

May Be Harming You

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SESSION 3 MEDICATION ERRORS SURGICAL ERRORS

Plan for the Course

- Session 1: Introduction and Definitions
- Session 2: Diagnostic Errors
- Session 3: Medication Errors, Surgical Errors
- Session 4: Communication Errors
- Session 5: US Healthcare System/Industry
- Session 6: Science and Technology
- Session 7: Comparison with Other Countries
- Session 8: Solutions, Reduction, Prevention

Plan for the Session

- Adverse Drug Events (ADE)
- National ADE Action Plan
- The Five "Rights"
- Look-Alike/Sound-Alike Drugs
- Interactions between food and medications
- Surgical Errors
- National Patient Safety Goals
- Universal Protocol

MEDICATION ERRORS

Medication Error

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer.

NCCMERP

Definition

- A *medication error* is an error (of commission or omission) that begins at any step from when a clinician prescribes a medication and ends when the patient actually receives the medication.
- An *adverse drug event* (ADE) is defined as harm experienced by a patient as a result of exposure to a medication.
- The occurrence of an ADE does <u>not</u> necessarily indicate an error or poor quality care.

Definitions

- *Preventable adverse drug events* result from a medication error that reaches the patient and causes any degree of harm.
- It is generally estimated that about ½ of ADEs are preventable.
- *Potential ADEs* are medication errors that do not cause any harm.

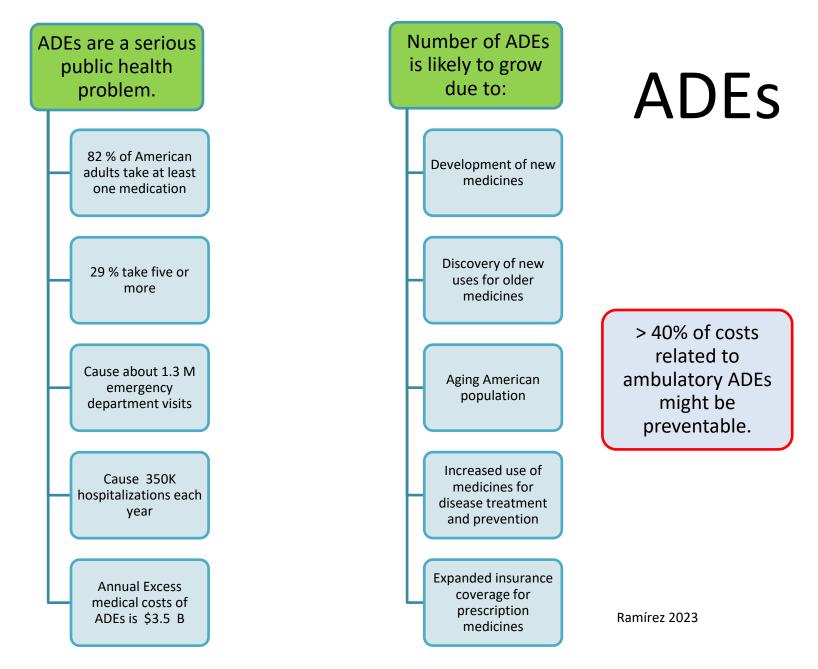
Definitions

- In an *ameliorable ADE* the patient experienced harm from a medication that could have been mitigated, though not completely preventable.
- A certain percentage of patients will experience ADEs even when medications are prescribed and administered <u>appropriately.</u>
- These *adverse drug reactions* or *non-preventable ADEs, are* commonly known as side effects.

Averse Drug Events (ADEs)

• ADEs caused an average increased hospital costs of \$4K per admission or about \$2.8M annually for a 700-bed teaching hospital.

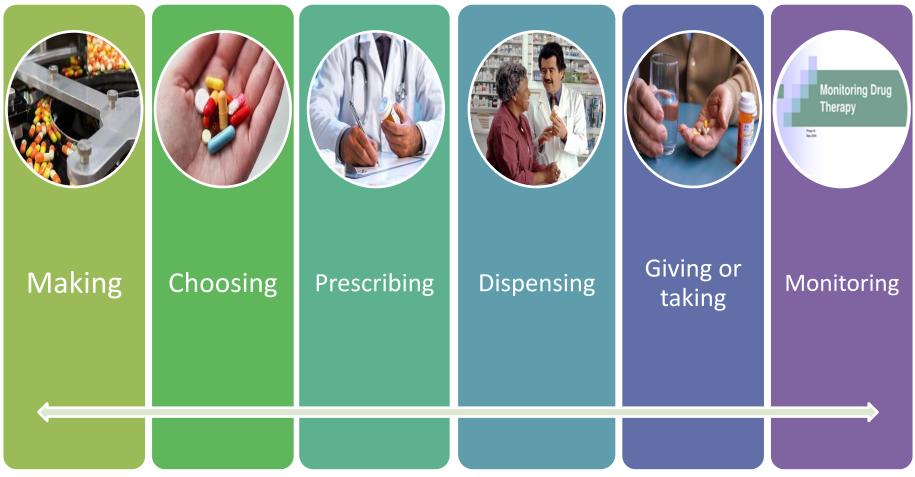
 <u>Extrapolating</u> data to the whole population, drug events affecting inpatients cost about \$2 B per year for the nation.



