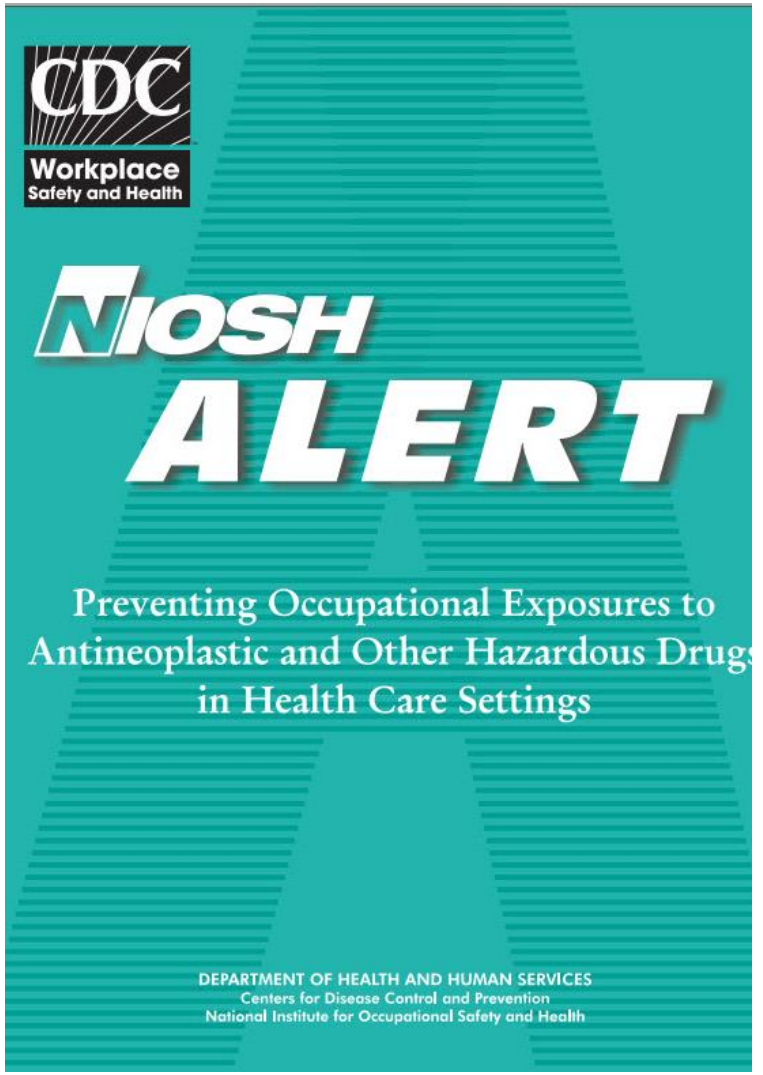
HAZARDOUS DRUG SAFETY:

HOW EUROPE CAN BENEFIT FROM LESSONS LEARNED IN THE U.S.

Seth Eisenberg RN OCN BMTCN

March 2025


CDC
Workplace
Safety and Health
NIOSH
ALERT
Preventing Occupational Exposures to
Antineoplastic and Other Hazardous Drugs
in Health Care Settings
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

HAZARDOUS DRUG DEFINITION

Defined by the **National Institute for Occupational Safety and Health** (NIOSH) as having any of the following:

- Carcinogenicity.
- Genotoxicity.
- Teratogenicity.
- Reproductive toxicity.
- Organ toxicity at low doses.
- Structure and toxicity that mimics existing hazardous drugs.

NIOSH, 2016

CONSEQUENCES OF EXPOSURE

- Lightheadedness
- Headache
- Dizziness
- Hair Loss
- Abdominal pain
- Nausea and vomiting
- Skin or mucous membrane reactions
- Nasal sores
- Contact dermatitis and eczema

- Menstrual cycle changes
- Infertility
- Spontaneous abortions
- Premature labor
- Congenital abnormalities
- Low-birth weight infants
- Learning disabilities in offspring of women who were exposed

Many chemotherapy drugs are also known or suspected carcinogens.

Hemminki, K. 1985; Stucker, I. 1990; Shortridge, L. 1995; Valanis, B. 1997; Fransman, W. 2007; Valanis, B. 1999; Martin, S. 2005; Ratner, P. 2010

MANY HDs ARE CARCINOGENIC

Known Carcinogens

- Arsenic Trioxide
- Busulfan
- Chlorambucil
- Cyclophosphamide
- Melphalan
- Thiotepa

Suspected Carcinogens

- Azacitidine
- Carmustine (BCNU)
- Cisplatin
- Doxorubicin
- Etoposide
- **Ganciclovir**
- Mitomycin
- Nitrogen mustard
- Procarbazine

Cancers

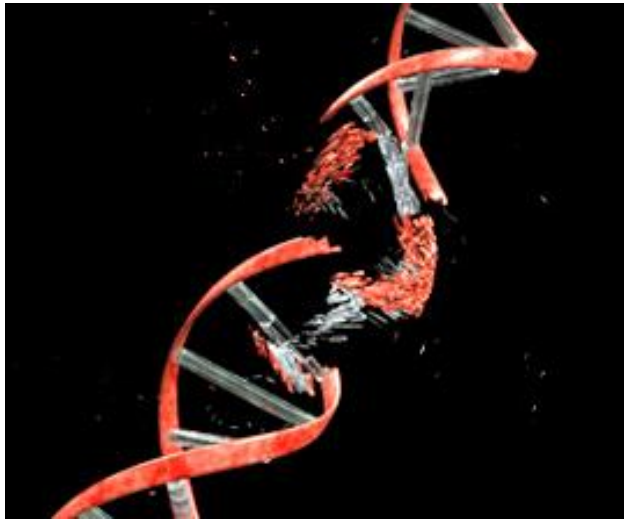
- Leukemia
- Lymphoma
- Breast Cancer
- Colorectal Cancer

Ratner, P. (2010); Skov, T. (1992); IARC Website: http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php

CHROMOSOMAL DAMAGE

- Most HDs alter DNA by damaging chromosomes, rendering them unable to reproduce.

- **Meta review of 17 studies demonstrated a significant association between hazardous drug exposure and increased chromosomal abnormalities (P < .001).**



Roussel, C. 2019 *Mutation Research -- Reviews in Mutation Research, 781.*

CHROMOSOMAL DAMAGE

> Am J Ind Med. 1999 Jul;36(1):159-65.
doi: 10.1002/(sici)1097-0274(199907)36:1<159::aid-ajim23>3.0.co;2-k.

Cancer mortality among women employed in health care occupations in 24 U.S. states, 1984–1993

S A Petralia [1], M Dosemeci, E E Adams, S H Zahm

Affiliations + expand

PMID: 10361602 DOI: 10.1002/(sici)1097-0274(199907)36:1<159::aid-ajim23>3.0.co;2-k

FULL TEXT LINKS

WILEY Full Text Article

ACTIONS

Cite

Collections

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- **Exposed female nurses had a 30% increase in mortality from leukemia and liver cancer, and an increased incidence of ovarian and breast cancer.**

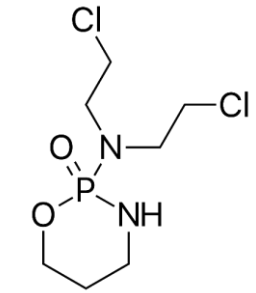
S.A. Petralia, M. et al. 1999

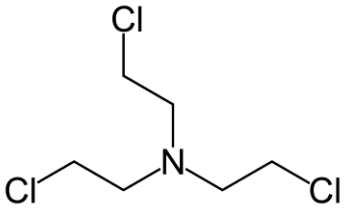
BRIEF GENEOLOGY OF CHEMOTHERAPY

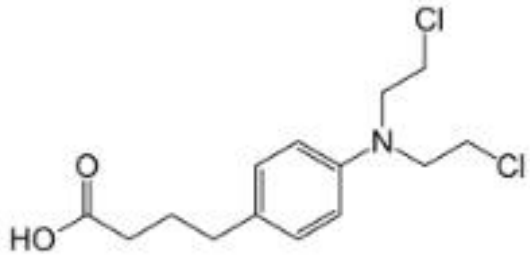
Cyclophosphamide (born 1958), son of…

Nitrogen mustard (born 1949), son of…

Mustard gas (born July 12, 1917)







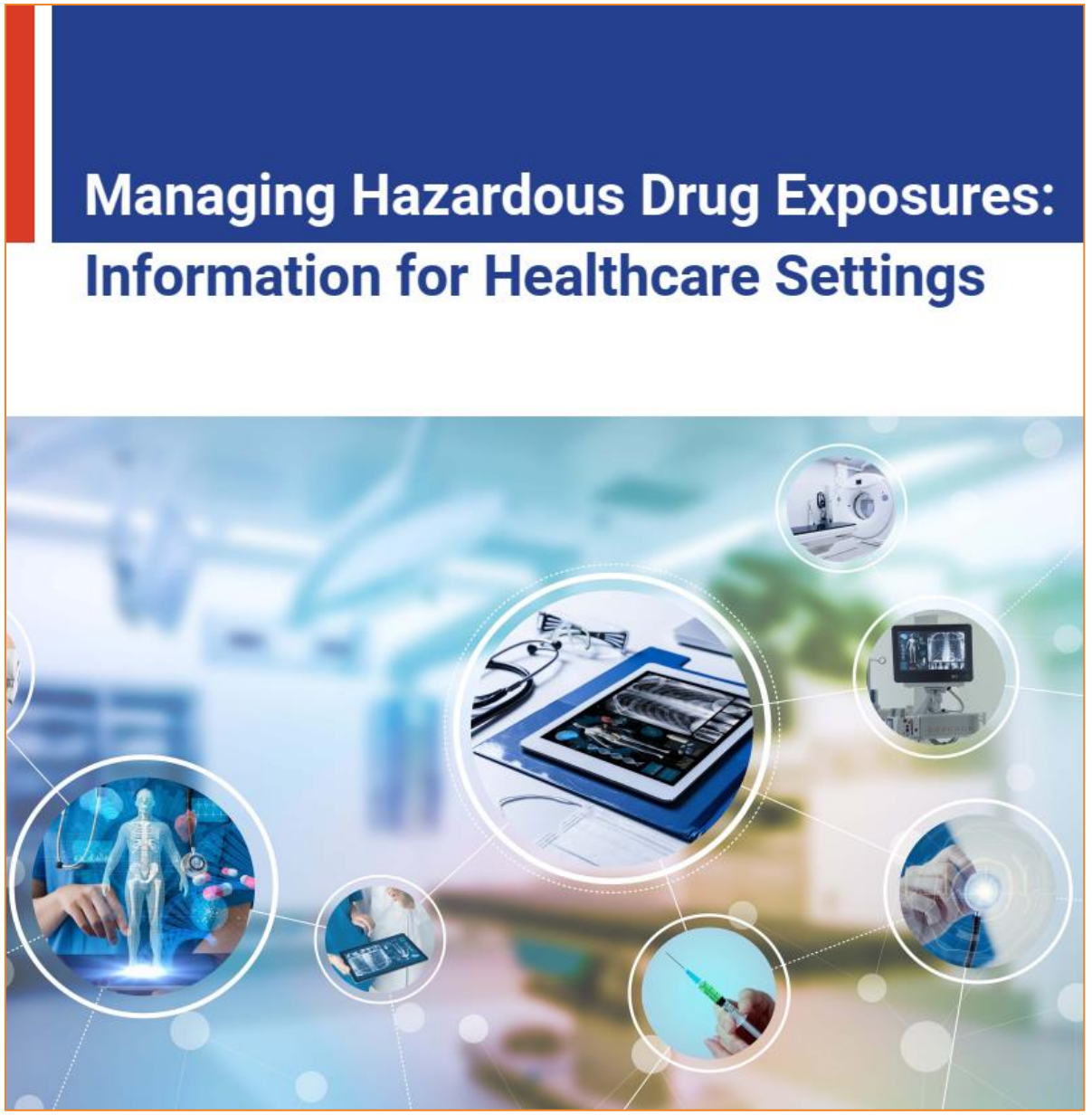
https://www.sciencehistory.org/distillations/magazine/a-brief-history-of-chemical-war

ABSORPTION OF HAZARDOUS DRUGS

- Dermatologic contact is the **primary** source of absorption.
- Inhalation of aerosols can occur under specific circumstances (e.g., compounding vials under pressure).

NIOSH RISK VARIABLES

- Specific drug toxicity (reproductive, cytotoxic, carcinogenic).
- Drug formulation (tablets, capsules, powders, liquids, etc.).
- Exposure route (ingestion, dermal absorption, inhalation).
- Workplace activity (compounding, administering, spill management).



Adapted from: NIOSH 2023, By Hodson, L et al. Managing hazardous drug exposures: information for healthcare settings.

QUESTION:

Would you consider handling these drugs differently if they were labelled like this?

THESE DANGERS ARE NOT NEW

- 1978: First identification that exposure to chemotherapy can lead to secondary malignancies.
- 1979: Positive urine mutagenicity (Ames Test) in nurses and pharmacists handling chemotherapy.

