Introduction to Hazardous Drugs

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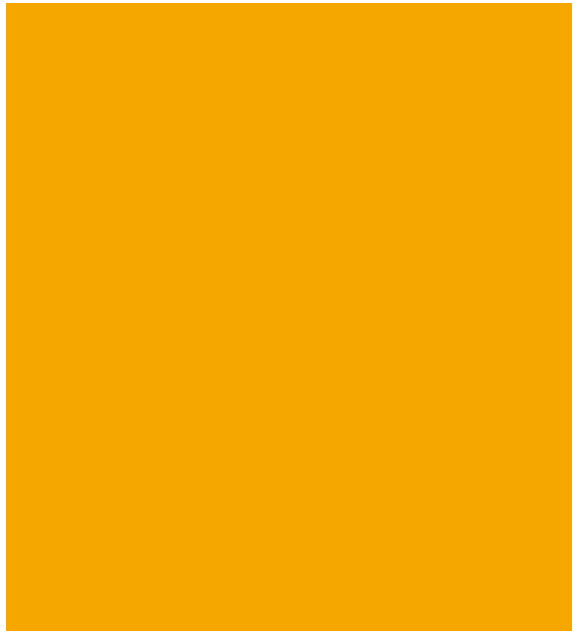
Objectives

1. Understand the definition of a hazardous drug and how to identify whether a medication is considered hazardous.
2. Understand the correct personal protective equipment (PPE) to wear for each type of hazardous drug handling activity.

