the patient's clinical record.
If **not**, **query** with the prescriber.

Allergic to another drug

DO NOT GIVE drug or related drugs
Check in **Micromedex®**, or with a pharmacist or physician

Do **NOT** **dispense** or **administer**. If treatment is prescribed or recommended, **contact** prescriber and **alert** them to the patient's history of allergy/anaphylaxis

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APPENDIX E

OPIOID INTOLERANCE DECISION ALGORITHM

Always check for any drug allergy before prescribing, dispensing and administering drugs

Does the patient have any known allergies?

YES

NO → Confirm with the patient and document "NKA" = No Known Allergy

When patients say they're allergic to an opioid, are all opioid analgesics off limits? The key is getting a detailed description of the reaction. Answer the questions below and follow the instructions to find the best options for your patient.
Check the symptoms the patient describes, and follow the instructions in the far right column.

Flushing, itching, hives, sweating, and/or mild hypotension **only**	Go to **A**
Itching, flushing, or hives at injection or application site **only**	Go to **A**
Severe hypotension	Go to **B**
Skin reaction other than itching, flushing, or hives (e.g., rash)	Go to **B**
Breathing, speaking, or swallowing difficulties	Go to **B**
Swelling of face, lips, mouth, tongue, pharynx, or larynx	Go to **B**

A

These symptoms may be due to a *pseudoallergy*. It's a result of histamine release, a pharmacologic side effect of some opioids. Options for this patient include:
1. A nonopioid analgesic (e.g., Acetaminophen, an NSAID)
2. Avoidance of Codeine, Morphine, and Meperidine, the opioids most commonly associated with pseudoallergy
3. Use of a more potent opioid less likely to release histamine. Highest potency is FentaNYL, then HYDROmorphone, then Oxycodone, then **Morphine** then **Codeine**, then **Meperidine**
4. If **needed**, concurrent administration of an antihistamine…an H1 (e.g., DiphenhydrAMINE) and perhaps an H2 blocker (e.g., Ranitidine)
5. Dose reduction, if tolerated.

B

This patient may have experienced a *true allergy*. Options for this patient include:
1. A nonopioid analgesic (e.g., acetaminophen, an NSAID)
2. An opioid in a chemical class different from the one to which the patient reacted, with close monitoring:
   - **Phenylpiperidines**: Meperidine, FentaNYL, SUFentanil, RemiFentanil.
   - **Diphenylheptanes**: Methadone
   - **Morphine group**: Codeine, Morphine, OxyCODONE, HYDROmorphone, PERCOCET (Acetaminophen/ OxyCODONE), TYLENOL #3 (Acetaminophen/ Codeine), FEVADOL PLUS or SOLPADINE (Acetaminophen/ Codeine/ Caffeine)
   - **Other**: TraMADol is contraindicated in patients with opioid allergy per USA and Canadian product labeling; however there is **NOT** good evidence for cross-sensitivity of TraMADol with opioids. Experts recommend using TraMADol *ONLY* for patients who have mild reactions to opioids.

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APPENDIX D

ASPIRIN SENSITIVITY ALGORITHM

Always check for any drug allergy before prescribing, dispensing and administering drugs

Does the patient have any known allergies?

YES

NO → Confirm with the patient and document "NKA" = No Known Allergy

Sensitive to Aspirin, a non-steroidal anti-inflammatory drug (NSAID) or COX-1 inhibitor (See list below)

DO NOT GIVE
- Aspirin
- Diclofenac
- Ibuprofen
- Indomethacin
- Ketorolac
- Naproxen

USE WITH CAUTION
- Acetaminophen greater than 650 mg
- Meloxicam greater than 7.5 mg
- Celecoxib

Do **NOT** **dispense** or **administer**. If treatment is prescribed or recommended, **contact** prescriber and **alert** them to the patient's history of allergy / anaphylaxis

Allergic to another drug

DO NOT GIVE drug or related drugs
Check in **Micromedex®**, or with a pharmacist or physician

Aspirin sensitivity is due to COX-1 inhibition, and ***NOT*** an actual immune response. Most NSAIDs also inhibit COX-1 and are therefore likely to also induce a sensitivity reaction.
Aspirin sensitivity involves symptoms that are respiratory in nature, such as rhinitis and worsening of asthma, or skin manifestations, such as urticaria and angioedema (swelling of the skin).