Donner, 1978; Falck et al, 1979

TIMELINE OF GUIDELINES AND STANDARDS IN THE U.S.

1979: Positive urine mutagenicity (Ames Test) in nurses and pharmacists handling chemotherapy.

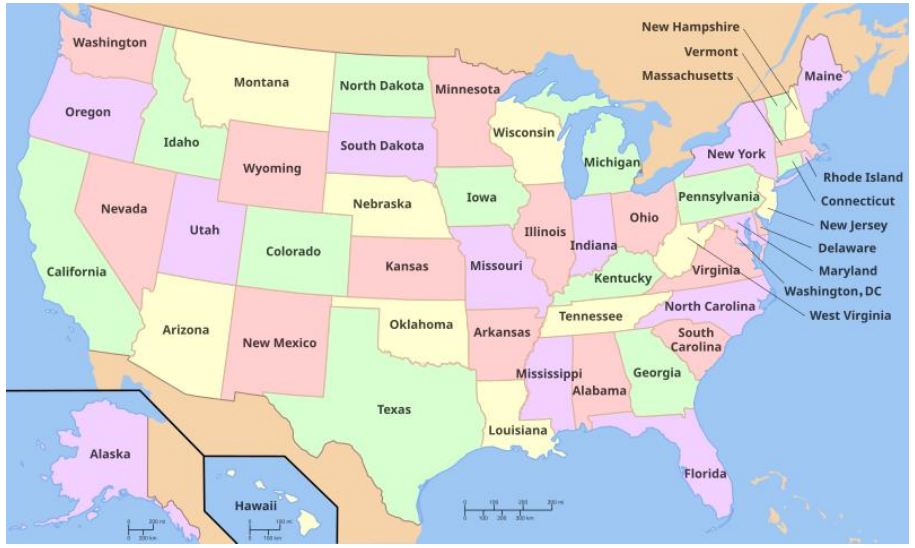
1981	1983	1984	1985	1986	2004	2023
ASHP (Harrison)	ASHP (Stolar, Power & Viele)	ONS (Polovich)	ASHP TAB (Power)	OSHA (Yodaiken)	NIOSH	USP <800>‡

ASHP: American Society of Health-System Pharmacists; ONS: Oncology Nursing Society; OSHA: Occupational Safety and Health Administration; NIOSH: National Institute for Occupational Safety and Health; USP: United States Pharmacopeia

U.S. AND EUROPE PRACTICES: SAME AND DIFFERENT

In the U.S.:

- Compounding or spiking HDs at the bedside is prohibited.
- Monoclonal antibodies are often handled differently than HDs.*
- Nurses are dependent upon the pharmacy for compounded medications.



*** Depends on organization and specific drug.**

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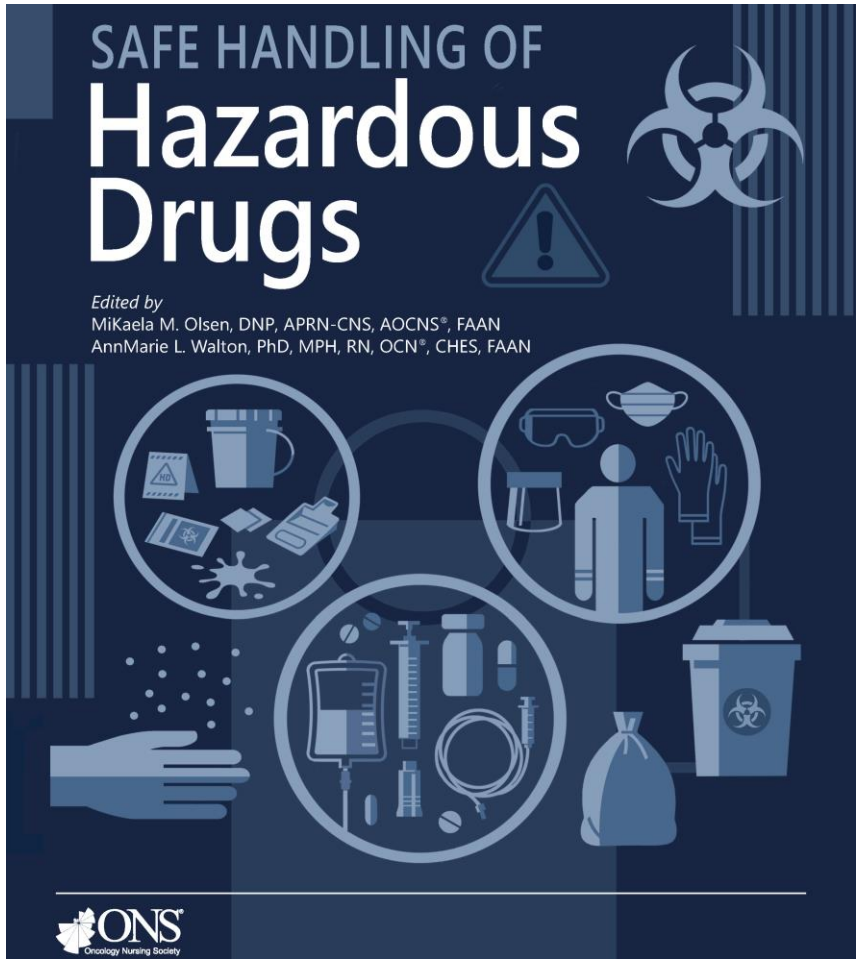
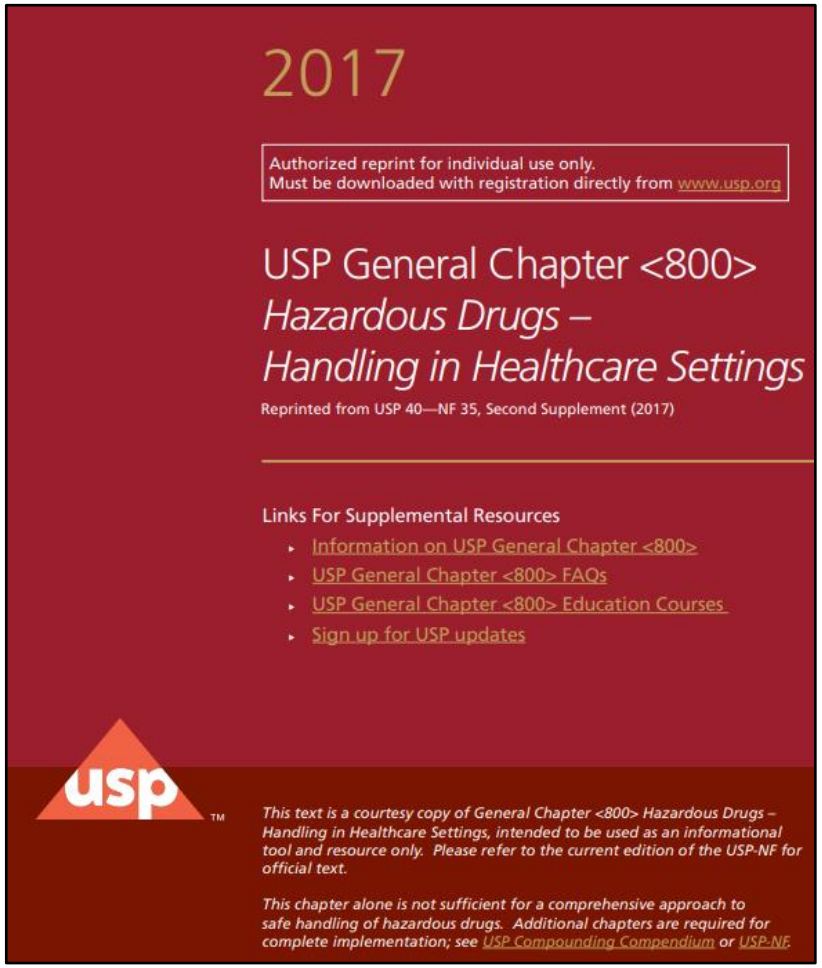
PROFESSIONAL ORGANIZATIONS

- American Society of Health-System Pharmacists (ASHP)
- Oncology Nursing Society (ONS)
- Infusion Nursing Society (INS)



UNITED STATES PHARMACOPEIA (USP)

- Mission of USP is to improve global health and ensure quality and safety of medications.
- Published chapters with numbers less than <1000> are **standards**:
  - <795> non-sterile compounding
  - <797> sterile compounding
  - <800> hazardous drugs (2016)
  - Original implementation date of 2019 but delayed until 2023.



https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare

USP <800> HIGHLIGHTS

- Utilizes evidence from **studies, scientific information, guidelines**, and experts to define standards from compounding to administration and disposal.
- Defines requirements for the type and use of Personal Protective Equipment (PPE).
- Requires all employees to have access to the organization's HD list.

https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare

USP <800> HIGHLIGHTS

- Provides expectations for staff education.
  - On hire and PRIOR to any handling activities
  - Annually (must be documented)
- Requires an **acknowledgement of risk** for all staff who may be potentially exposed to HDs.
- Requires the use of Closed System Transfer Devices (CSTDs) for HD administration.

https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare

USP <800> ENFORCEMENT

- State Board of Pharmacy
- A designated state agency (e.g., Department of Health)
- The Federal Drug Administration (FDA)
- Medicare (CMS)
- The Joint Commission Hospital Accreditation (TJC)

Eisenberg, S. USP <800> and Strategies to Promote Hazardous Drug Safety. Journal of Infusion Nursing, 2018, 41(1); Kienle P. Prepare for Compliance: The USP Chapter <800> Answer Book. 2017;14(10):18-21; Eisenberg, S. A Call to Action for Hazardous Drug Safety: Where we have been and where we are now, Clinical Journal of Oncology Nursing, 2016 20(4).

HOW EXPOSURE OCCURS

IT STARTS IN THE PHARMACY

Eisenberg S. Tips for Supporting Nursing's Use of CSTDs. Supplement to Pharm Purch Prod. 2020;17(10):1.; Eisenberg, S. & Klein, C. Safe Handling of Hazardous Drugs in Home Infusion. 2021, Journal of Infusion Nursing, 44(3).

COMPOUNDING WITH NEEDLES

- Puncturing a vial releases drug into the primary engineering control (PEC) and in the cleanroom.

Connor, T.2005; Power, L. 2014; Redic, K. et al, 2016; Fleury-Souverain, S. et al, 2014; Eisenberg, S. 2018

IT STARTS IN THE PHARMACY

- Compounding with a needle results in aerosolization and droplet contamination.
- IV bags or tubing can become contaminated on the outside which can then contaminate the patient care areas.

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Connor, T.2005; Power, L. 2014; Redic, K. et al, 2016; Fleury-Souverain, S. et al, 2014; Eisenberg, S. 2018

SIZE MATTERS

- Large bore needles tend to drip.

Connor, T.2005; Power, L. & Coyne,J. 2018; Redic, K. et al, 2016; Fleury-Souverain, S. et al, 2014; Eisenberg, S. 2018

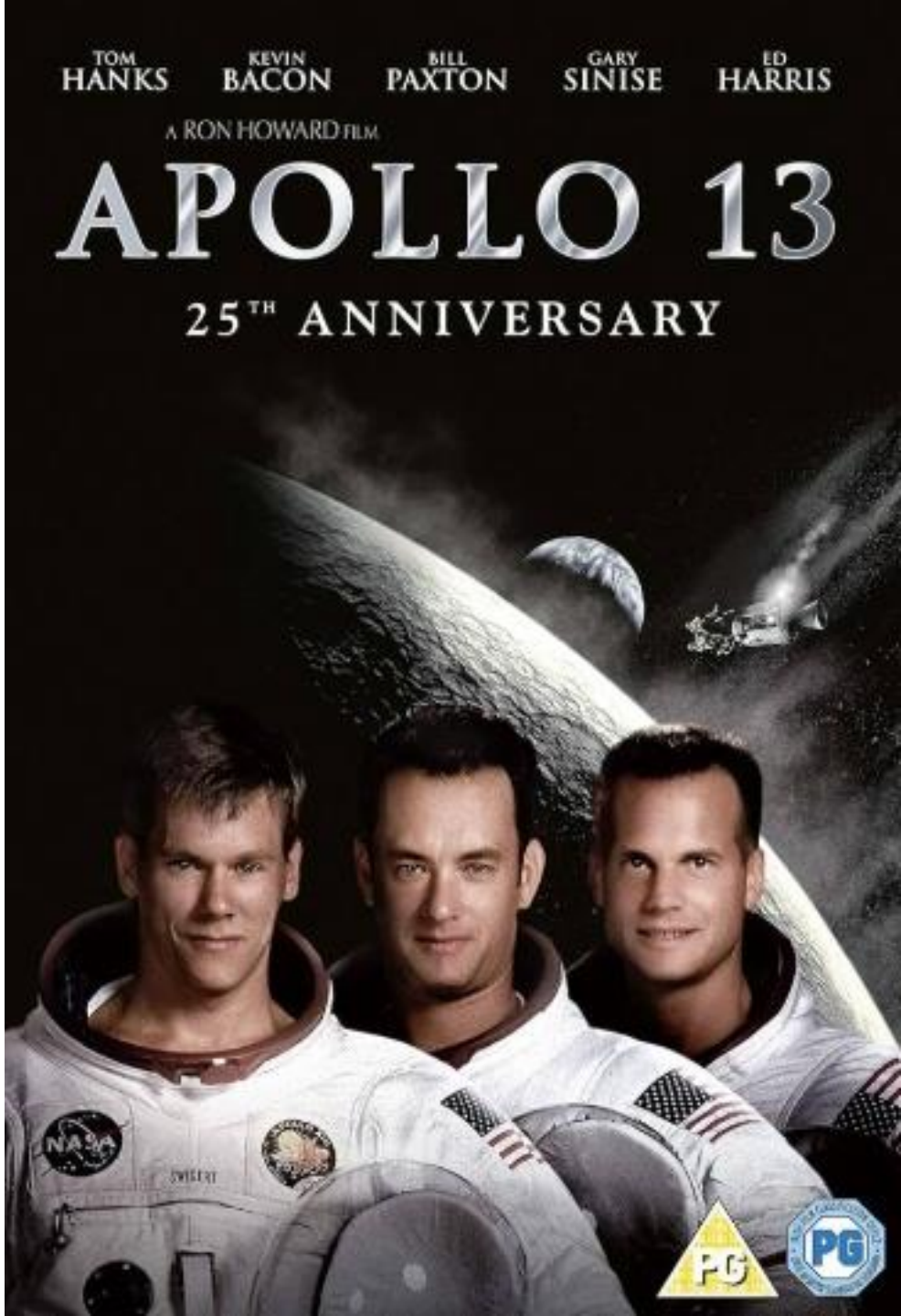
COMPOUNDING WITH NEEDLES

- Modern needles and syringes were designed in the late 19th century for subcutaneous injections, **100 years before the first hazardous drug guidelines**.