Multiple Players

Food and Drug Administration (FDA)	National Council on Patient Information and Education (NCPIE)	Institute for Safe Medication Practices (ISMP)	U.S. Pharmacopeia (USP)
National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP)	Institute for Healthcare Improvement (IHI)	Office of Disease Prevention and Health Promotion (ODPHP)	Federal Interagency Steering Committee for Adverse Drug Events (FISCADE)
National Action Plan for Adverse Drug Events (ADE Action Plan)	Substance Abuse and Mental Health Services Administration (SAMHSA)	Centers for Disease Control and Prevention (CDC)	Agency for Healthcare Research and Quality (AHRQ)
		and etc., etc.	Ramírez 2023

Stages of Potential Drug Errors



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Potential ADEs

Manufacturing



Making

Problems in manufacturing the product to be used:

- wrong strength
- contaminants
- adulterants
- wrong packaging
- misleading packaging

Misleading Packaging Z-PAK vs EZCpak



Potential ADEs Choosing



Choosing

Problems in choosing and prescribing a medicine:

- irrational
- inappropriate
- ineffective
- under
- over

Prescribing

Potential ADEs Prescribing



Writing

Writing, phoning or e-sending the prescription:

- spelling errors
- legibility
- look-alike medssound-alike meds
- "LASA" meds

- wrong recipient
- faulty software

Potential ADEs Dispensing



Dispensing

Problems in dispensing the prescription:

- wrong drug
- wrong formulation
- wrong label
- wrong patient
- absence of warnings
- no checking for cross-reactions or allergies

Potential ADEs Giving or Taking

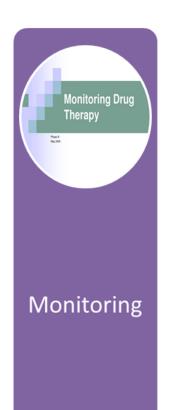


Giving or taking

Problems in administering or taking the drug

- wrong dose
- wrong route
- wrong frequency
- wrong duration
- interactions with foods or other meds
- how do I take this?

Potential ADEs Monitoring



Problems with monitoring therapy

- failure to follow up results of therapy
- failure to alter therapy if needed
- erroneous alteration
- side effects
- no therapeutic/toxic levels checked

NATIONAL ADE ACTION PLAN

National Action Plan for Adverse Drug Event Prevention



Medication Without Harm



WHO Global Patient Safety Challenge

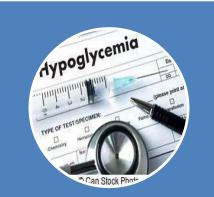


3 Targets for the National ADE Action Plan



Anticoagulants:

bleeding is the primary ADE of concern.





Opioids:

accidental overdoses, oversedation, and respiratory depression are primary areas of ADE concern.

Diabetes agents:

hypoglycemia is the primary ADE of concern.

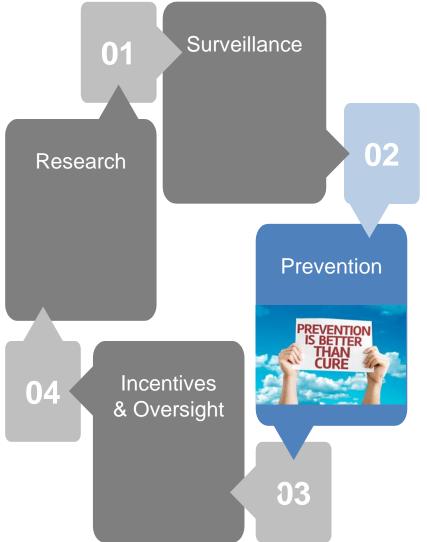




Surveillance

Coordinate existing federal surveillance resources & data to assess ADEs' health burden and rates with:

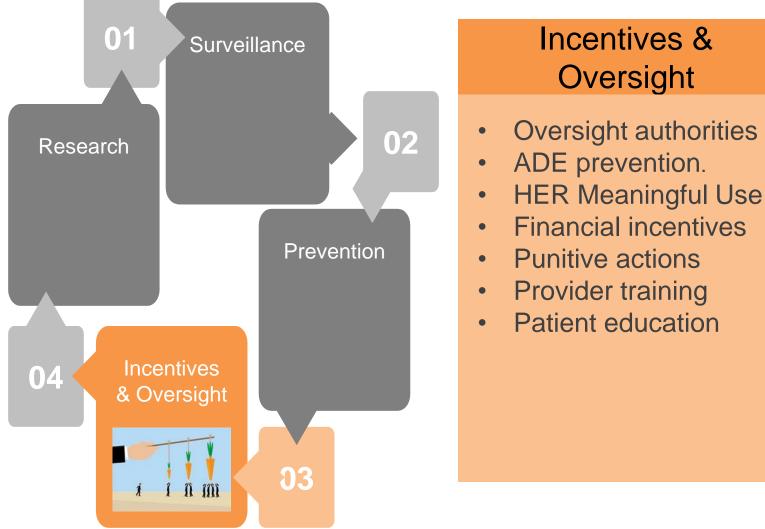
- Real-time data reporting
- Reduce provider
 burden
- Improve patient access to health information