The chance for cross-reactivity between aspirin and NSAID in a patient with a true allergic reaction to either is less likely.

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APPENDIX G

SULFA DRUGS ALLERGY CROSS-REACTIVITY ALGORITHM

Always check for any drug allergy before prescribing, dispensing and administering drugs

Does the patient have any known allergies?

YES

NO → Confirm with the patient and document "NKA" = No Known Allergy

Allergic to Sulfa Drugs (See list below)

DO NOT GIVE

Sulfa Antibiotics:
- Co-Trimoxazole
- Silver SulfADIAZINE
- Sulfacetamide
- Sulfamethoxazole

Diuretics:
- Diazoxide
- DYAZIDE (Triamterene / Hydrochlorothiazide)
- Hydrochlorothiazide
- Indapamide
- MODURETIC (AMILoride / Hydrochlorothiazide)

Other
- AcetaZOLAMIDE
- SulfaSALAZINE
- Zonisamide

USE WITH CAUTION
- Bumetanide
- Celecoxib
- Dapsone
- Dorzolamide
- Furosemide
- Gliclazide
- GlipiZIDE
- GlyBURIDE (Glibenclamide)
- Metolazone
- Procainamide
- Simeprevir (NFD)
- Tamsulosin

Avoid if history of **anaphylaxis** to Sulfa.

Use may be considered in other Sulfa allergic patients. If treatment is prescribed or recommended, **check** that the Sulfa allergy has been considered, discussed fully with the patient and documented in HIS-CPR, and in the patient's clinical record.
If **not**, **query** with the prescriber.

Allergic to another drug

DO NOT GIVE drug or related drugs
Check in Micromedex®, or with a pharmacist or physician

Do **NOT** **dispense** or **administer**. If treatment is prescribed or recommended, **contact** prescriber and **alert** them to the patient's history of allergy/anaphylaxis

Agents containing sulfur, sulfates, sulfites and saccharin are **NOT** sulfonamides and **DO NOT** cross-react. They are also chemically unrelated to sulfonamides and there is **NO** risk of cross-sensitivity.
NOTE: Sulfites may cause their own reactions such as dyspnea, wheeziness and chest tightness in patients with asthma.