Macht D. 1916. The history of intravenous and subcutaneous injecting of drugs. *JAMA*. LXVI

“HOUSTON, WE HAVE A PROBLEM!”

- Wipe testing studies have repeatedly shown environmental contamination in settings where HDs are **compounded and administered**.
- Don’t take my word for it.



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PARTIAL LIST OF SURFACE WIPE TESTING STUDIES

Falck	1979		Fleury-Souverain	2014		Crul	2020
Hirst	1984		Power	2014		Friese	2020
Everson	1985		Rampal	2014		Hori	2020
Monteith	1987		Friese	2015		Huff	2020
Sessink	1992		Hon	2015		Palamini	2020
Ensslin	1994		Rampal	2015		Soubieux	2020
Sessink	1997		Yuki	2015		Walton	2020
Bos	1998		Connor	2016		Yu	2020
Labuhn	1998		Polovich	2016		Bláhová	2021
Mason	2000		Redic	2016		Eisenberg et al	2021
Rai	2000		Bohlandt	2017		Labrèche	2021
Anderson	2001		Roland	2017		Kåredal	2022
Nygren	2002		Baniasadi	2018		Leso	2022
Mason	2003		Chauchat	2018		Miyazawa	2022
Connor	2005		Dugheri	2018		Sottani	2022
Fransman	2005		Koller	2018		Eisenberg	2023
Hedmer	2005		Fleury-Souverain	2018		Hon	2023
Power	2005		Power	2018		Maeda	2023
Touzin	2008		Rampal	2019		Marchal	2023
Schierl	2010		Friese	2019		Nda	2023
Hama	2012		Hon	2020		Pirot	2023
Hedmer	2012		Rampal	2020		Tanigawa	2023
Naito	2012		Yuki	2020		Villa	2023
Friese	2013		Connor	2021		Sessink	2024
Hon	2013		Polovich	2021			
Schreiber	2013		Redic	2021			
Yuki	2013		Bohlandt	2022			

EXPOSURE DURING CHEMOTHERAPY ADMINISTRATION

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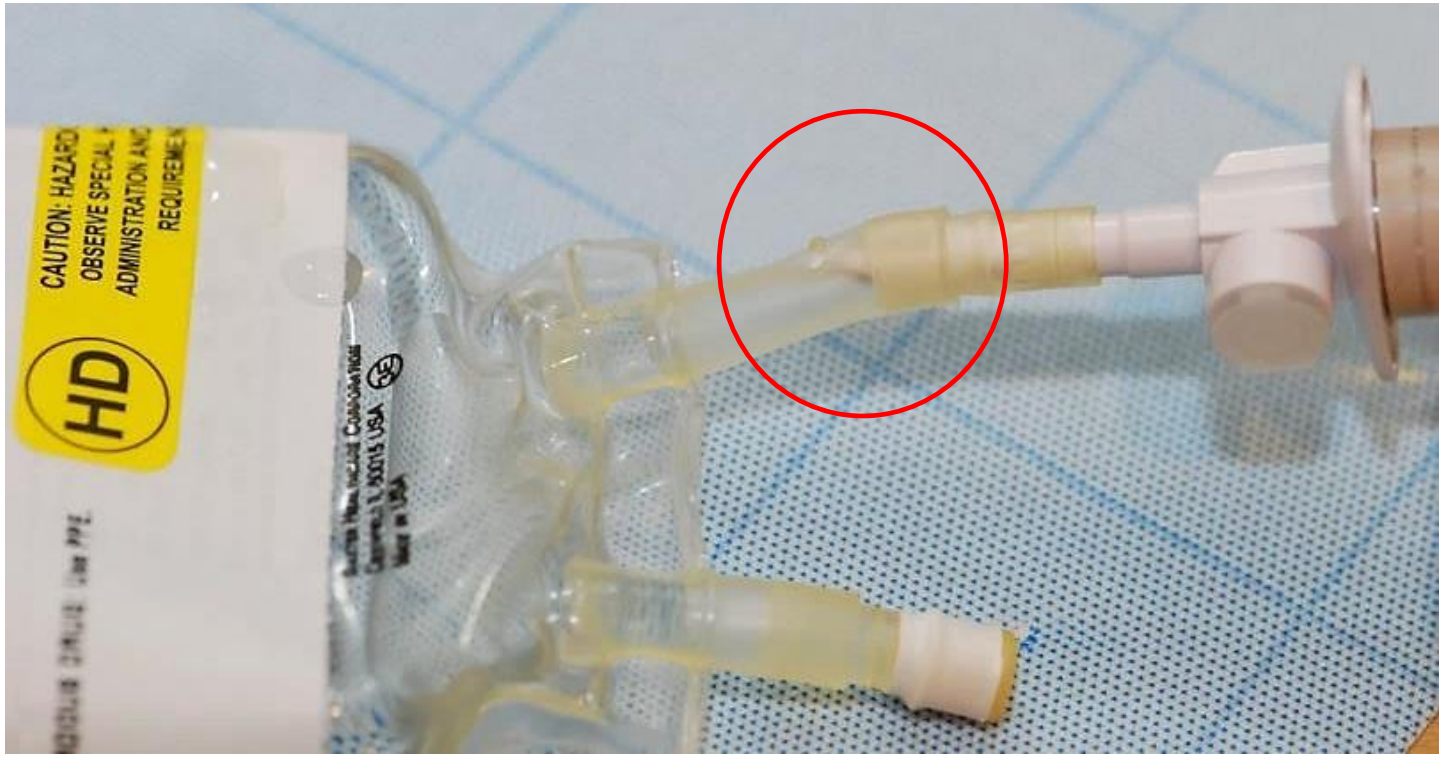
HOW EXPOSURE OCCURS

- Spiking and unspiking IV bags/bottles at the bedside.



HOW EXPOSURE OCCURS

- Priming of tubing at the bedside.

Olsen, M. & Walton, AM 2024, ONS.

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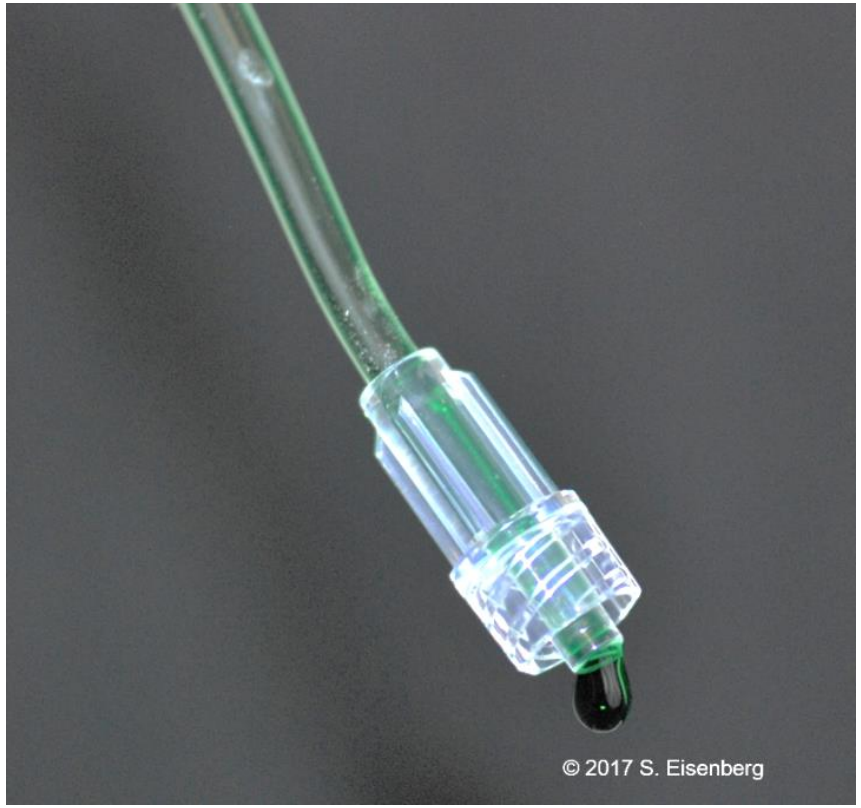
HOW EXPOSURE OCCURS

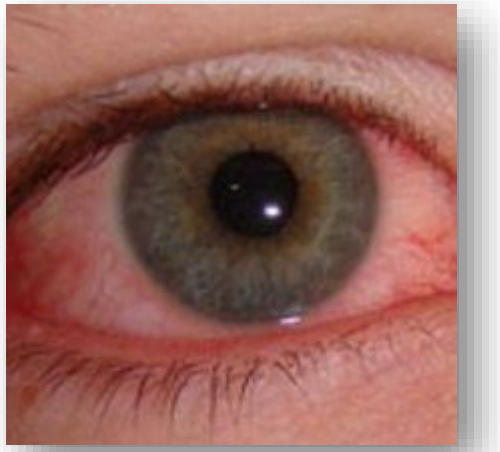
- Connecting and disconnecting.

Eisenberg, S. 2018 Journal of Infusion Nursing; Eisenberg, S. 2017 CJON

HOW EXPOSURE OCCURS

- Leakage from distal end of tubing after disconnecting from patient.

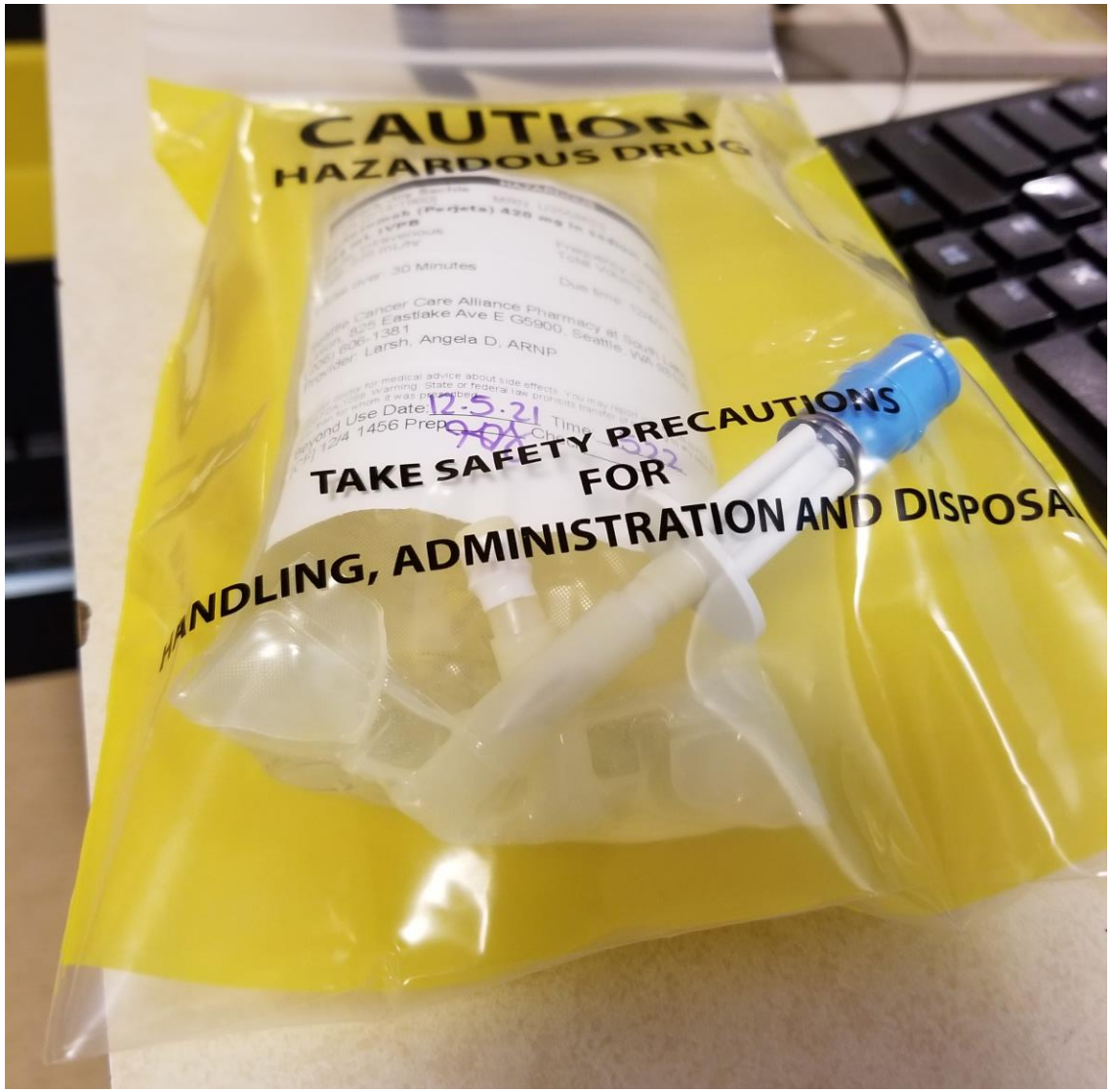




Eisenberg, S. 2017 CJON

HOW EXPOSURE OCCURS

- Improperly sized transport bags.