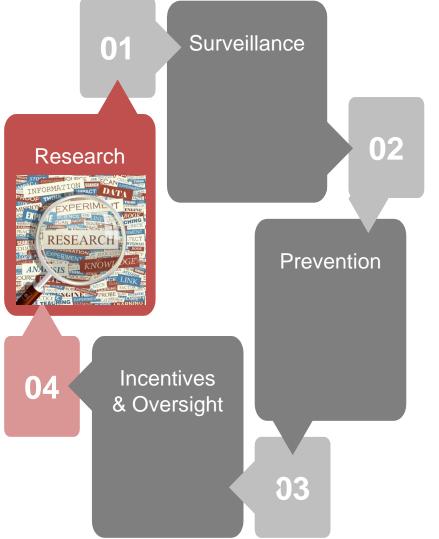


Prevention

Share evidence-based prevention tools across federal agencies and non-federal providers and patients:

- Flowsheets
- e-prescribing
- Patient panels
- Clinical guidelines
- Share best practices





Research

- Identify current knowledge gaps for ADE prevention.
- Answer research questions
- Identify best practices
- Develop new research questions

FDA Guidance

- Tablets and other oral dosage forms should have distinct and legible imprint codes so drug product and strength can be verified.
- Oral dosing devices (syringes, spoons) co-packaged with a liquid medication should be appropriate for the doses to be measured.



Look-alike pills:

Hydrocodone Bitartrate/Acetaminophen 10mg-325mg Tablet Mallinckrodt Inc Pharmaceuticals Group

Ciprofloxacin Hydrochloride 500mg PD-RX Pharmaceuticals



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FDA Guidance

• Package design should protect the consumer against incorrect use.

• Skin meds should not be packaged in containers that look like eye, ear, nose, or oral products.

• Similar-looking containers result in people putting a skin product in the eye, ear, nose, or mouth.

Preventing ADEs 5 Prescriptions for Prescribers

- **R** Education
- **R** Special study modules
- **R** Proper assessment (could link to prescribing license)
- **R** A national prescription form for hospitals
- **R** Guidelines and computerized prescribing systems

ADE Prevention

Patient Actions

- Keep an updated list of your medications and share it with all your health care providers.
- Follow directions carefully when taking your meds, and measure liquids with an appropriate device, such as a syringe or a cup, not a spoon.
- Perform any testing ordered by your doctor.

ADE Prevention

Patient Actions

- Take all medications only as directed: Do not skip doses, take extra doses, or stop taking your medications without consulting your doctor.
- Have pills in an organizer to avoid errors.
- Do not share your medications with others, or use someone else's medications.



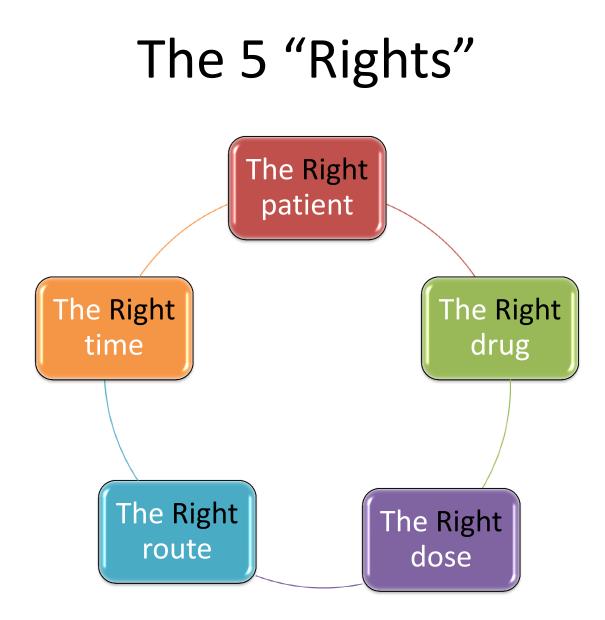
ADE Prevention

Patient Actions

Ask questions if you have any doubts or concerns about your medications:

- name
- purpose
- dose
- side effects
- interactions
- precautions
- missed doses
- adverse reactions

THE 5 "RIGHTS"



The "5 Rights"

- Broadly stated goals or desired outcomes of safe medication practices that offer no guidance or procedures on how to achieve them.
- Holding practitioners accountable for doing the "5 rights" fails to ensure medication safety.
- Adding a 6th, 7th, or 8th "right" (e.g., right reason, right formulation, right line attachment) is not the answer, either.

The 5 "Rights"

- Medication "rights" focus on individual performance and ignore system defects that may make completing the tasks difficult or impossible.
- Medication "rights" should be accepted as one goal of the medication process, and not seen as the "be all and end all" of medication safety.