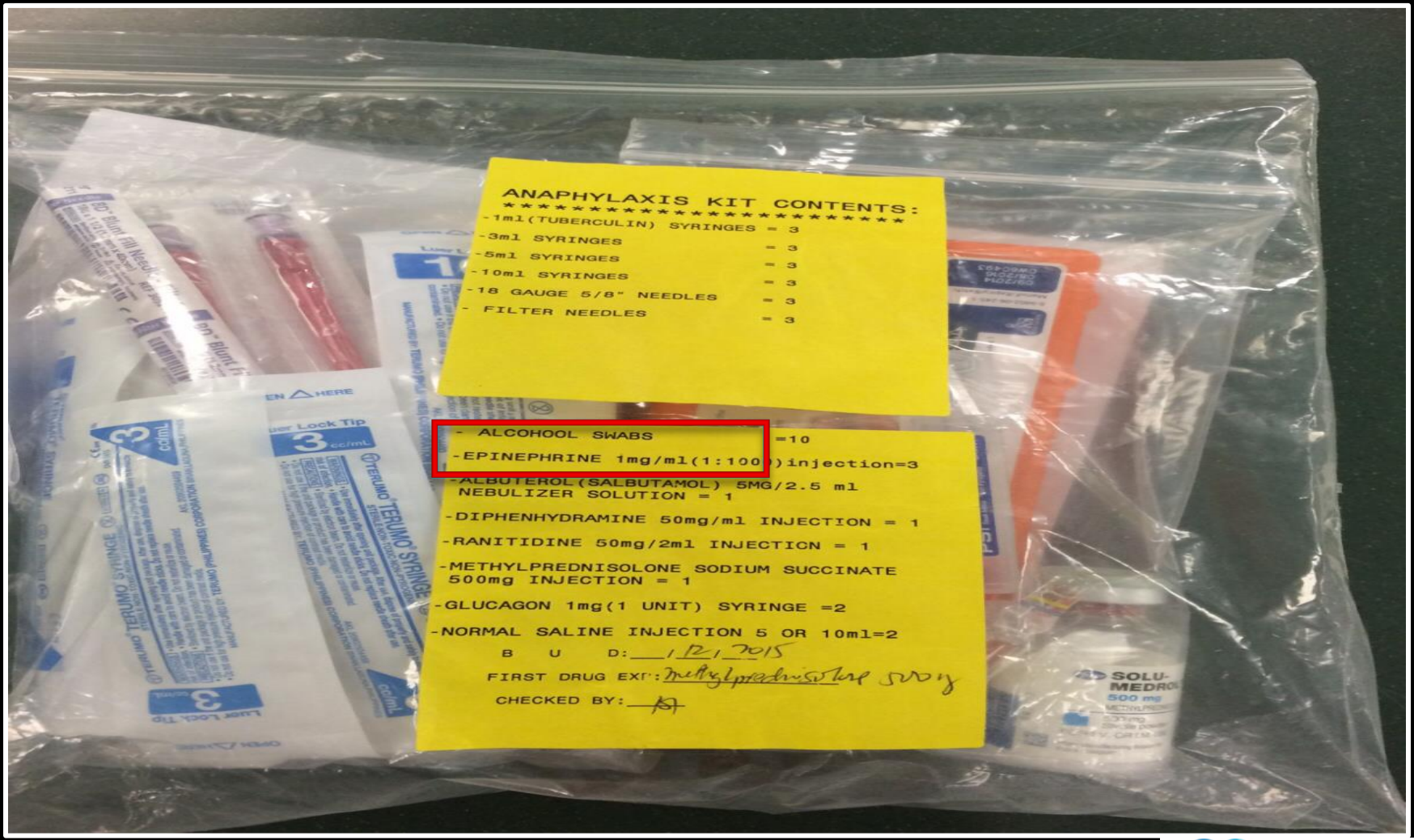
Remember.....!

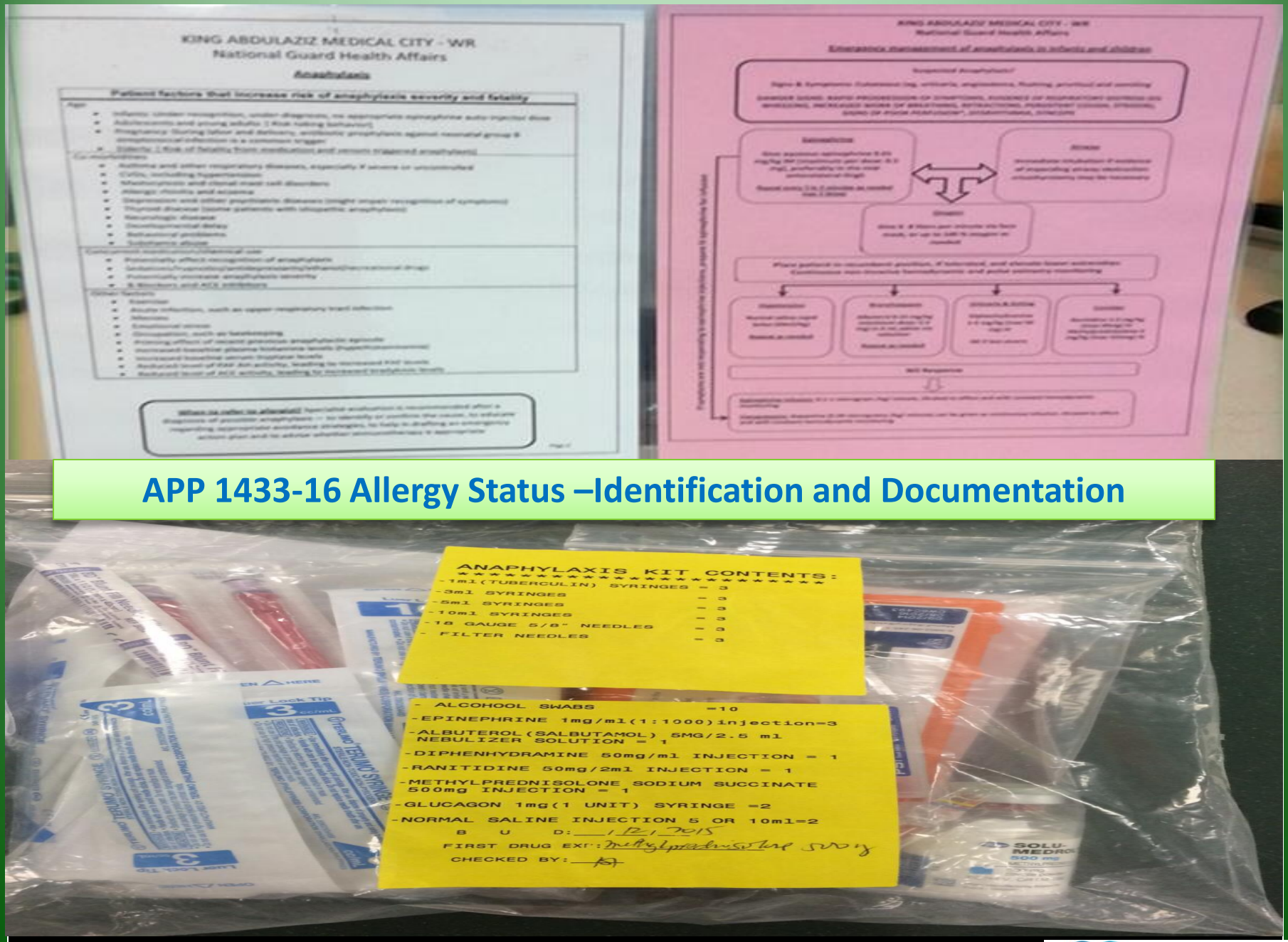
- Pre-medication WILL **NOT** prevent anaphylaxis if given prior to the allergenic drug
- Pre-medication **ONLY** approved for previous Radio Contrast Media (RCM) reactions less than one (1) hour