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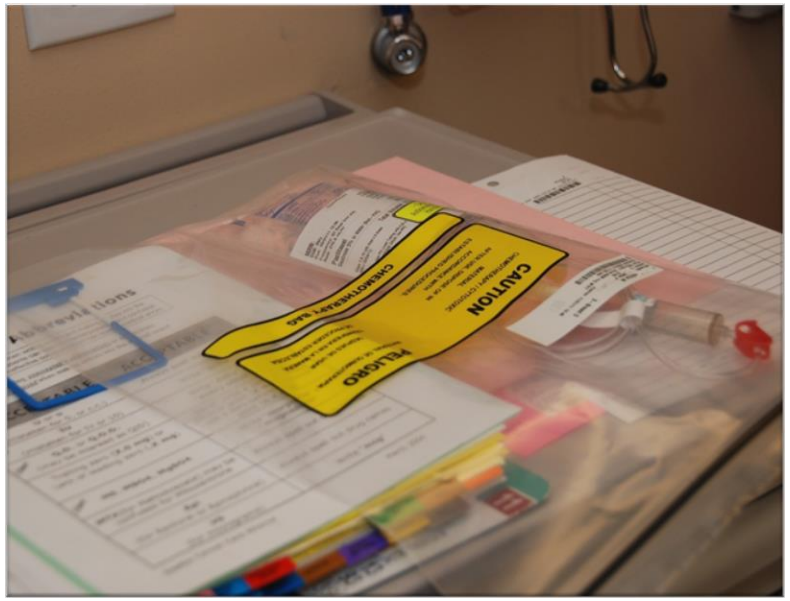
HOW EXPOSURE OCCURS

- Reaching inside of transport bag or placing chemotherapy on unprotected surfaces.



Olsen, M. & Walton, AM 2024, ONS.

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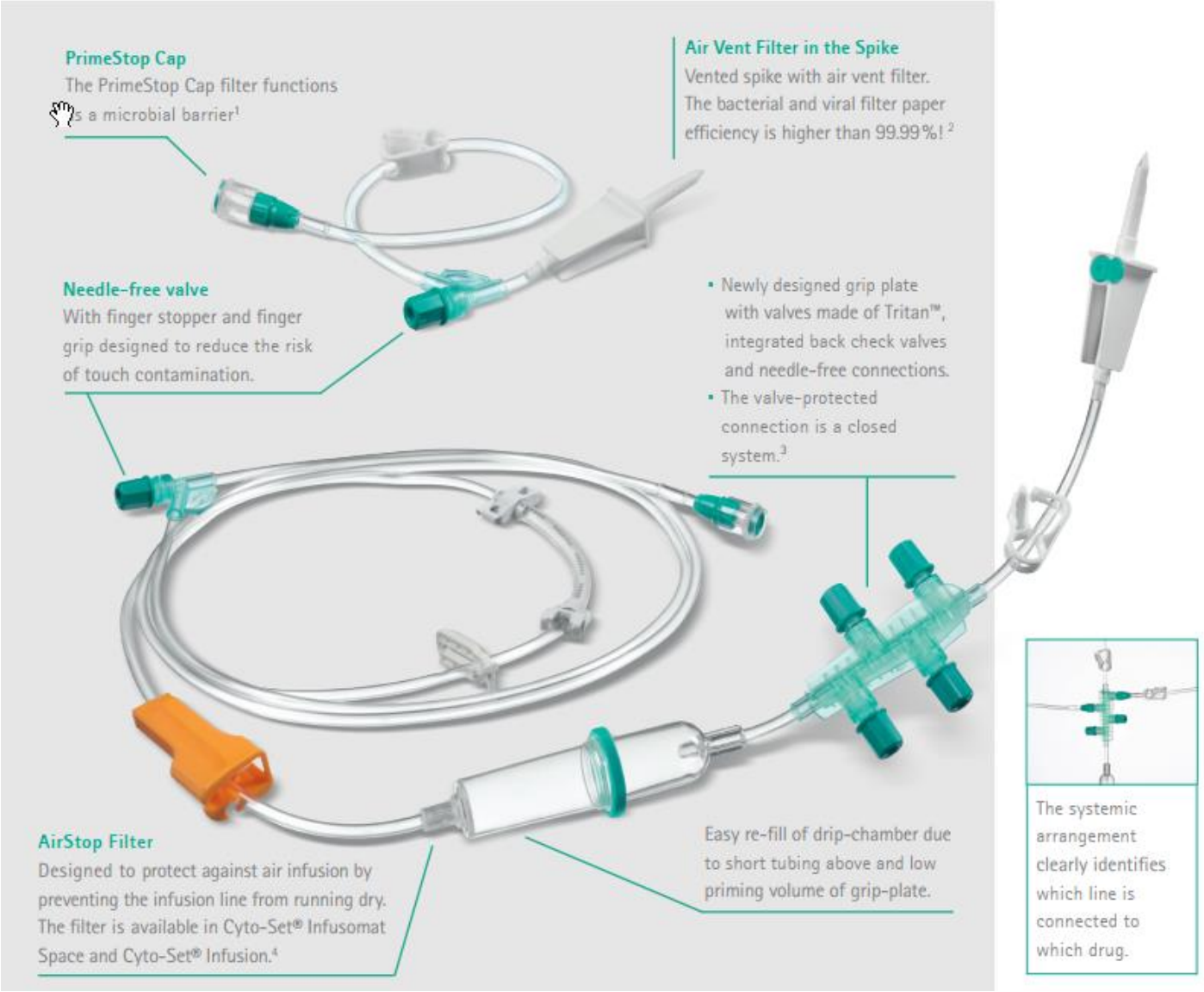
HOW EXPOSURE OCCURS

- The type of tubing set used for administration.



HOW EXPOSURE OCCURS

- Spills before, during and after administration.

Eisenberg, S. 2018 Journal of Infusion Nursing; Eisenberg, S. 2017 CJON ; Olsen, M. & Walton, AM 2024, ONS.

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A TEAM EFFORT

- Preventing HD exposure takes a multidisciplinary approach.

The Hazardous Drug Sandbox

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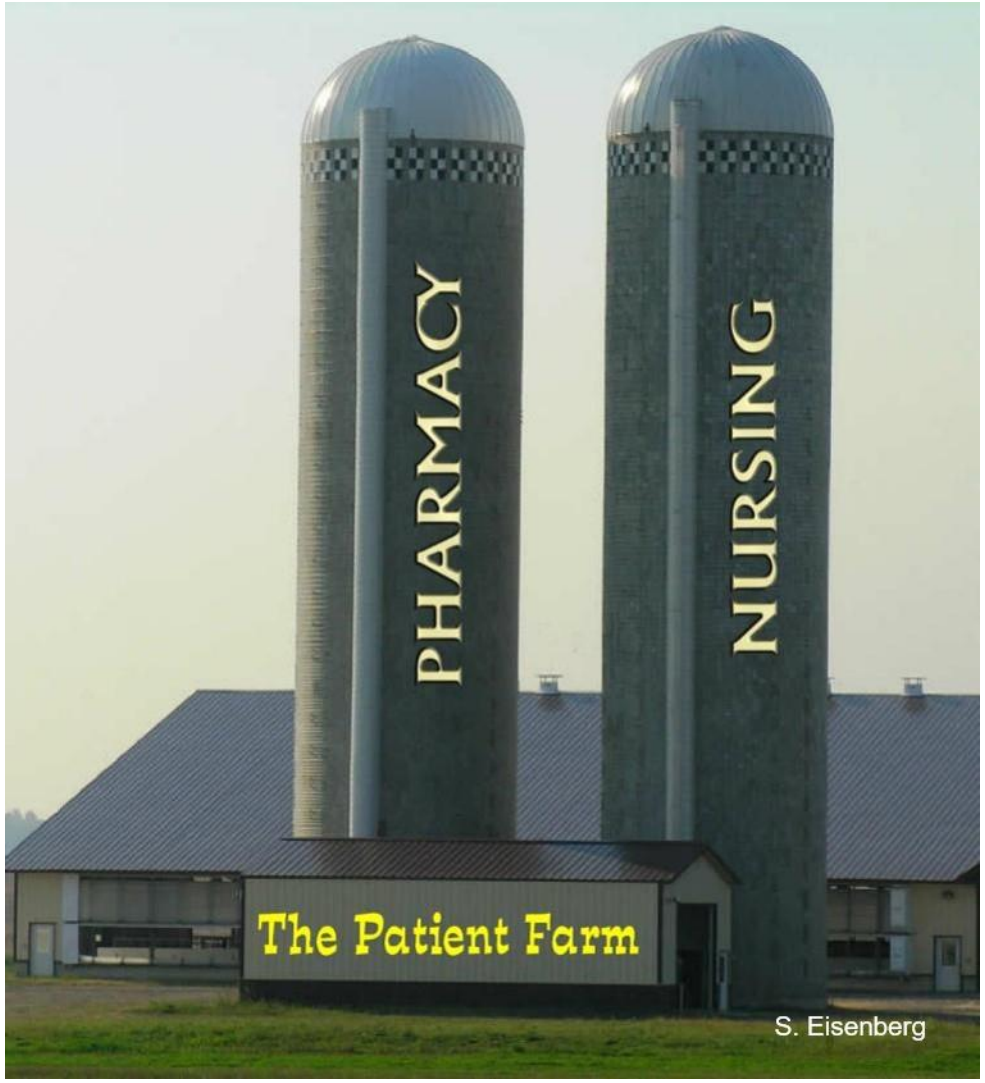
A TEAM EFFORT



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SAFETY EQUIPMENT

CLOSED SYSTEM TRANSFER DEVICES (CSTDs)

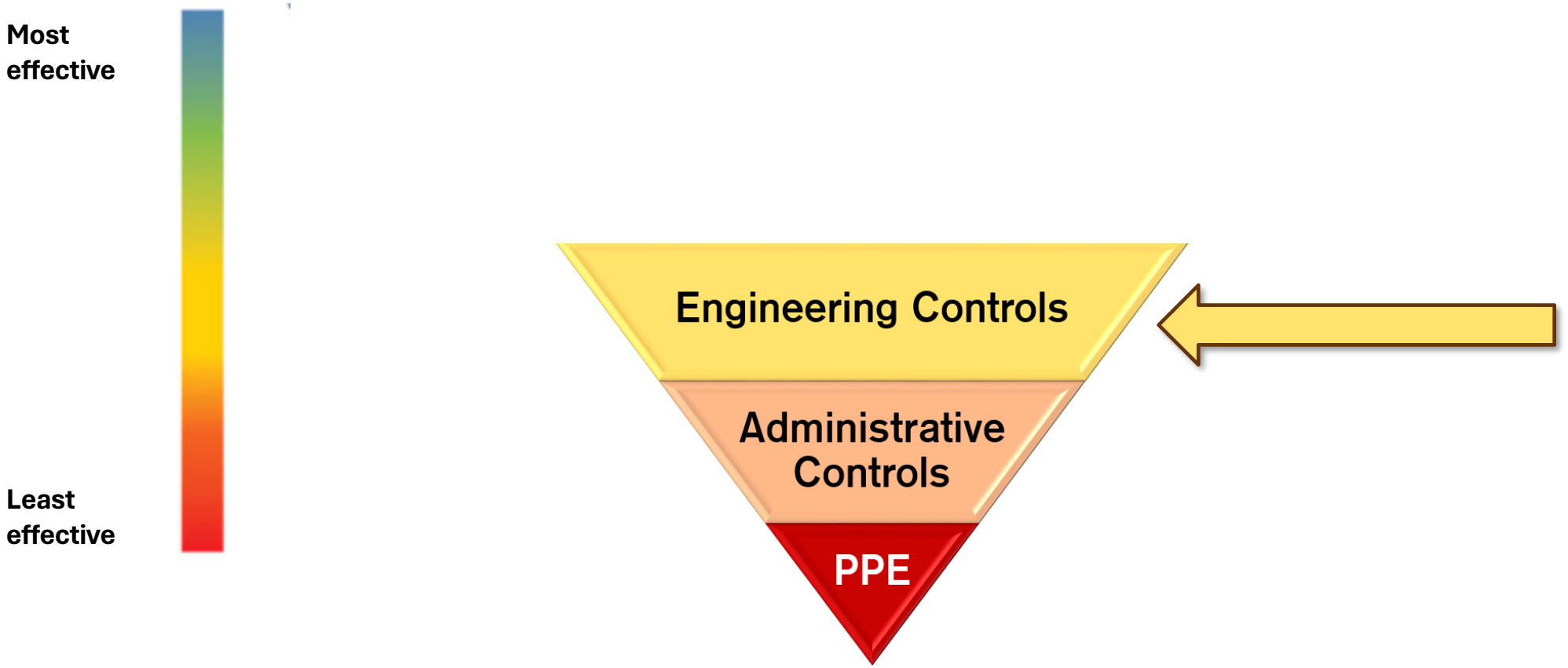
PERSONAL PROTECTIVE EQUIPMENT (PPE)

"An ounce (or 28.35g) of prevention is worth a pound (or 2.2kg) of cure."