Background on Hazardous Drugs



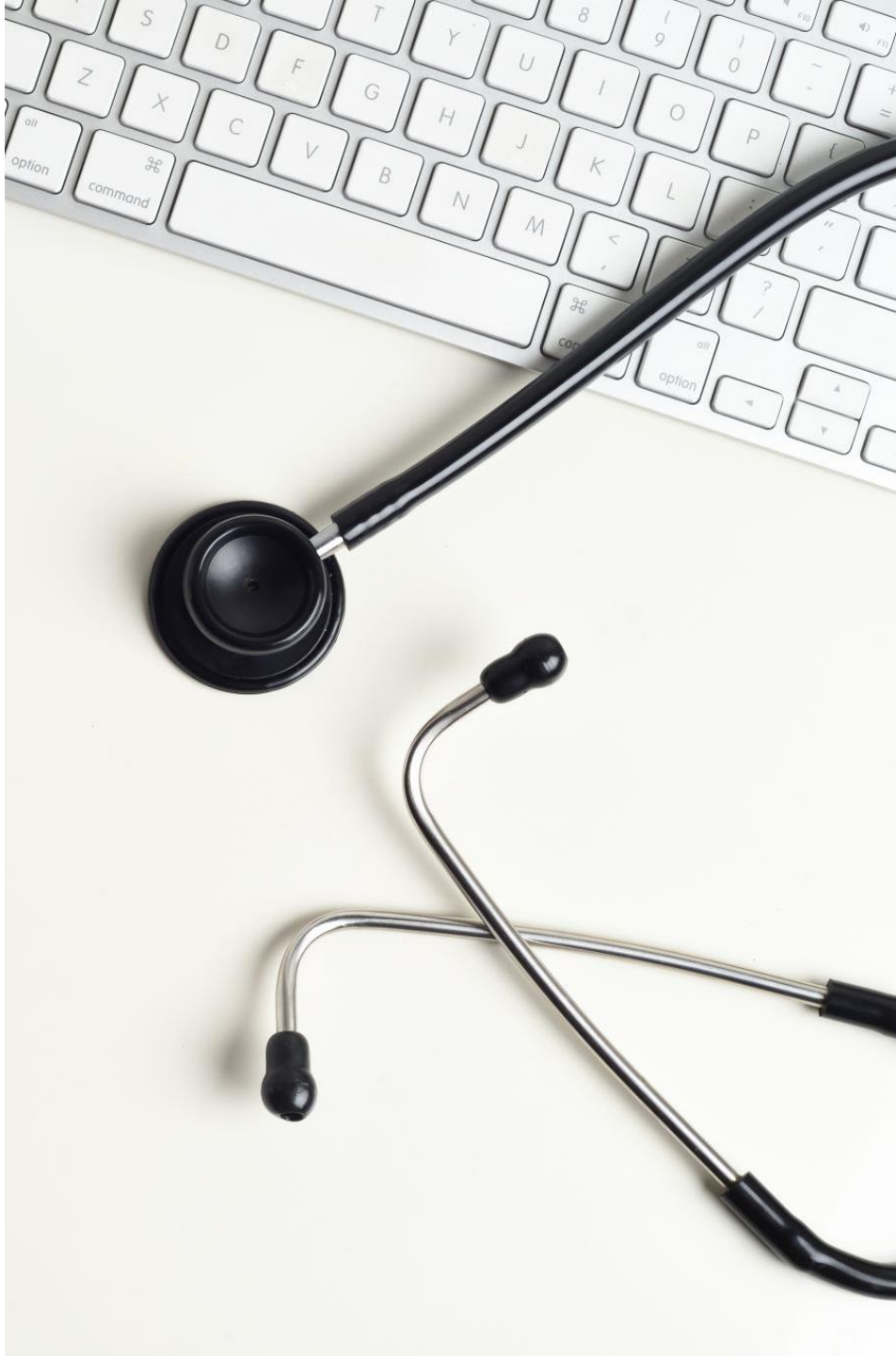
Background – Hazardous Drugs

CHEMOTHERAPY + **MANY COMMON MEDICATIONS!** = **HAZARDOUS DRUGS**

(NIOSH, 2016)

Background – Hazardous Drugs

- Many hazardous drugs are given for non-oncology reasons
- Hazardous drugs are found in all healthcare settings
  - Med/Surg units
  - Critical Care units
  - Emergency depts
  - Clinics
  - Not just oncology areas



Background – Hazardous Drugs

The National Institute for Occupational Safety and Health (NIOSH)

- Issued a safety alert about the dangers of hazardous drugs in 2004
- Publishes a hazardous drug list and best practices for hazardous drug safety
- Most recent list published in 2016 greatly expanded the list of drugs that are hazardous

(NIOSH, 2016)

Image: (CDC, 2014)

Background – Hazardous Drugs

WA State Hazardous Drugs Law WAC 296-62-500

- Requires healthcare facilities to have a hazardous drug control program that includes:
  - Written hazardous drug list or inventory
  - Current workplace hazard assessment for hazardous drugs
  - Hazardous drug policies and procedures
- Applies to all workers in healthcare facilities

(Safety+Health, 2011; WAC 296-62-500, 2014; WHCA, n.d.)