Acute Anaphylaxis Management

1. EPINEPHrine
2. EPINEPHrine
3. EPINEPHrine
4. EPINEPHrine
5. EPINEPHrine
6. EPINEPHrine
7. EPINEPHrine
8. EPINEPHrine
9. EPINEPHrine
10. EPINEPHrine
11. EPINEPHrine
12. EPINEPHrine
13. EPINEPHrine
14. EPINEPHrine
15. EPINEPHrine
16. EPINEPHrine

Anaphylaxis Kit:
Standardized Kit available through Pharmaceutical Care Services Department for inclusion in Floor Stock





APP 1433-16 Allergy Status –Identification and Documentation

Allergy Documentation

- Allergy status must be documented **before** any medication(s) is / are administered, except in emergencies.
- Assessment and documentation of an allergy is a diagnosis and must be determined by a **physician**, and attention given to the diagnosis of Allergy prior to prescribing.
- It is the Physician's responsibility to verify and document allergy in the HIS-CPR, as well as on the patient's clinical record / order sheet, which should lead to the patient's chart to be "flagged" with allergy statement.

Allergy Status

Known allergy	Name the substance; for medications the generic name(s) of medication(s) must be documented
No Known Allergy	The patient / carer and clinical records are clear that the patient has never experienced an allergic reaction or severe adverse reaction to any substance
Allergy status is not yet ascertained	**ONLY** to be used in exceptional circumstances where it has not been possible to ascertain allergy status on admission. Allergy status must be confirmed as soon as possible