Benjamin Franklin

NIOSH HAZARDOUS DRUG HIERARCHY OF CONTROL

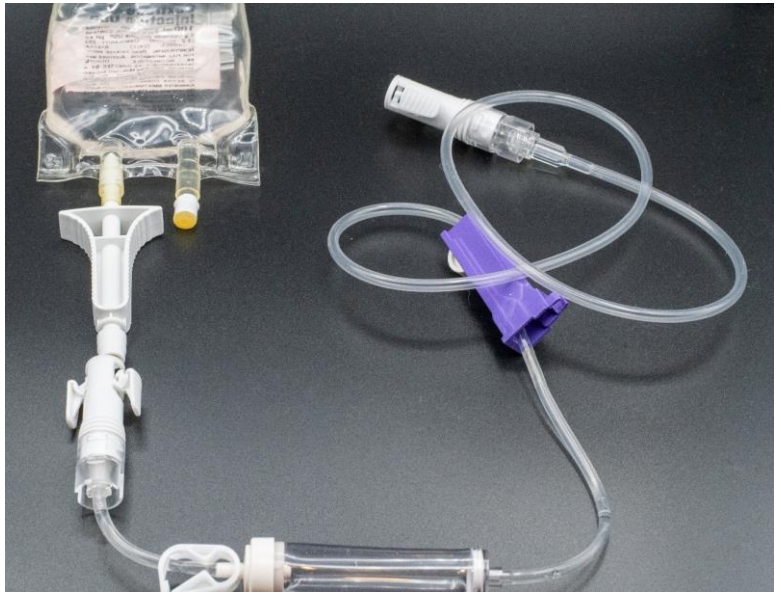
Lowering the risk of healthcare worker exposure infographic.



https://www.cdc.gov/niosh/hierarchy-of-controls/about/index.html

CLOSED SYSTEM TRANSFER DEVICES

USP <800> recommends CSTDs for HD compounding and requires them for administration.



Eisenberg, S. USP <800> and Strategies to Promote Hazardous Drug Safety. *Journal of Infusion Nursing*, 2018, 41(1).

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CLOSED SYSTEM TRANSFER DEVICES (CSTDs)

- Restrict HD liquid or vapor from escaping into the environment.
- The first CSTD was approved in the U.S. for compounding in 1998.
- Initial adoption was slow due in part to **denial of the problem**.

contains vapors and aerosols from release.

CSTD EVOLUTION

- Eventually other manufacturers produced CSTDs, and improvements were made.
- Since then, more than 25 studies have proven their ability to reduce or eliminate contamination.

Bartel	2018
Brechtelsbauer	2023
Clark & Sessink	2013
Connor	2002
Contractor	2015
Favier	2012
Ferrario	2020
Gourd	2017
Harrison	2006
Jorgenson	2008
Kicenuik	2017
Levin & Sessink	2021
Miyake	2013
Nygren	2008
Picardo	2021
Sessink	2011, 2024
Siderov	2010
Simon	2016
Vyas	2014, 2016
Wick	2003
Zock	2010

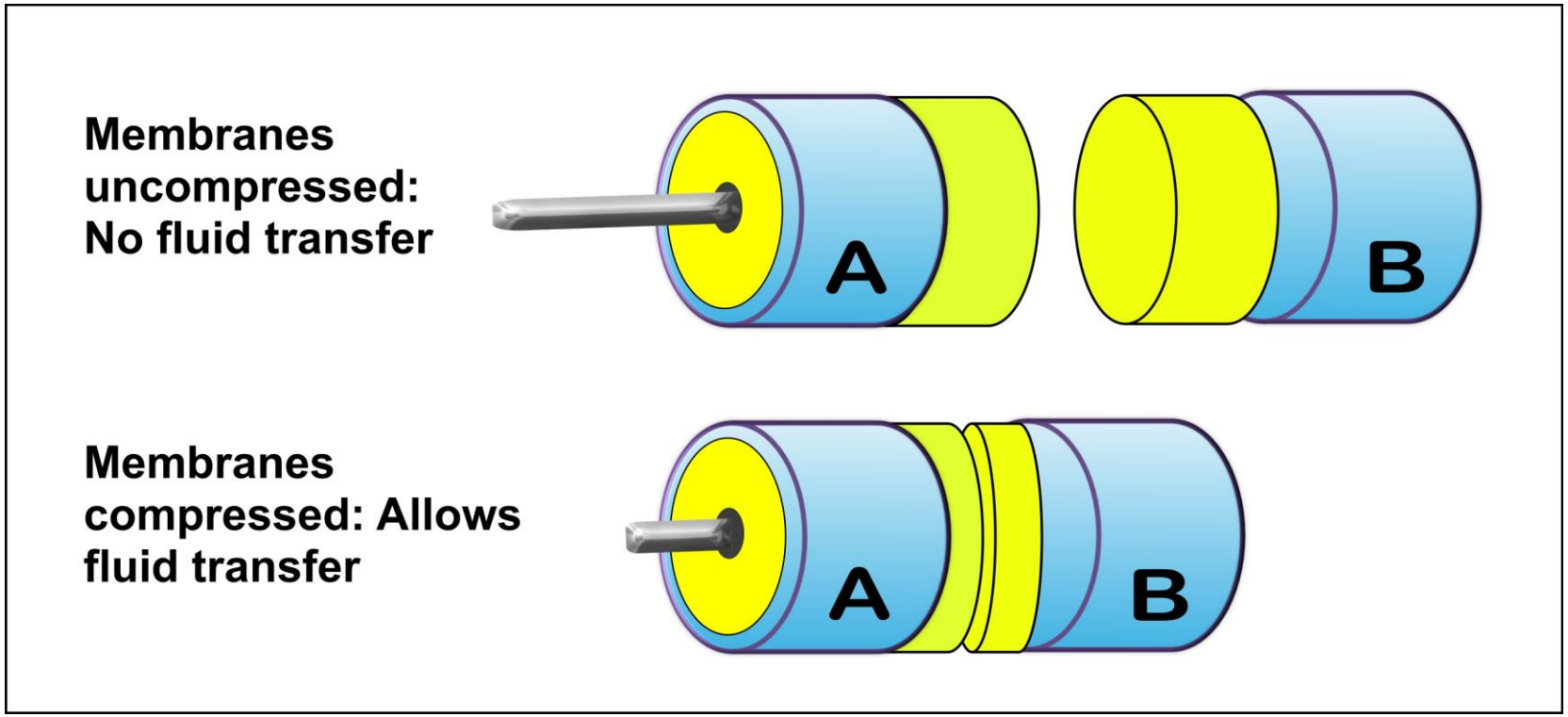
THREE CSTD COMPONENTS

- A vial adapter.
- A connecting device for transferring drug and administration.
- A bag adapter (with or without tubing).

Eisenberg, S. 2018

CSTD BASIC DESIGNS

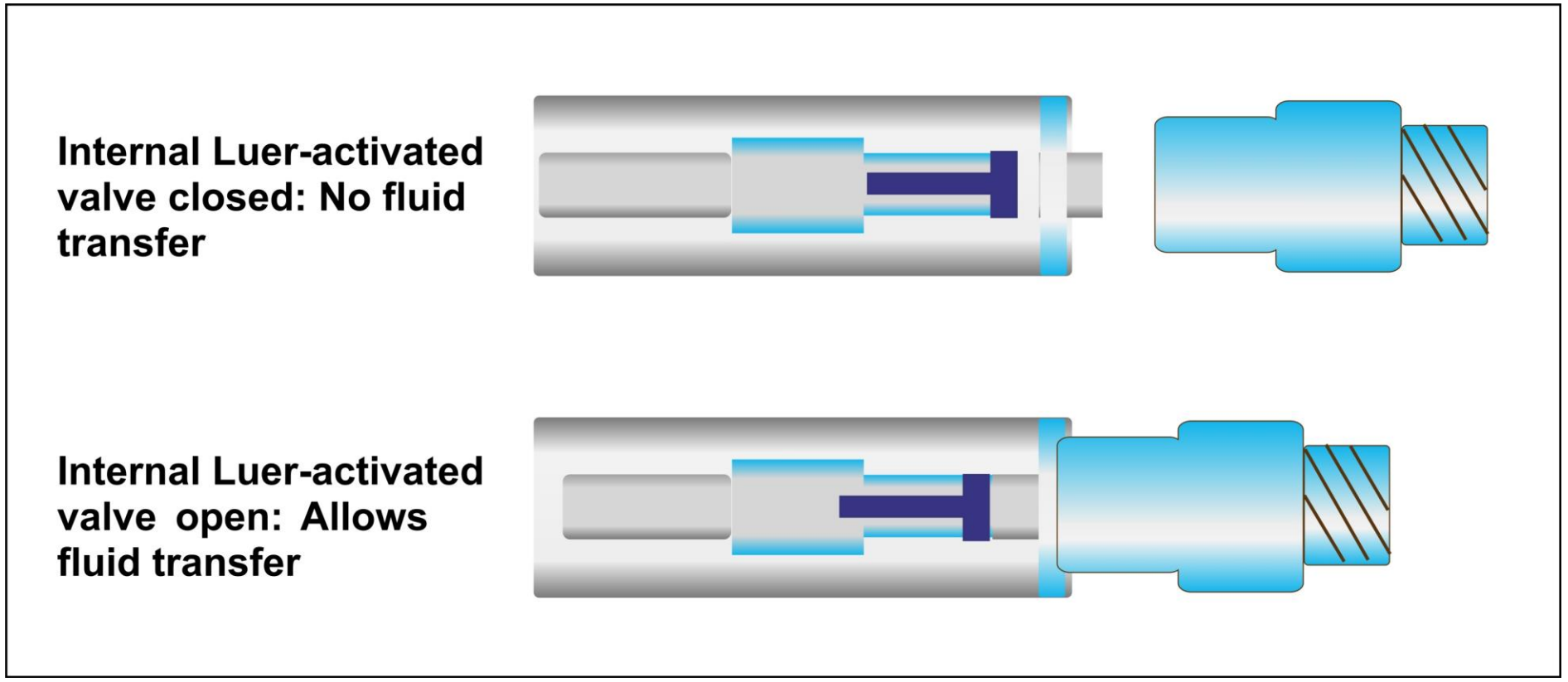
- Membrane design:



Eisenberg, S. 2018

CSTD BASIC DESIGNS

- Luer design.