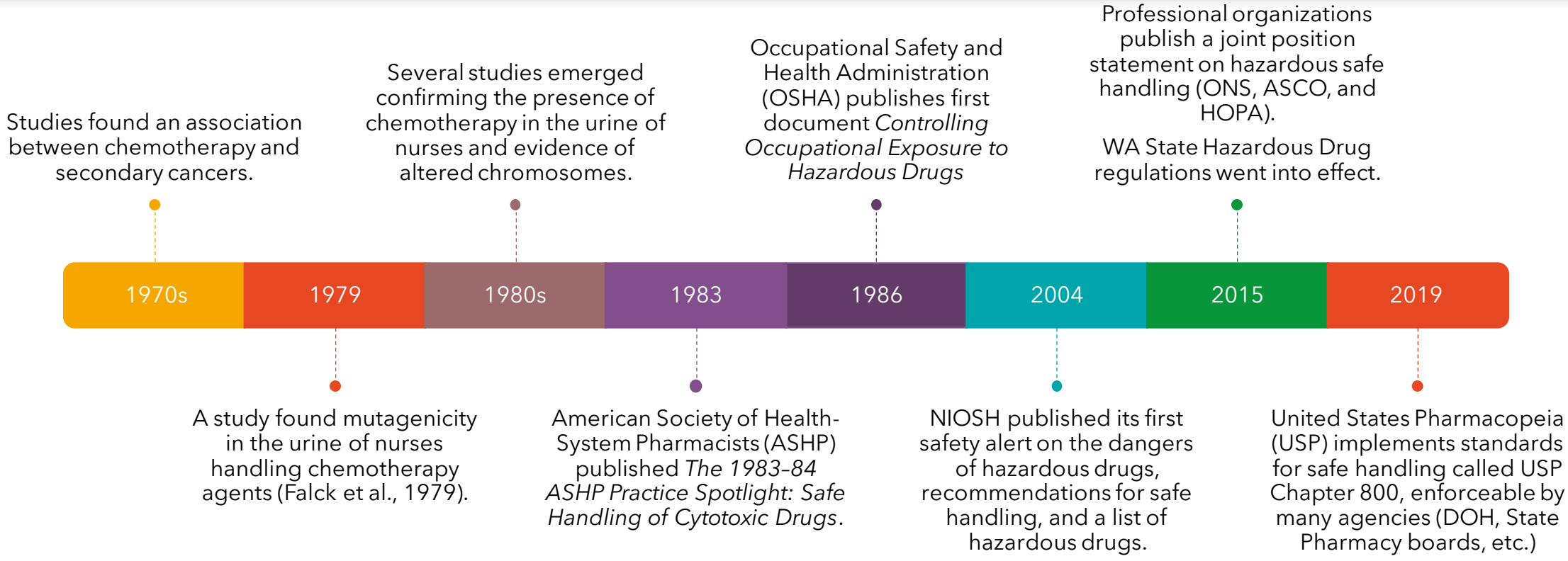
WAC 296-62-500

Policies & Procedures Required

- Engineering controls
- Personal Protective Equipment (PPE)
- Safe handling practices
- Cleaning and waste handling
- Spill plan
- Personnel issues (e.g. pregnant workers)
- Training

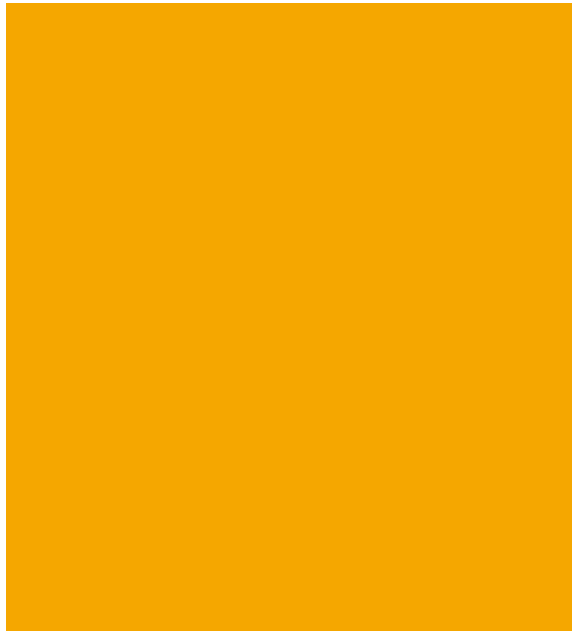
(WAC 296-62-500, 2014; WHCA, n.d.)

Timeline – History of Hazardous Drugs



(Durland & Ahmadian-Moghadam, 2022; Ensslin et al., 1994; Evans & Mcilvena, 2022; Falck et al., 1979; NIOSH, 2023; Sessink & Bos, 1999; USP, 2017)

Exposure Risks & Routes of Exposure



Exposure Risks

Acute Effects

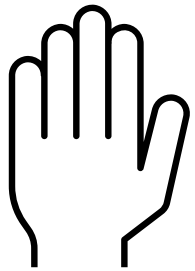
- Headaches
- Nausea
- Skin rashes
- Hair loss
- Allergic type reactions
- Hearing loss

Long-term Effects

- Reproductive problems
  - Infertility
  - Miscarriage
  - Birth defects
- Cancer
- Organ damage (cardiac, kidney, etc.)

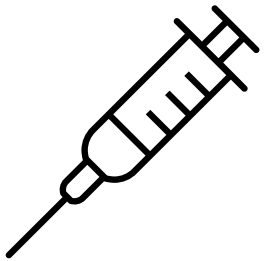
(Alehashem & Baniasadi, 2018; Elshaer, 2017; Nassan et al., 2021; NIOSH, 2019; Roussel et al., 2019).