Allergy Status

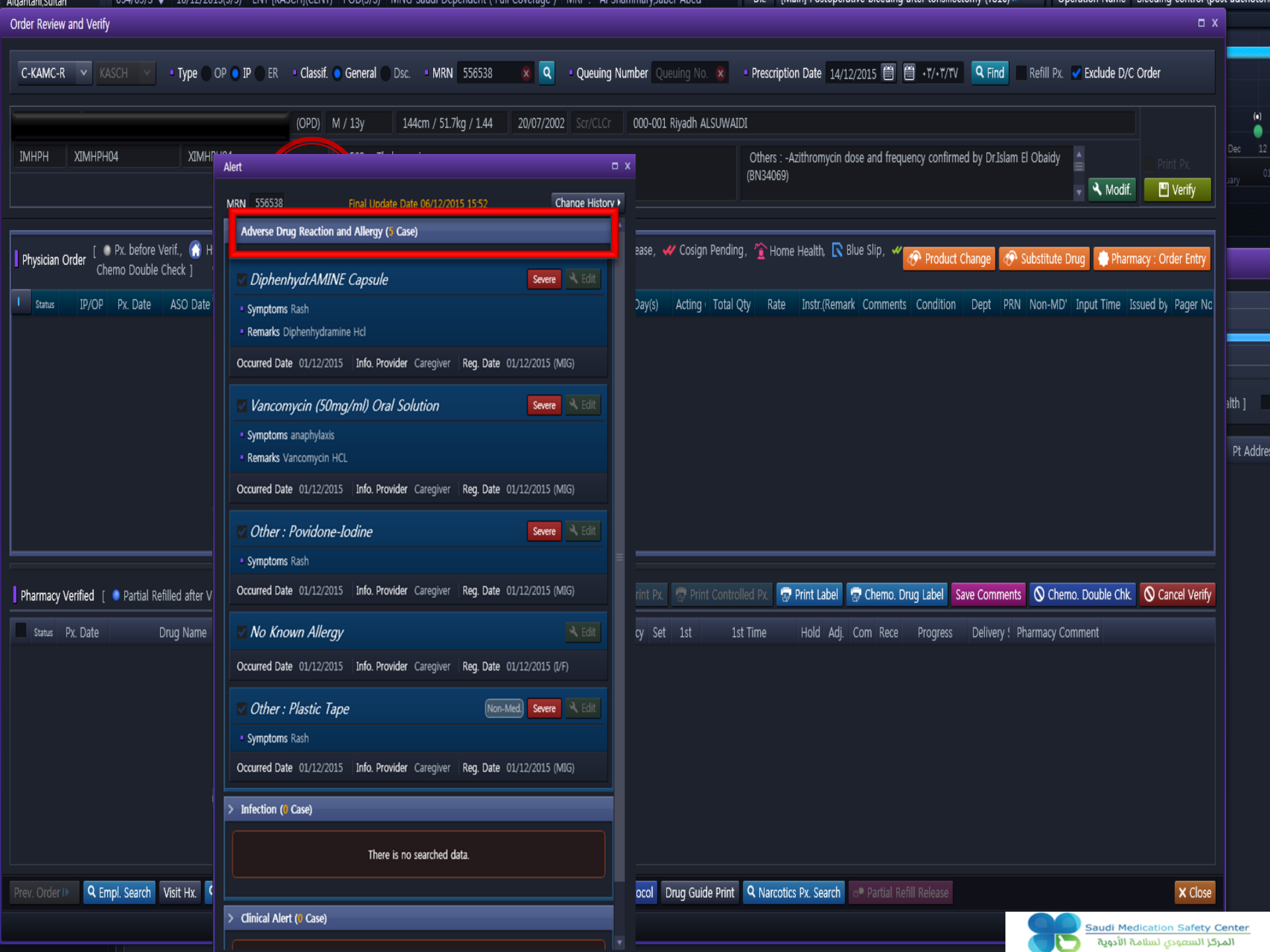
If a patient has documented previous known allergies, and upon investigation a physician deems the patient does not have the noted allergy:

- ✓ He / She must write an order to change the allergy status
- ✓ Document in the progress notes of the clinical record
- ✓ Update in the HIS-CPR

In the case of new allergies diagnosed by physician:

- ✓ He / She must write an order to change the allergy status
- ✓ Document in the progress notes of the clinical record
- ✓ Update in the HIS-CPR

If the physician is in doubt about the allergy, referral should be made to an immunologist for confirmation