The "5 Rights"

 The practitioners' duty is to follow the rules and procedures designed by the organization to produce the best outcomes, not only to achieve the "5 rights".

 If the procedural rules cannot be followed because of system issues, practitioners must report the problem so it can be remedied.

Questions? 1



LOOK ALIKE/SOUND ALIKE or SOUND ALIKE/LOOK ALIKE (LASA/SALA) MEDICATIONS

"LASA" Drugs Look-Alike, Sound-Alike

- Almost 25% of medication errors reported result from confusion with look alike/sound alike drugs.
- Many drugs have similar letters, similar generic names, or confusing brand-to-generic names.
- When combined with illegible handwriting, another doctor, pharmacist, or especially the patient could get the drug wrong.

"LASA" Drugs Look-Alike, Sound-Alike

- In one case, a patient reported taking *Plaxil* at home but was really taking *Plavix*, a common blood thinner.
- The doctor misinterpreted *Plaxil* (which is not a drug) as *Paxil*, a common antidepressant medication.
- In another example, a doctor wrote an order for the bronchodilator *Foradil*; it was misinterpreted as *Toradol* (an NSAID).

"LASA" Drugs

Best Practices

- Use brand & generic names on prescriptions/labels.
- Include purpose of the medication on prescriptions.
- Configure computer menu screens so look-alike names don't appear consecutively.
- Draw attention to differences between look-alike product names(Tall Man Lettering).

Tall Man Letters

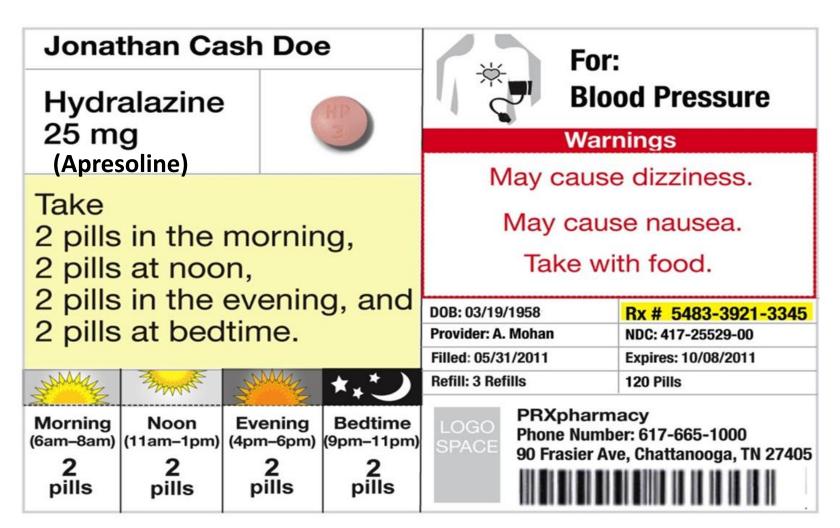
- In 2008, ISMP started a list of drug name pairs and trios with bolded uppercase Tall Man Letters to draw attention to the differences in look-alike drug names.
- The list includes mostly generic-generic drug name pairs, but a few brand-brand or brand-generic name pairs are included.
- An FDA list of drug names with recommended Tall Man Letters was initiated in 2001 with the agency's Name Differentiation Project.

Tall Man Letters

- Simple, straightforward technique that is one strategy to mitigate the risk of errors due to similar drug names.
- The use of Tall Man Letters has been endorsed by:
 - ISMP (Institute for Safe Medication Practices)
 - The Joint Commission (recommended but not required)
 - FDA, as part of its Name Differentiation Project
 - World Health Organization
 - International Medication Safety Network (IMSN)

	Generic Drug Names	Tall Man Letter name
	chlorpropamide	chlorproPAMIDE
	chlorpromazine	chlorproMAZINE
Some drug		
names that	dimenhydrinate	dimenhyDRINATE
are easily	diphenhydramine	diphenhyDRAMINE
confused		
	hydralazine	hydrALAZINE
and their	hydroxyzine	hydrOXYZINE
Tall Man		
Letter (TML)	prednisone	predniSONE
spelling.	predinsolone	predniSOLONE
	sulfadiazine	sulfADIAZINE
	sulfisoxazole	sulfISOXAZOLE

Ideal Prescription Label



Dangerous Abbreviations

Abbreviation	Mistaken for	Recommend
Ng or ng (nanogram)	mg (miligram)	nanogram or nanog
μg (microgram)	Mg (miligram)	mcg
Period after abbreviations (mg., mL., etc)	Period seen as number "1"	Use, mg, mL, without a terminal period.
AZT (zidovudine, Retrovir)	Azithtromicin, azaTHIOprine, aztreonam	Use complete drug name
HCT (hydrocortisone)	hydrochlorothiazide	Use complete drug name
Na before drug name (Na bicarbonate)	No bicarbonate	Use complete drug name
MgSO4 (magnesium sulfate)	MSO4 (morphine sulfate)	Use complete drug name

ISMP 2021

High-Alert Medications

3 Best Practices To Avoid Medication Errors:

• Separate Storage

• Auxiliary Labeling

- Standardize:
 - Prescribing
 - Preparation
 - Administration

High-Alert Medications 2000 Joint Commission List

- The 5 medications are:
 - Insulin
 - Opiates and Narcotics,
 - Injectable concentrated potassium chloride or phosphate
 - Injectable sodium chloride solutions above 0.9%
 - Intravenous anticoagulants like heparin
- The Joint Commission recommends strategies that confirm the correct drug, dosage, patient, time, and route.