Exposure Routes



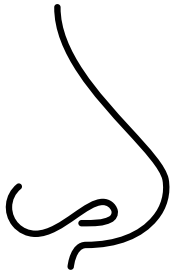
Absorption

Direct Contact



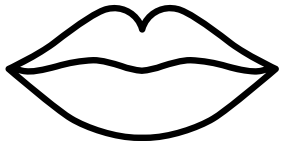
Injection

Needlestick



Inhalation

Breathing Drug Vapors

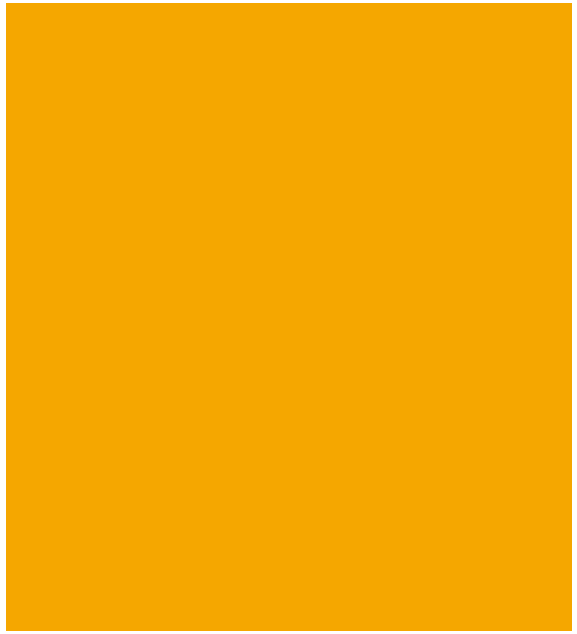


Ingestion

Contaminated Surfaces

(NIOSH, 2023; OSHA, 2016)

Definitions & Characteristics



Hazardous Drug Definitions & Characteristics

- A drug is considered hazardous if it demonstrates one or more of these characteristics:

Characteristic	Description
Carcinogenicity	Causes cancer
Teratogenicity	Causes birth defects or developmental toxicity
Reproductive toxicity	Impairs fertility, harmful to fetuses
Organ toxicity at low doses	Damages organs
Genotoxicity	Causes DNA or chromosomal damage

- Some hazardous drugs only have one of these traits while others have several of these traits

(NIOSH, 2016)

Categories of Hazardous Drugs

Table 1

Antineoplastic (anti-cancer)

- Meets one or more of the NIOSH criteria for a hazardous drug
- Cytotoxic – damages cells
- Hazardous to males or females trying to conceive, pregnant, or breast feeding.

Table 2

Non-Antineoplastic

- Meets one or more of the NIOSH criteria for a hazardous drug
- Non-cytotoxic
- Hazardous to males or females trying to conceive, pregnant, or breast feeding.

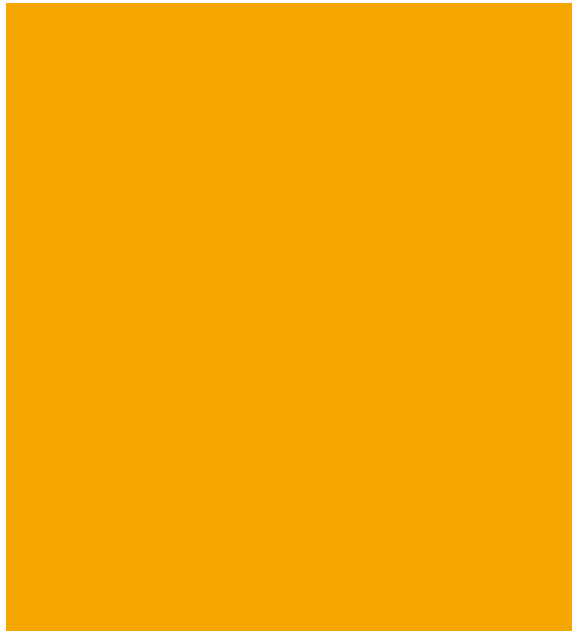
Table 3

Reproductive Hazard

- Reproductive toxicity only
- Potential occupational hazard to males or females trying to conceive, pregnant or breast feeding.