Eisenberg, S. 2018

EXAMPLES OF MEMBRANE CSTD SYSTEMS

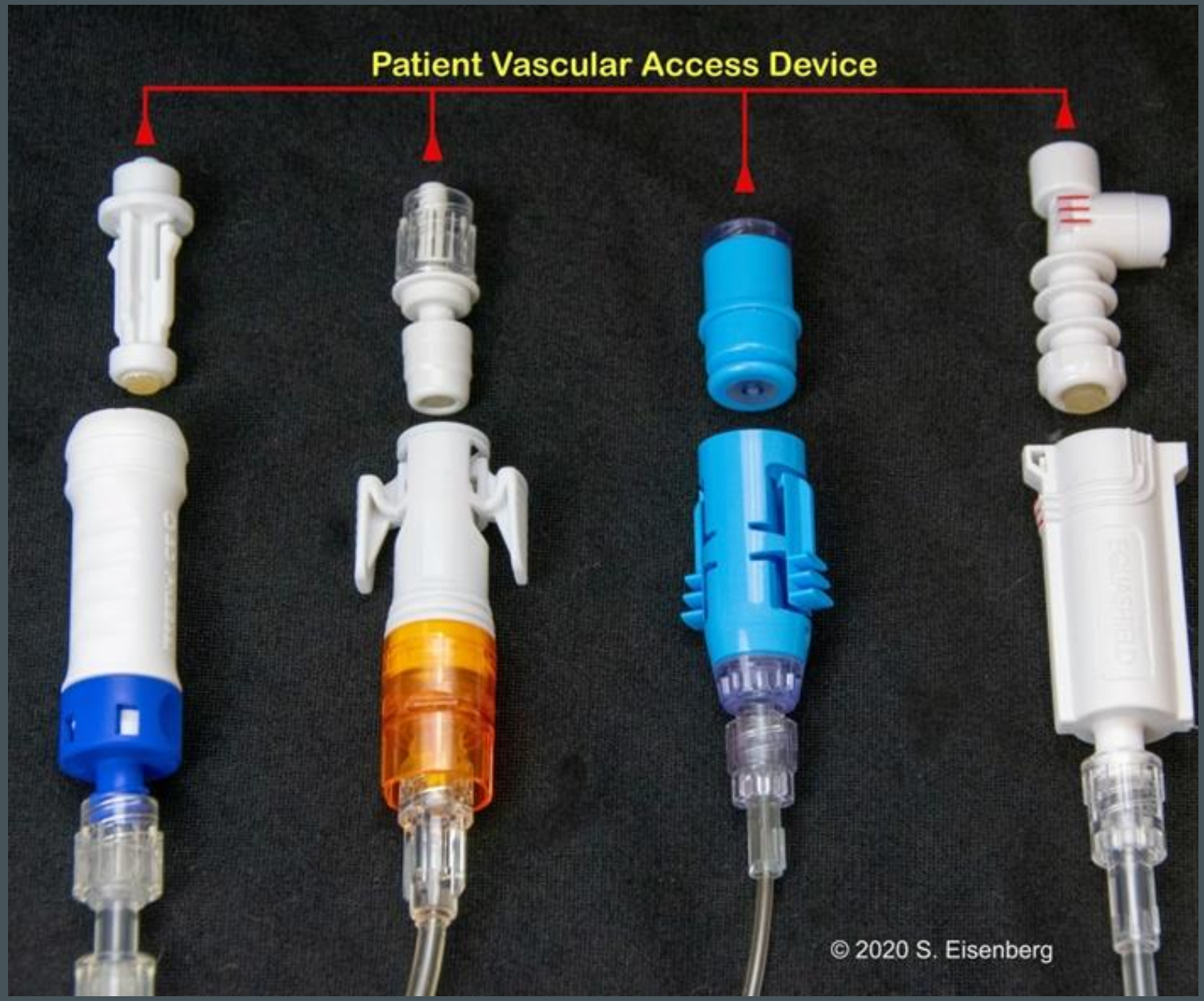
Chemfort (Simplivia) [B Braun OnGuard in U.S.]

ChemoLock (ICU Medical)

Equashield (Equashield)

Phaseal Optima (BD)

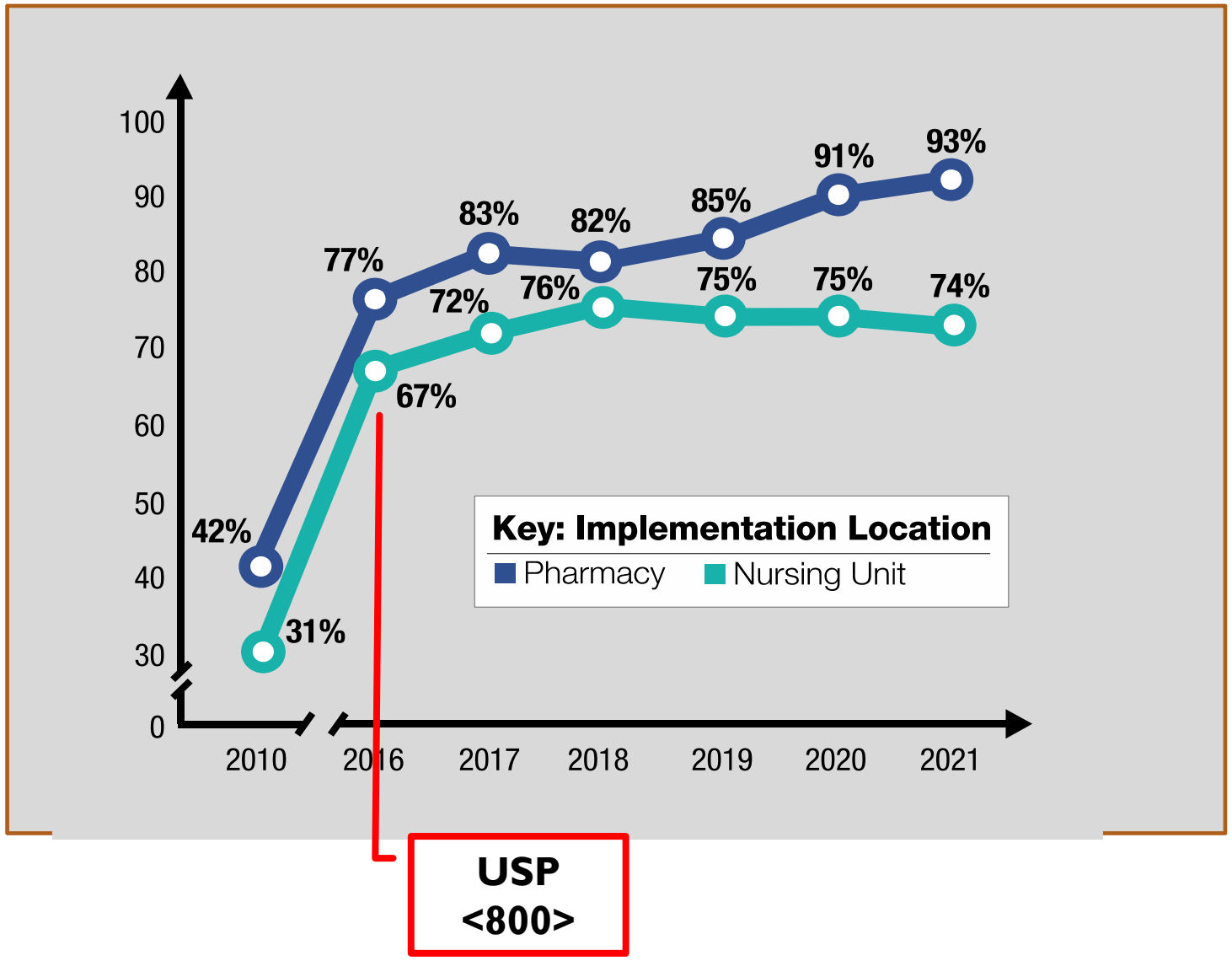
EXAMPLES OF MEMBRANE CSTD WITH LUER ADAPTERS



EXAMPLE OF MEMBRANE AND LUER HYBRID SYSTEM

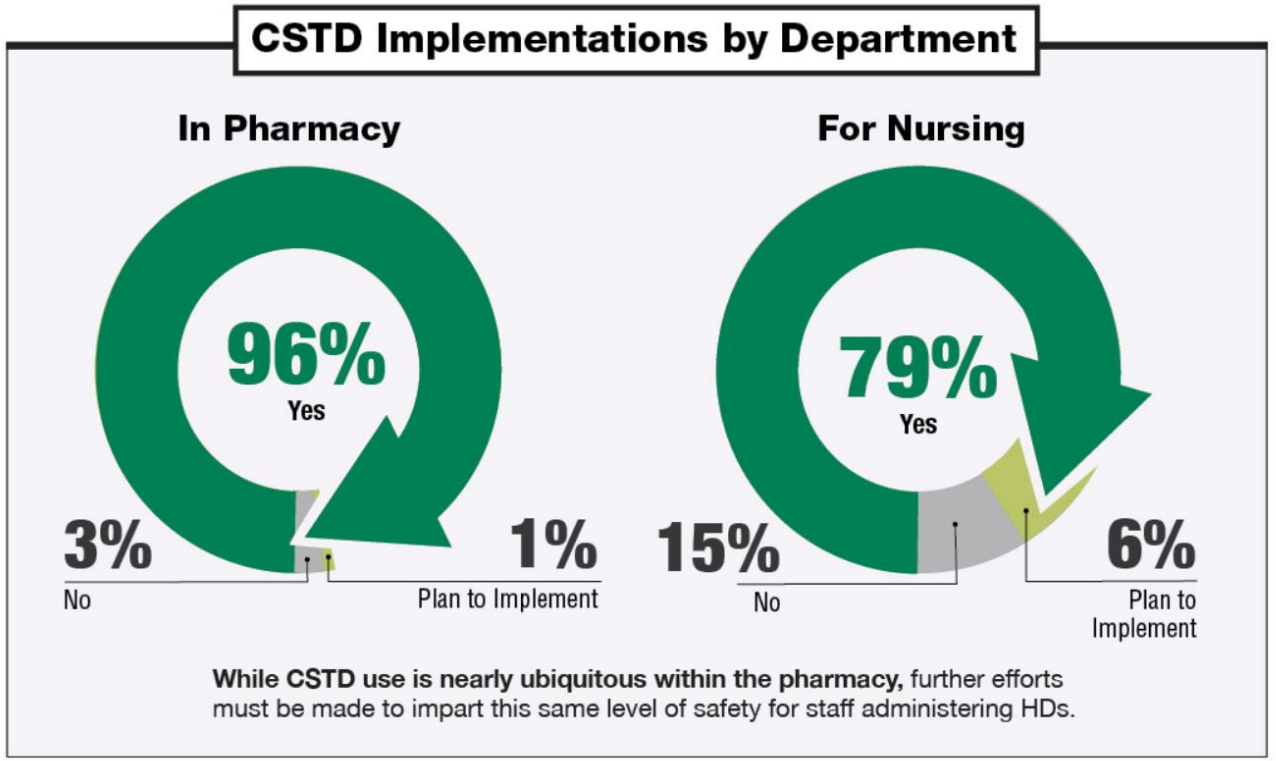
CSTD ADOPTION 2010 - 2021

The power of standards



Source: State of Pharmacy Compounding. *Pharm Purch Prod.* 2021;4:1-56

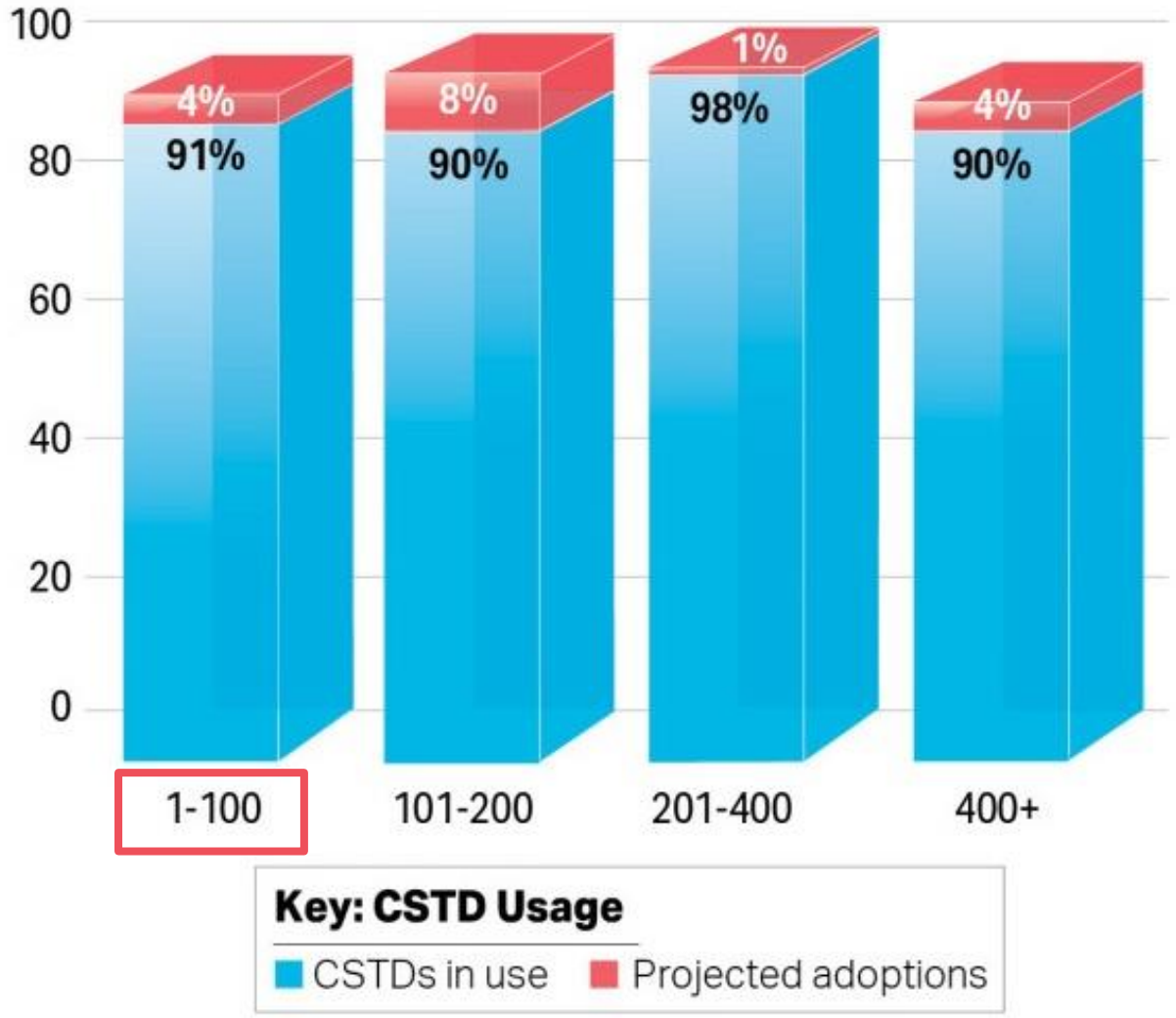
CSTD IMPLEMENTATION BY DEPARTMENT



PPPmag.com, 2022, August

2024 CSTD ADOPTION BY FACILITY SIZE

Number Of Beds



Source: https://www.pppmag.com/article/3257

FINANCIAL IMPLICATIONS

The actual cost of CSTDs is a small percentage of a U.S. pharmacy's operating budget. For example:

Annual medication acquisition: $9 million	Annual CSTD cost: $50,000

Massoomi, F. 2012 "CSTD as a Cost of Doing Business." PPPmag.com November

CSTDs: ENHANCING WORKFLOW

Safety does not always increase the workload.