Order Review and Verify
C-KAMC-R
KASCH
Type OP IP ER
Classif. General Dsc.
MRN 556538
Queuing Number Queuing No.
Prescription Date 14/12/2015
Find
Refill Px.
Exclude D/C Order
(OPD) M / 13y
144cm / 51.7kg / 1.44
20/07/2002
Scr/CLCr
000-001 Riyadh ALSUWAIDI
IMHPH
XIMHPH04
Others : -Azithromycin dose and frequency confirmed by DrIslam El Obaidy (BN34069)
Print Px.
Modif.
Verify
Alert
MRN 556538
Final Update Date 06/12/2015 15:52
Change History
Adverse Drug Reaction and Allergy (5 Case)
DiphenhydrAMINE Capsule
Severe
Edit
Symptoms Rash
Remarks Diphenhydramine Hcl
Occurred Date 01/12/2015 Info. Provider Caregiver Reg. Date 01/12/2015 (MIG)
Vancomycin (50mg/ml) Oral Solution
Severe
Edit
Symptoms anaphylaxis
Remarks Vancomycin HCL
Occurred Date 01/12/2015 Info. Provider Caregiver Reg. Date 01/12/2015 (MIG)
Other : Povidone-Iodine
Severe
Edit
Symptoms Rash
Occurred Date 01/12/2015 Info. Provider Caregiver Reg. Date 01/12/2015 (MIG)
No Known Allergy
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Occurred Date 01/12/2015 Info. Provider Caregiver Reg. Date 01/12/2015 (I/F)
Other : Plastic Tape
Non-Med.
Severe
Edit
Symptoms Rash
Occurred Date 01/12/2015 Info. Provider Caregiver Reg. Date 01/12/2015 (MIG)
Infection (0 Case)
There is no searched data.
Clinical Alert (0 Case)
Physician Order
Px. before Verif.,
Chemo Double Check]
Cosign Pending,
Home Health,
Blue Slip,
Product Change
Substitute Drug
Pharmacy : Order Entry
Status IP/OP Px. Date ASO Date
Day(s) Acting Total Qty Rate Instr.(Remark Comments Condition Dept PRN Non-MD' Input Time Issued by Pager No
Pharmacy Verified
Partial Refilled after V
Print Px.
Print Controlled Px.
Print Label
Chemo. Drug Label
Save Comments
Chemo. Double Chk.
Cancel Verify
Status Px. Date Drug Name
Set 1st 1st Time Hold Adj. Com Rece Progress Delivery Pharmacy Comment
Prev. Order
Empl. Search
Visit Hx.
Drug Guide Print
Narcotics Px. Search
Partial Refill Release
Close
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How to Reduce the Risk of Medication Error with Known Allergens: Recommendations

1. Check allergy status immediately before prescribing, dispensing or administering drugs: Every drug, Every patient, Every time.
2. Understand allergies and cross-allergies.
3. Educate patient / carer of their allergy status. Patients need to have a clear understanding of which drugs(s) to avoid. The patient is the one constant factor irrespective of where health care is delivered.
4. Standardize allergy history taking & documentation.
5. Maximize the impact of computerized prescribing.

APP 1433-16: Allergy & Hypersensitivity Recording & Documentation

بسم الله الرحمن الرحيم

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APP

MINISTRY OF NATIONAL GUARD - HEALTH AFFAIRS
ADMINISTRATIVE POLICY AND PROCEDURES

NUMBER	:	**APP 1433-16**
TITLE	:	**ALLERGY STATUS - IDENTIFICATION AND DOCUMENTATION**
ORIGINATING DEPT.	:	**SAUDI MEDICATION SAFETY CENTER (7559)**
ORIGINAL DATE	:	**OCTOBER 2012**
REVISED DATE	:	**SEPTEMBER 2015**

1. PURPOSE

To define the process in identification and documentation of patient allergy/intolerance status in order to prevent patient harm within the Ministry of National Guard – Health Affairs (MNG-HA) healthcare and all affiliated facilities.

2. APPLICABILITY

To all healthcare staff involved in the medication use process related to the medications listed in the MNG-HA Drug Formulary within all MNG-HA healthcare and all affiliated facilities.

3. RELATED REFERENCES

3.1 APP 1429-03: Prescribing and Dispensing Medication Guidelines

3.2 APP 1430-10: Clinical Record Content and Documentation Standards

3.3 APP 1430-27: Patient Admission (H&P) Assessment

Safe Patient Care Is Our Goal