Leafy Green Vegetables Mayonnaise Grapefruit Alcohol Meat and Fish Dairy/Calcium Chocolate, pickled, cured, fermented foods Potassium-rich foods St. John's Wort Caffeine Nut-containing Drugs



INTERACTION BETWEEN FOODS and MEDICATIONS

Leafy Green Vegetables



- Spinach, kale, collard greens and broccoli can make medications to prevent blood clots less effective.
- Leafy green veggies are rich in vitamin K, which interacts with the anticoagulant warfarin (Coumadin).
- Vitamin K is used by the body to make some blood-clotting factors, whereas warfarin reduces the action of vitamin K.
- Consistent consumption allows medication to be adjusted accordingly.

Mayonnaise

- Mayonnaise, and certain oils such as canola, soybean and olive oils change how warfarin works in your body.
- People who eat lots of coleslaw have cabbage (which has vitamin K) mixed with mayonnaise.



 Mixing green veggies with mayo results in a vitamin K double whammy.

Grapefruit

- Impacts how digestive enzymes break down and absorb certain medications, producing fluctuating levels of those meds.
- Grapefruit can interact with these drugs or drug classes:
 - Statin drugs to manage cholesterol including <u>Lipitor</u> (atorvastatin), <u>Zocor</u> (simvastatin) and <u>Mevacor</u> (lovastatin).
 - Erectile dysfunction drugs like Viagra (sildenafil).
 - Chemotherapies such as vincristine and docetaxel.
 - Calcium channel blockers to treat high blood pressure.
 - Immune-suppressing drugs like cyclosporine for transplant patients.
 - Allergy medications with *fexofenadine* like <u>Allegra.</u>
- Drinking grapefruit juice in large quantities is more likely to cause systemic side effects than eating a single grapefruit in the morning.

Alcohol

Metronidazole (Flagyl): Avoid any alcohol, even alcohol-containing mouthwashes.

Warfarin (<u>Coumadin</u>): Several beers may raise blood levels of warfarin and cause dangerous anticoagulation.

Insulin and oral Diabetes drugs: Extends their effects and results in hypoglycemia.

Antihistamines Taking sedating drugs like <u>Benadryl</u> increases side effects.

Acetaminophen pain relievers: Avoid alcohol because of possible liver damage.

Antidepressants Improves mood initially, but later acts as a depressant on the CNS.

Meat and Fish

• High-protein foods can compete with the neurotransmitter that's deficient in the brains of people with Parkinson's disease.

 Parkinson's treatment replaces *dopamine* with a medication like <u>Sinemet</u> (*Levodopa*), which converts to *dopamine* in the brain.

Protein-rich food will compete for absorption, and produce lack of control of Parkinson's symptoms.

The medication should be taken on an empty stomach or higher protein amounts saved for the end of the day.

Dairy/ Calcium

- Casein, calcium and magnesium, found in milk and dairy foods can interfere with absorption of drugs in the body.
- Antibiotics are affected by consuming yogurt, milk, or cheese when taking the drug.
- Calcium in dairy can interfere with absorption of meds like thyroid-replacement medications.

Chocolate, Pickled, Cured and Fermented foods

- Aged cheeses, smoked fish, chocolate, beer, wine and some processed meats all contain *tyramine*, which interacts with specific drugs to treat depression.
- Tyramine slows the breakdown of old antidepressants, called monoamine oxidase (MAO) inhibitors, which can lead to a hazardous rise in blood pressure.
- Patients need to learn to avoid foods high in *tyramine*.

Potassium-rich foods

- Avocados, potatoes, white beans, spinach, and bananas, may interact with BP meds causing high potassium levels and abnormal heart rhythms.
- Angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers and potassiumsparing diuretics can also elevate potassium.
- Interactions and special instructions should be on stickers on medication bottles.



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St. John's Wort

- Herbal remedy that can actually reduce the effect of some treatments.
- It causes the liver to release certain enzymes, so if taken in herbal teas or supplements, it can interfere with medications including:
 - *statin* drugs to treat high cholesterol
 - the ED drug <u>Viagra</u>
 - *digoxin* medications for heart conditions

Caffeine

- Large quantities of coffee or energy drinks could exacerbate the effects of drugs that stimulate the central nervous system.
- When caffeine and medications like **Adderall** (*amphetamine/dextroamphetamine*) are combined, they cause a powerful additive effect.
- A person taking Adderall, would likely feel a stronger impact, including greater side effects.