Original Article

JOURNAL OF ONCOLOGY PHARMACY PRACTICE

There was a statistically significant decrease in preparation time using any of the 3 tested CSTDs compared to using a needle.

Nurgat, Z. et al 2019 JOPP

CSTDs: ENHANCING WORKFLOW

Bonded IV sets.

Prevent loose connections, save assembly time, and ensure compliance.

CSTDs: ENHANCING WORKFLOW

Direct spikes.

- Prevent needle-stick injuries.
- Available in multi-packs.
- Save compounding time.

CSTDs: ENHANCING WORKFLOW

- Changing from regular tubing to a direct spike CSTD saved our pharmacy 2 hours of technician time every day.

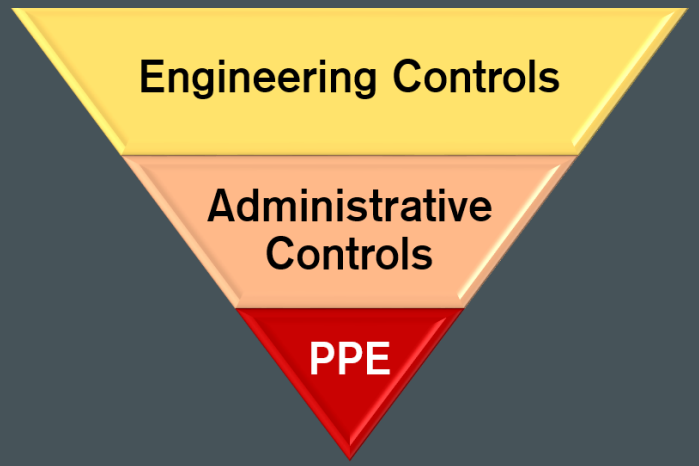
728 hours per year

CSTDs: ENHANCING WORKFLOW

Direct spikes.

Faster, safer drug administration.

PPE:
(Personal Protective Equipment)



Seth Eisenberg, *Oncology Nursing Lecturer, USA. Brussels March7th, 2025*

PPE COMPONENTS

- **Chemotherapy gown**
  - Tested against hazardous drugs.
  - Long sleeves with elastic cuffs.
  - Closed in front (no snaps or buttons).
  - SINGLE USE.
- **Gloves**
  - Two pair of chemotherapy-tested (one under the gown cuff and one over the cuff).

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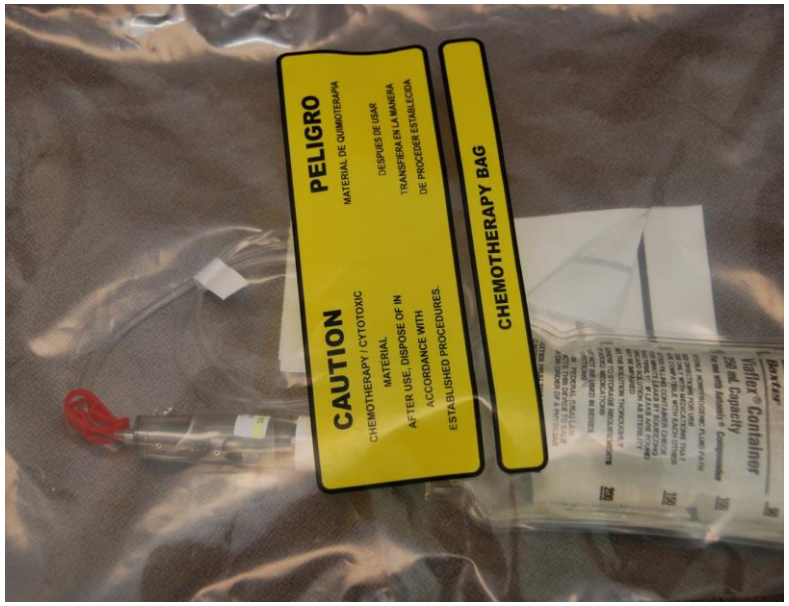
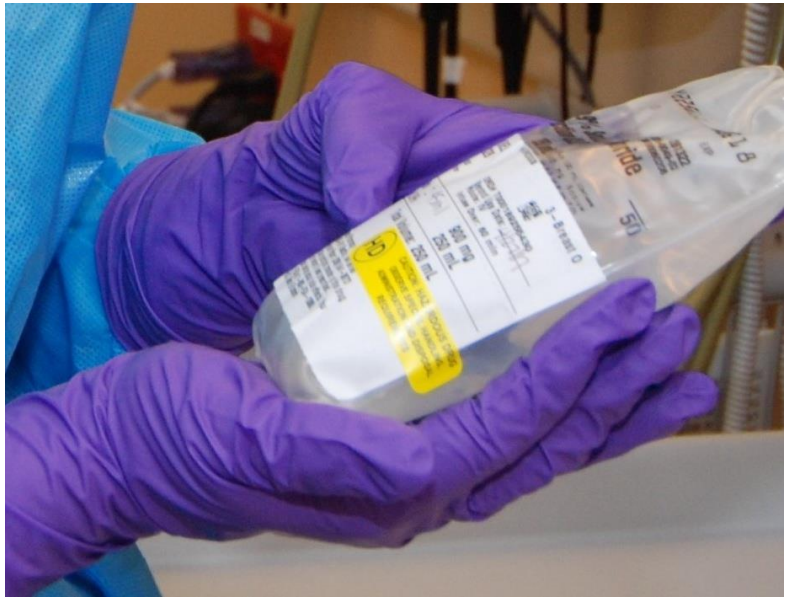
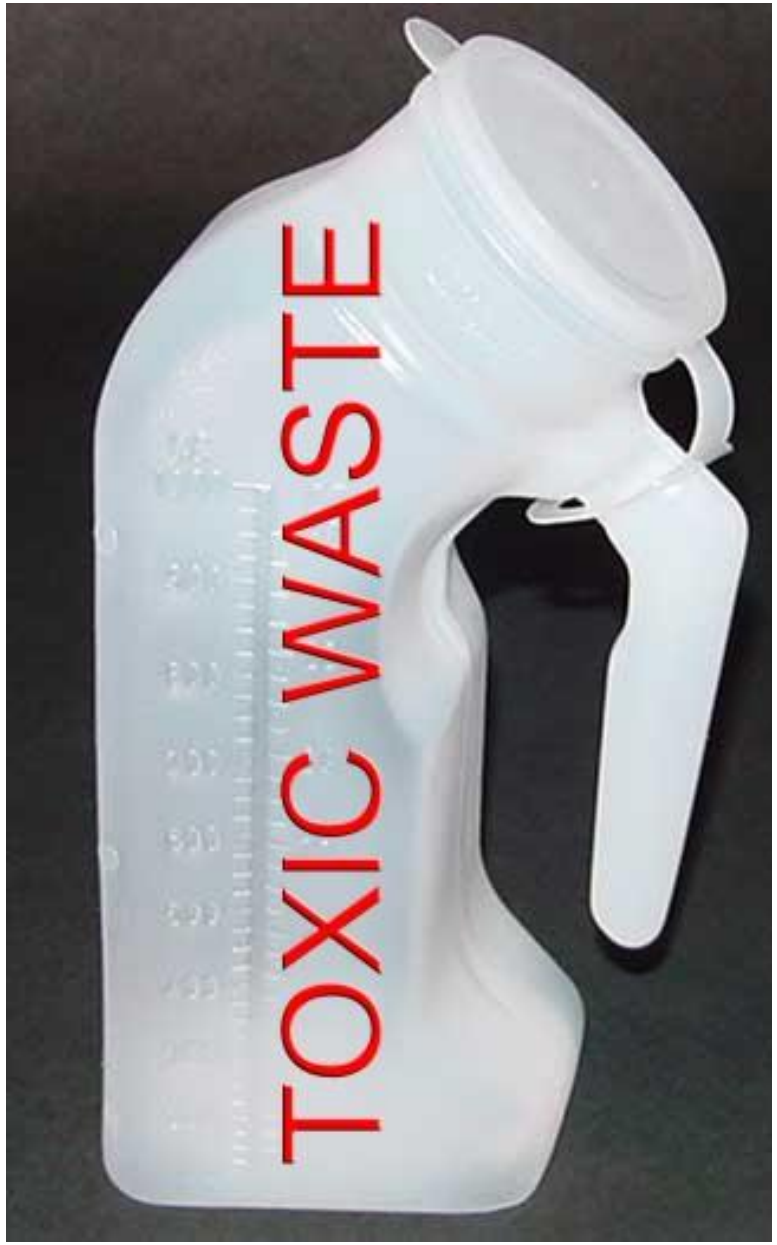
PPE

- **Must be worn when:**
  - Handling HD bags, bottles or syringes.
  - Administering HDs.
  - Disconnecting bags and tubing.
  - Disposing.
  - Cleaning a spill.

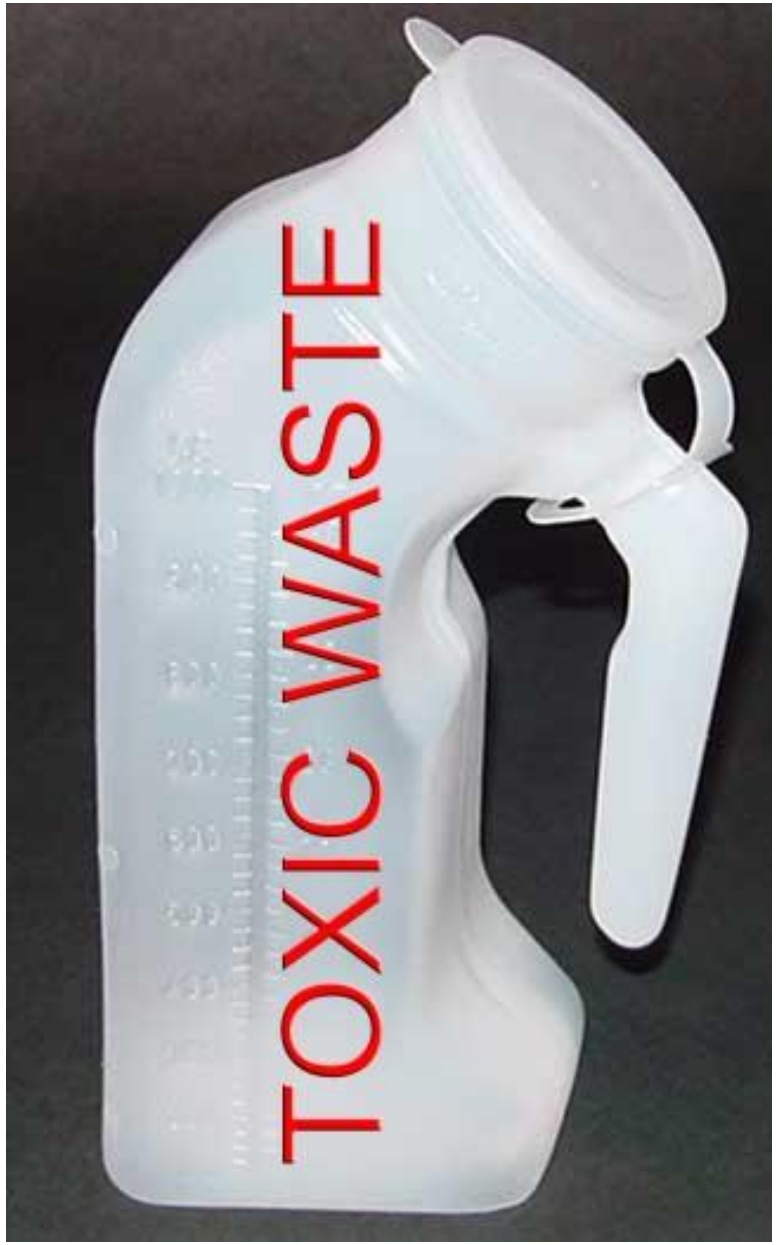




AND HANDLING EXCRETA FROM PATIENTS RECEIVING HDs.