(NIOSH, 2016)

Pharmacology of Common Hazardous Drugs



Pharmacology – Table 1 Hazardous Drugs

Antineoplastic agents, cytotoxic, used to treat cancer, many different drug classifications

Alkylating Agent

- Cyclophosphamide (PO, IV)
- Indications: Many cancers (breast, ovarian, leukemias, lymphomas, multiple myeloma, etc.)
- MOA: Breaks DNA helix strand, preventing replication; cell cycle phase nonspecific. Prodrug that must be metabolized to active metabolites in liver.
- Carcinogen, fetal harm

Antimetabolite

- Methotrexate (IM, IV, IT, PO)
- Indications: Many cancers (breast, head & neck, leukemias, lymphomas, osteosarcoma, etc.)
- Non-oncology: rheumatoid arthritis, ectopic pregnancy
- MOA: Folate antimetabolite incorporates into DNA chain, inhibiting DNA synthesis, repair, and replication.
- Possibly carcinogenic, fetal harm

Miscellaneous

- Goserelin (Zoladex) (SC)
- Indications: breast cancer, endometriosis, prostate cancer
- Non-oncology: hormone therapy for transgender females
- MOA: Gonadotropin-releasing hormone agonist; suppresses pituitary gonadotropins leading to suppression of testosterone in males and decreases estradiol in females
- Fetal harm

(IARC, 2023; Micromedex, 2024; NIOSH, 2016; Polovich et al., 2014)

Pharmacology – Table 2 Hazardous Drugs

Non-antineoplastic agents, non-cytotoxic, many different drug classifications

Hormone

- Medroxyprogesterone acetate (Depo-Provera) (PO, SC, IM)
- Indications: contraception, abnormal uterine bleeding, endometriosis
- Mechanism of Action: inhibits pituitary gonadotropins, preventing follicular maturation and causes endometrial thinning
- Possibly carcinogenic, fetal harm

Immunosuppressant

- Tacrolimus (PO, IV, topical)
- Indications: organ rejection prophylaxis in solid organ transplant, prevention of graft-vs-host disease in BMT
- Mechanism of Action: binds to protein FKBP-12 and calcineurin dependent proteins, inhibiting calcineurin phosphatase activity thereby inhibiting T-lymphocyte activation
- Secondary cancers, fetal harm

Anticonvulsant

- Phenytoin (PO, IV)
- Indications: seizures, status epilepticus, refractory trigeminal neuralgia
- Mechanism of Action: decreases seizure activity by increasing efflux of Na ions from neurons in motor cortex during nerve impulse generation, stabilizing neuronal membranes
- Possibly carcinogenic

(IARC, 2023; Micromedex, 2024; NIOSH, 2016)

Pharmacology – Table 3 Hazardous Drugs

Drugs with reproductive toxicity only, many different drug classifications

5-alpha-reductase Inhibitor

- Finasteride (PO)
- Indications: BPH, androgenetic alopecia
- Mechanism of Action: inhibits an isoenzyme that metabolizes testosterone to dihydrotestosterone (DHT) in prostate, liver, skin, (DHT responsible for prostate growth & alopecia)
- Risk to male fetus

Antifungal

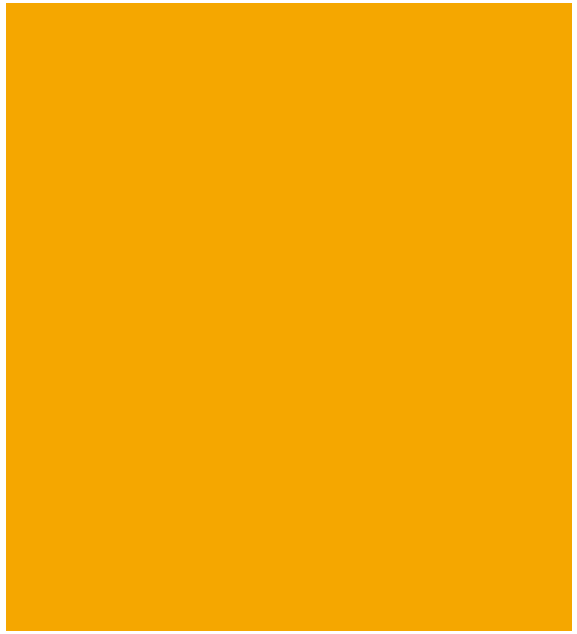
- Fluconazole (PO, IV)
- Indications: treatment of candidiasis (local or systemic), antifungal prevention in BMT patients
- Mechanism of Action: Interferes with fungal cytochrome P450 activity, decreasing ergosterol synthesis and inhibiting fungal cell membrane formation
- Congenital abnormalities