Nut-containing drugs

(can cause allergic reactions)

- Topicals like:
 - Andiroba Oil: an astringent which is rich in omega-3 fatty acids
 - Anti-Itch Poison Ivy Remedy: contain sweet almond oil
 - Boots Cradle Cap Cream: contain almond oil
 - Boots Derma Care Emollient Cream: almond oil
 - Breathe Easy Chest Rub: contain sweet almond oil
- Orals like:
 - Prometrium capsules: contains peanut oil
 - Adbec Multivitamin Drops: contain peanut oil
- Injectables like: Sustanon, contains peanut oil

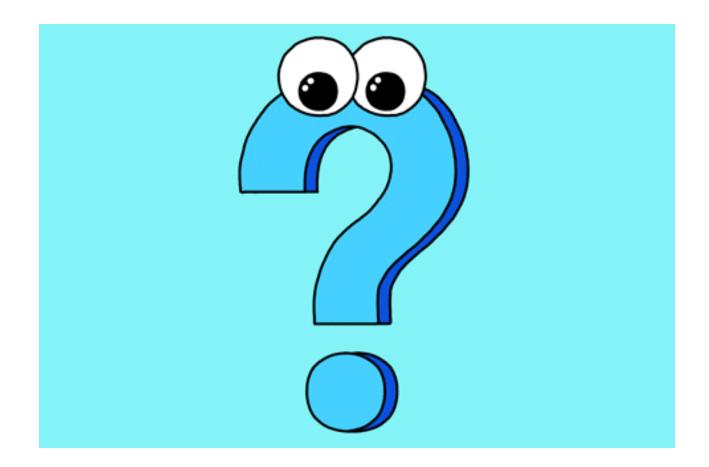
Shellfish and Fish

- Some glucosamine sulfate supplements are made from the shells of crabs, lobster or shrimp.
- Fish oil does not contain protein from shellfish flesh, but may have minute traces of these proteins, and could produce an allergic reaction.
- Experts recommend that people with shellfish allergy should avoid fish oil, and may find vegetable or flax seed oils acceptable.

Food Fortification

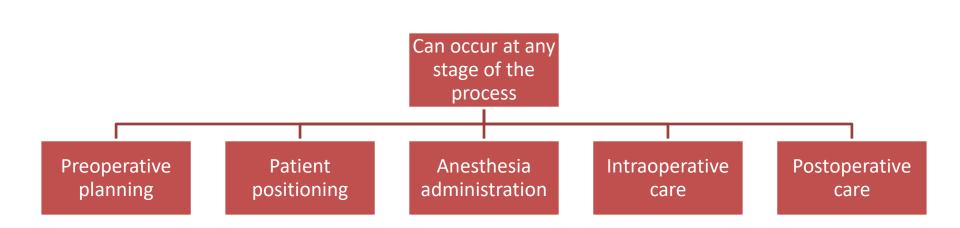
- Some medications interact with vitamins and minerals added to cereal, bread and milk, like calcium, iron, zinc, and magnesium.
- If you are taking an antibiotic like tetracycline, doxycycline or ciprofloxacin and consume calcium-fortified orange juice or a fortified energy bar, cereal or smoothie, the minerals may bind with the drug and inhibit its absorption.
- If a drug's package insert warns not to take the medication with calcium supplements, antacids, iron-containing supplements or dairy products, watch for interaction with fortified foods that contain those nutrients.

Questions? 2



SURGICAL ERRORS

Surgical Errors



Surgical Error

- Unintentional, preventable injury in the perioperative period that is not considered a known acceptable risk of surgery and could have been avoided by following appropriate protocols.
- Type of medical error that includes:
 - retained foreign bodies
 - mislabeled surgical specimens
 - wrong-site/side errors
 - wrong-procedure errors
 WSPEs
 - wrong-patient errors

WSPEs

- Classified as "Never events" and are indicative of serious underlying systemic safety problems.
- Relatively rare: approximately 1 in 112K procedures performed in the OR.
- If other settings like ambulatory surgery or interventional radiology are added, the rate significantly increases.
- VA data showed that ½ of WSPEs occurred out of the OR.

Surgical Error Common Causes

• Miscommunication or lack of communication

• Unnecessary or emergent procedures

• Insufficient training at all levels

• Provider fatigue and burnout

Surgical Errors

Can lead to complications like:

- bleeding
- infection
- tissue and organ damage
- unnecessary additional surgery
- loss of limb
- prolonged hospital stay
- long-term disability
- DEATH