Anticoagulant

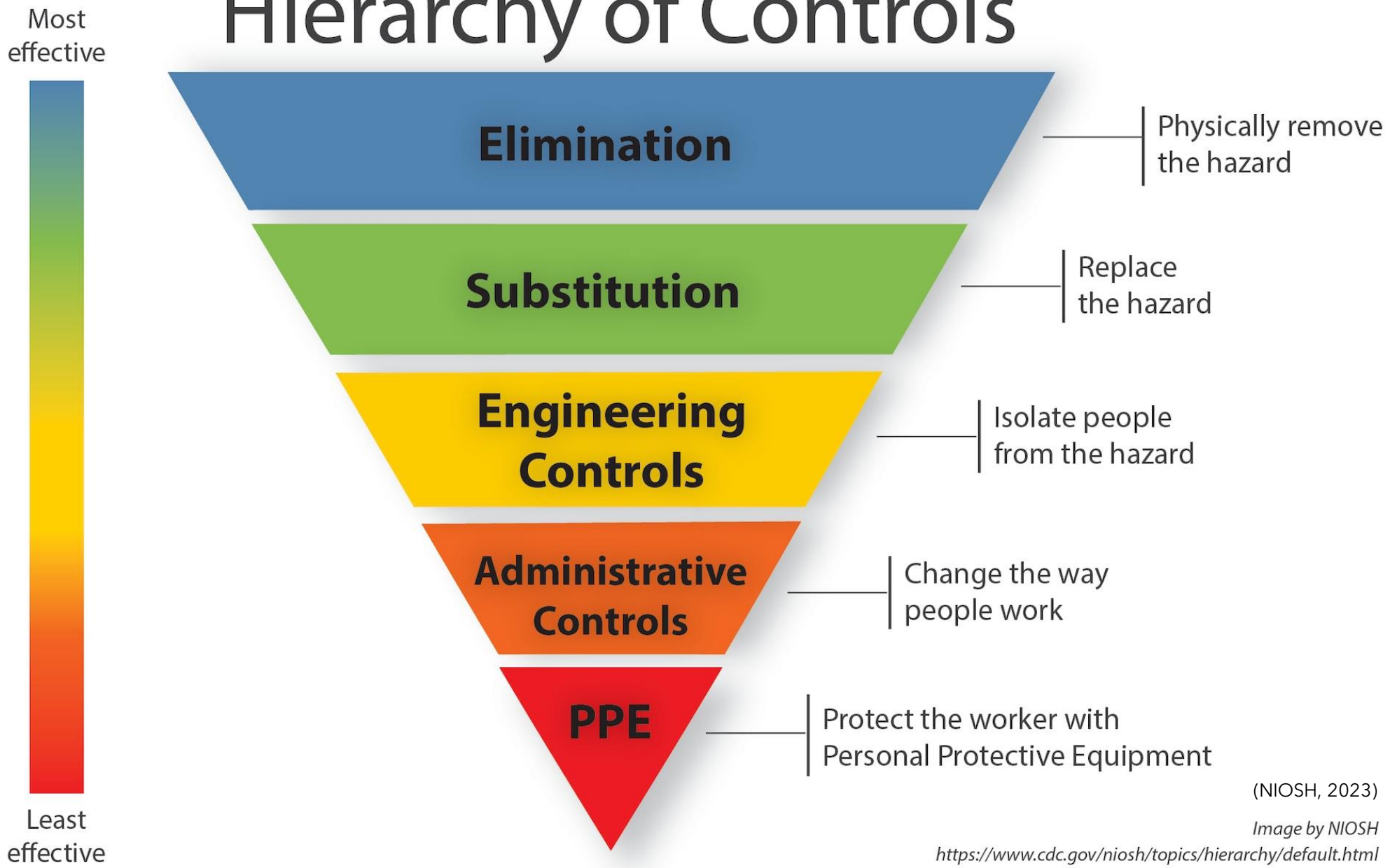
- Warfarin (PO)
- Indications: treatment of thromboembolic disorders or prevention of embolic complications
- Mechanism of Action: blocks the regeneration of vitamin K(1) epoxide, inhibiting synthesis of vitamin K-dependent clotting factors
- Fetal abnormalities