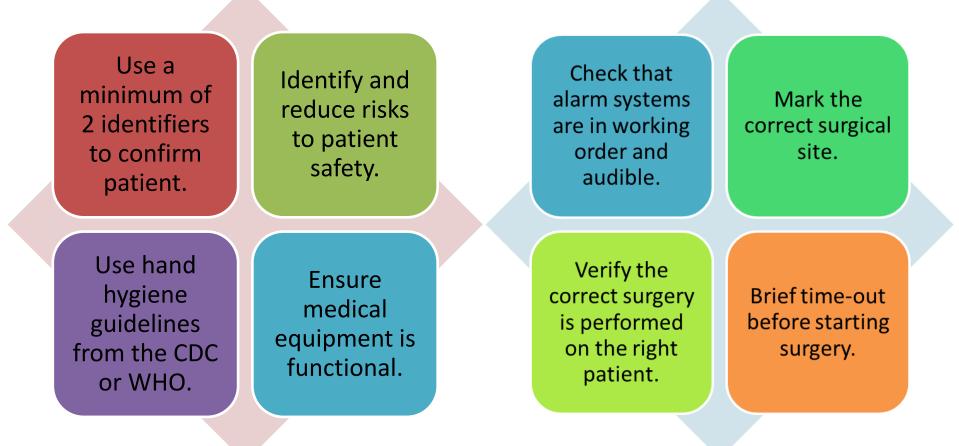
Prevention of Surgical Errors

Measures that enhance patient safety and improve quality of care:

- standardized checklists
- team training
- communication training
- advanced technologies
- ongoing quality improvement initiatives

In 1998, the Joint Commission made an effort to eliminate wrong-site surgery by creating National Patient Safety Goals and a Universal Protocol for Preventing WSPEs.

National Patient Safety Goals to eliminate wrong-site surgery



Universal Protocol

Joint Commision

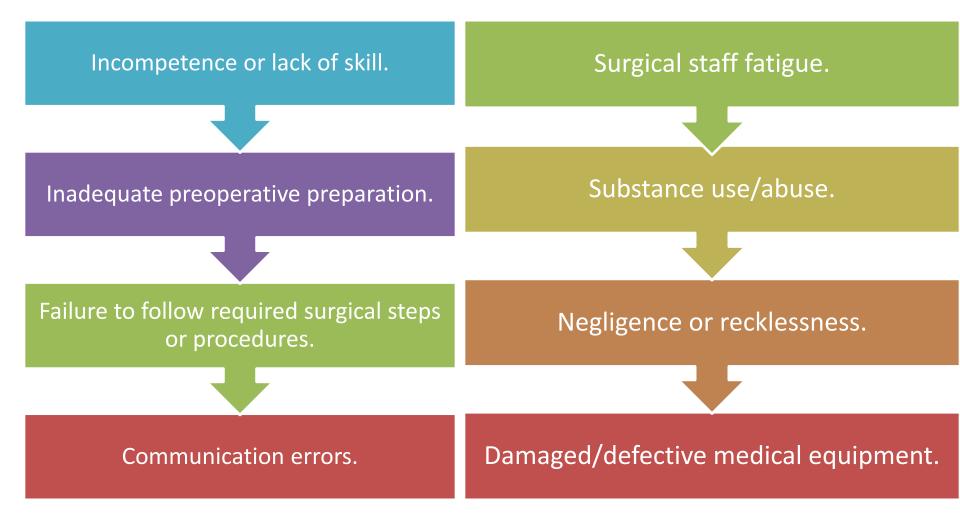
- Guidelines that give the <u>minimum</u> requirements for physicians to help prevent basic surgical mistakes.
- Implementation is <u>required</u> by all accredited hospitals, ambulatory care, and office-based surgical facilities.
- It consists of three key steps:
 - conducting a pre-procedure verification process
 - marking the procedure site
 - performing a time-out

Surgical Site Markings

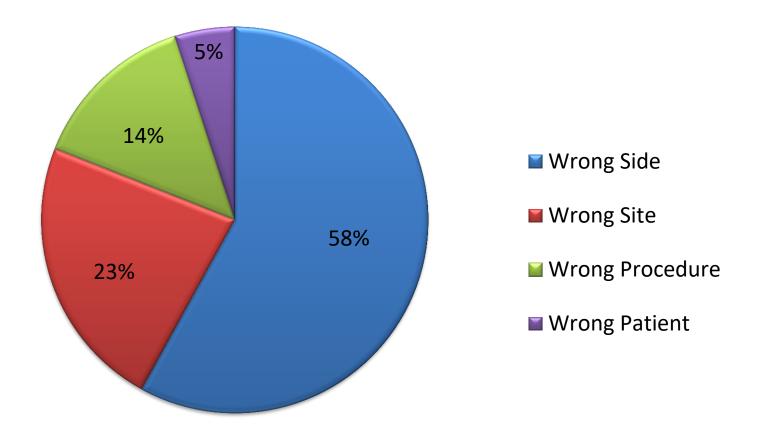




Causes of Surgical Error



Orthopedic Surgery Errors 2019, USA



World Statistics

- Victims of surgical errors:
 - 60% suffered temporary injury
 - 33% had permanent injuries and
 - 7% of cases led to wrongful death

 The annual incidence rate of adverse events among hospitalized patients who received an operation was 3.0%

Unsafe Surgery

- WHO reports that globally, unsafe surgical care procedures cause complications in up to 25% of patients, with high rates of illness, disease and death.
- 7M surgical patients annually suffer significant complications, 1M of whom die during or shortly after surgery.
- Deaths related to complications from surgery have decreased in the past 50 years, but they remain 2 to 3 times higher in low- and middle-income countries than in high-income countries.

US Surgical Errors

- Analysis of US malpractice claims, showed that over 80K "never events" occurred between 1990 and 2010 in US according to a Johns Hopkins study (4K per year).
- The estimate is that 39 times a week, surgeons leave objects (towels, sponges, instruments) inside patients.
- Also, surgeons perform the wrong surgery or operate on the wrong body part around 20 times a week.

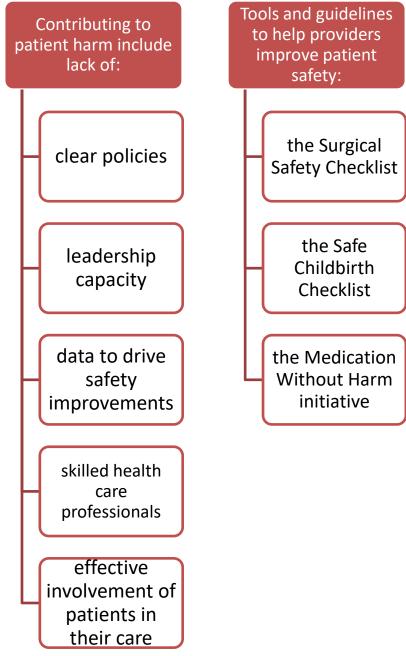
US Surgical Errors

- The study examined data from the National Practitioner Data Bank (NPDB), which analyzes medical malpractice claims.
- Over 20 years they found >9,744 paid claims (cost >\$1.3B) of which:
 - ~7% died
 - ~33% were permanently injured
 - ~60% were temporarily injured

US Surgical Errors

- Adverse surgical events are more frequently related to errors occurring before or after the procedure than by technical surgical mistakes during the operation.
- These include:
 - breakdown in communication within and amongst the surgical team, care providers, patients, and their families
 - delay in diagnosis or failure to diagnose
 - delay in treatment or failure to treat

WHO AND PATIENT SAFETY



WHO and Patient Safety

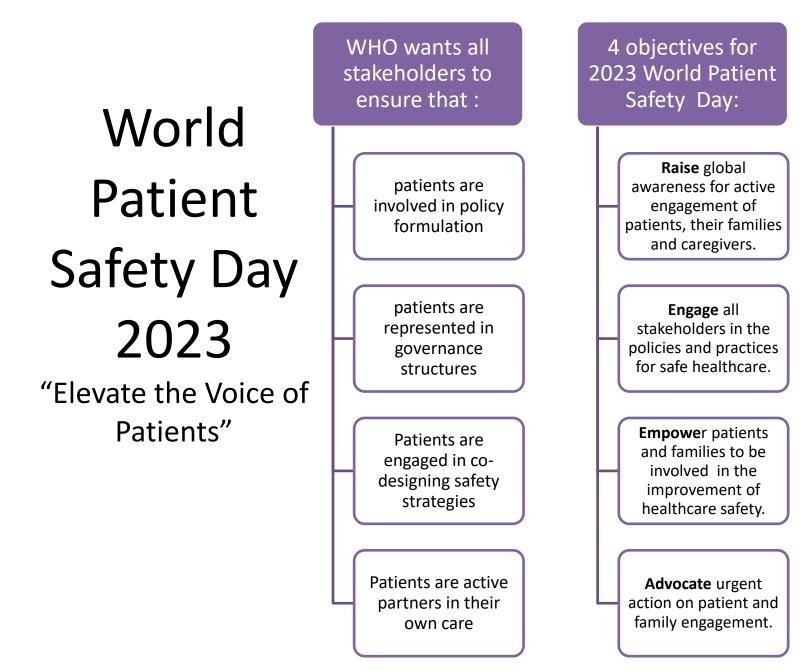
WHO and Patient Safety

- Patient and family engagement is one of the 7 strategic objectives of the Global Patient Safety Action Plan 2021-2030.
- "Patients, families and caregivers can serve as vigilant observers of a patient's condition and can alert health care professionals when needs arise."
- "Given proper information, the patient and family can help to be the eyes and ears of the system."

World Patient Safety Day

 WHO World Patient Safety Day occurred on September 17th, 2023.

 WHO data indicate that unsafe surgical care can cause complications in up to 25% of patients, resulting in 1M deaths annually, during or immediately after surgery.



Radiation Errors

- Worldwide, every year there are:
 - >3.6 B x-ray examinations
 - ~10% of them occur in children
 - 37 M nuclear medicine procedures
 - 7.5 million radiotherapy procedures
- A review of 30 years of published data estimates that the overall incidence of errors in overexposure to radiation and wrong-patient or wrong-site applications is around 15 per 10K treatment courses.
- Inappropriate or unskilled use of medical radiation can lead to health hazards, both for patients and staff.

Final Questions ?



Session 4: Communication Errors

September 28, 2023

- Communication Errors
- Barriers to communication
- Language issues
- Communication tools
- Low Literacy
- Health Literacy