(Micromedex, 2024; NIOSH, 2016)

Safe Handling of Hazardous Drugs



Hierarchy of Controls



(NIOSH, 2023)

Image by NIOSH
https://www.cdc.gov/niosh/topics/hierarchy/default.html

Personal Protective Equipment (PPE)

- PPE should be worn when:
  - Preparing
  - Handling
  - Administering
  - Disposing
  - Handling bodily fluids contaminated with hazardous drugs
  - Cleaning spills (drug & body fluid spills)

(NIOSH, 2023)

Gloves

- Disposable
- Powder-free
- Tested for use with chemotherapy
- Meet ASTM D6978 standards
- Change every 30 minutes or immediately if damaged or contaminated

(NIOSH, 2023; Oncology Nursing Society, n.d.; OSHA, 2016; Polovich & Olsen, 2018)

Image: (Medline, 2024)

Gowns

- Disposable, single use only
- Polyethylene-coated, polypropylene or other laminate, lint-free material
- Low-permeability
- Solid front, long sleeves, tight cuffs, with back closure
- No seams on the front that could allow hazardous drug to pass through

(NIOSH, 2023; Oncology Nursing Society, n.d.; OSHA, 2016; Polovich & Olsen, 2018)

Face/Eye Protection

- Face shield
  - To protect against splashing
- Goggles
  - When working above eye-level
  - Spill clean up (unless you are wearing a full PAPR hood)

(NIOSH, 2023; Oncology Nursing Society, n.d.; OSHA, 2016; Polovich & Olsen, 2018)

Respiratory Protection

- Risk of inhalation exposure to hazardous drugs from aerosols or vapors
- Cleaning hazardous drug spills or hazardous drug contaminated bodily fluid spills
- Crushing, mixing, or manipulating hazardous drug tablets/capsules outside a containment device
- PAPR offers the best protection or use a fit-tested N-95
- Surgical masks provide no respiratory protection from hazardous drugs

(NIOSH, 2023; Oncology Nursing Society, n.d.; OSHA, 2016; Polovich & Olsen, 2018)

Basics of Administration

Intact pill/capsule

PPE: Single pair of chemotherapy-tested gloves

Injection (SC or IM)

PPE: Double pair of chemotherapy-tested gloves, chemo gown, face-shield*

* if splash potential

Intravenous (IV)

PPE: Double pair of chemotherapy-tested gloves, chemo gown, face-shield*

* if splash potential

(NIOSH, 2023; Polovich & Olsen, 2018)

Handling Body Fluids

- Hazardous Drug Handling Precautions
  - Period when all body fluids of patients receiving hazardous drugs must be handled wearing PPE
  - Minimum of 48 hours after last dose
  - Longer period for some drugs
- PPE required: Double pair of chemotherapy tested gloves, chemo gown, and face-shield*

  * if splash potential

(NIOSH, 2023; Polovich & Olsen, 2018)

Basics of Disposal

Trace Chemotherapy Waste

- Used PPE
- Empty hazardous drug containers

Hazardous Drug Sharps

- Empty syringes & needles

Pharmaceutical Waste

- Bulk drugs (full, partially full medication containers)
- Spill clean-up items

Summary

- Hazardous drugs: Any drug that demonstrates carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity or genotoxicity
- NIOSH publishes a hazardous drug list and safe handling guidelines
- PPE must be worn during hazardous drug preparation, handling, administration, disposal, spill clean-up and when handling body fluids from patient receiving hazardous drugs

(NIOSH, 2016)

Hazardous Drug Resources

- *NIOSH Hazardous Drug Exposures in Healthcare*
  - https://www.cdc.gov/niosh/topics/hazdrug/default.html
- *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016*
  - https://www.cdc.gov/niosh/docs/2016-161/default.html
- *Managing Hazardous Drug Exposures: Information for Healthcare Settings*
  - https://www.cdc.gov/niosh/docs/2023-130/2023-130.pdf?id=10.26616/NIOSHPUB2023130
- Micromedex or UpToDate for drug specific information

Thank you!

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Questions?