LET'S TALK ABOUT EXCRETA!



EXAMPLES OF HDs EXCRETED IN URINE

Drug	% Excreted in Urine
Azacitidine	95%
Bleomycin	75% unchanged
Carmustine	60-70%
Clofarabine	49-60% unchanged
Cyclophosphamide	25% unchanged
Fludarabine	25% unchanged
Methotrexate	89-90% unchanged
Carboplatin	60-80%
Doxorubicin	5-12% unchanged
Etoposide	30-55% unchanged

www.setheisenberg.net (retrieved February 2025)

Seth Eisenberg, *Oncology Nursing Lecturer, USA. Brussels March7th, 2025*

THE INVISIBLE DANGER IN PATIENT BATHROOMS

- Wipe testing for hazardous drugs has shown contamination in patient bathrooms.
- Contaminated surfaces can include the toilet rim, seat, flush handle, sink, door handle and floor.
- Although gloves are often worn by nurses when inside a bathroom, touch contamination in other areas can occur.

Eisenberg, S., Ito, K. & Rodriguez, 2021, CJON; Walton AL, et al 2019 ONF; Viegas, S. et al. 2018. Arh Hig Rada Toksikol.

BATHROOM SURFACE WIPE TESTING

- HDs were found in a patient bathroom **and in a staff bathroom** located behind a locked security door.

Hazardous Drug Contamination

Presence of bathroom contamination in an ambulatory cancer center

Seth Eisenberg, RN, OCN®, BMTCN®, Kimberly Ito, RN, BSN, OCN®, and Angela Rodriguez, MSN, RN, CNS-BC, AFN-BC, OCN®, SANE-A®

BACKGROUND: Many hazardous drugs (HDs) are excreted in urine and feces, and evidence has shown that bathrooms of patients receiving chemotherapy at home are contaminated with HDs. However, little information exists on bathroom contamination in ambulatory clinics where HDs are administered.

OBJECTIVES: This project aimed to determine the presence of HD residue in the patient and staff bathrooms of an ambulatory cancer center.

HAZARDOUS DRUGS (HDs) ARE DEFINED BY THE National Institute for Occupational Safety and Health (NIOSH, 2016) as having any of the following properties: carcinogenicity, genotoxicity, teratogenicity, reproductive toxicity, organ toxicities at low doses, and structure and toxicity profile of new drugs that mimic drugs previously determined to be hazardous. Studies in healthcare workers (HCWs) who compounded or administered HDs during the 1980s and 1990s demonstrated many adverse health effects ranging from nausea and vomiting to reproductive issues and spontaneous abortions (Fransman et al., 2007; Hemminki et al., 1985; Lawson et al., 2012; Lorente et al., 2000; Martin, 2005; Shortridge et al., 1995; Valanis et al., 1997). Currently, there are no acceptable levels of exposure to HDs, and NIOSH (2016) recommends the ALARA (as low as reasonably achievable) principle, which is used in radiation safety.

Eisenberg, S., Ito, K. & Rodriguez, 2021, Clinical Journal of Oncology Nursing, 25(2)

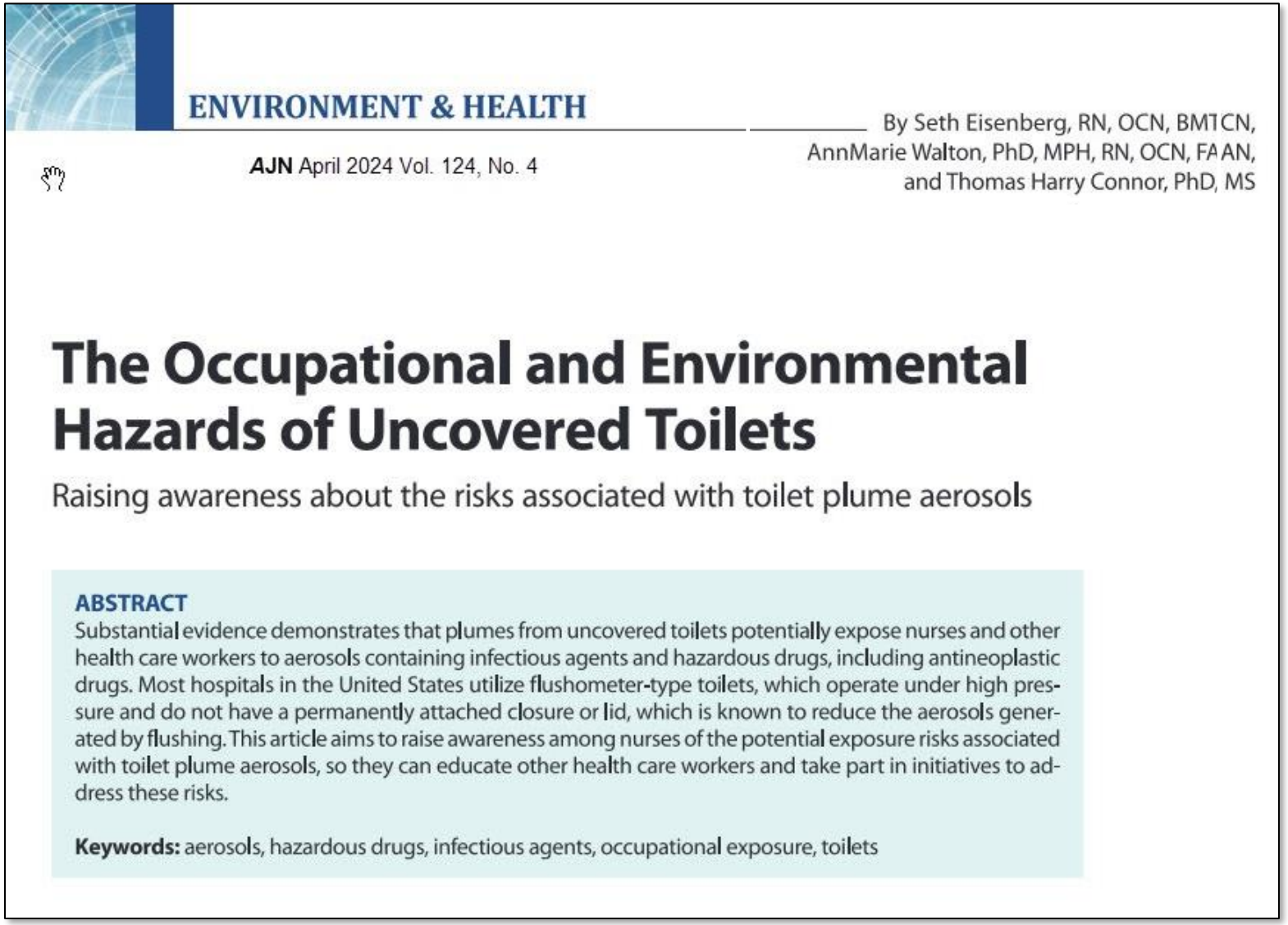
TOILET PLUME AEROSOLS

WHO LET THE DROPS OUT?

Photo credit: John Crimaldi. Used by permission.

LITERATURE REVIEW

- There is sufficient evidence that flushing uncovered hospital toilets may expose healthcare workers to **hazardous drugs and bioaerosols.**



ENVIRONMENT & HEALTH

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By Seth Eisenberg, RN, OCN, BMTCN, AnnMarie Walton, PhD, MPH, RN, OCN, FAAN, and Thomas Harry Connor, PhD, MS

The Occupational and Environmental Hazards of Uncovered Toilets

Raising awareness about the risks associated with toilet plume aerosols

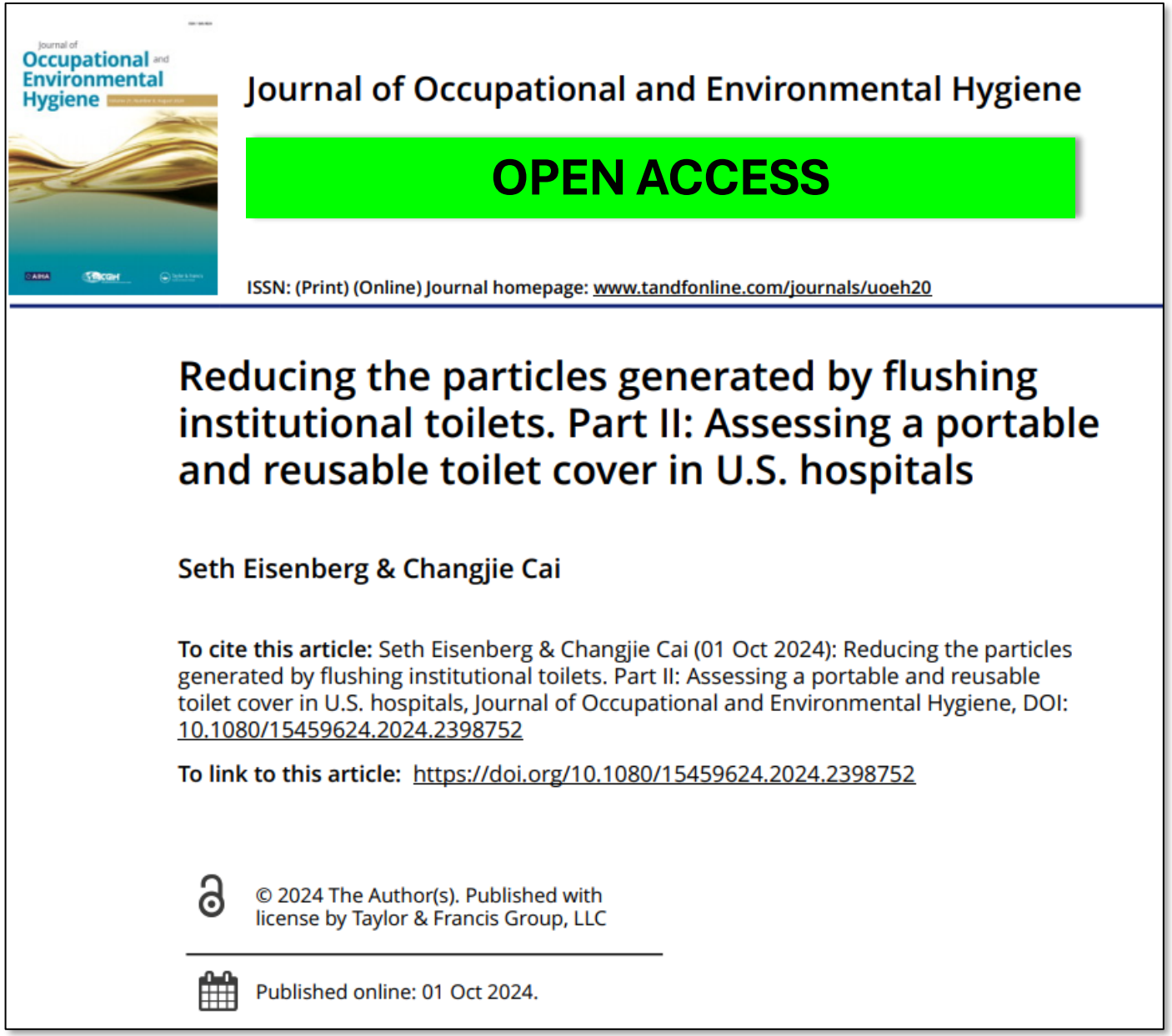
ABSTRACT

Substantial evidence demonstrates that plumes from uncovered toilets potentially expose nurses and other health care workers to aerosols containing infectious agents and hazardous drugs, including antineoplastic drugs. Most hospitals in the United States utilize flushometer-type toilets, which operate under high pressure and do not have a permanently attached closure or lid, which is known to reduce the aerosols generated by flushing. This article aims to raise awareness among nurses of the potential exposure risks associated with toilet plume aerosols, so they can educate other health care workers and take part in initiatives to address these risks.

Keywords: aerosols, hazardous drugs, infectious agents, occupational exposure, toilets

2024 MULTI-CENTER STUDY

- 15 hospitals in 9 states.
- Departments included HEPA and non-HEPA filtered, inpatient and outpatient.
- 145 toilets measured for 60 seconds uncovered and covered.



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Reducing the particles generated by flushing institutional toilets. Part II: Assessing a portable and reusable toilet cover in U.S. hospitals

Seth Eisenberg & Changjie Cai

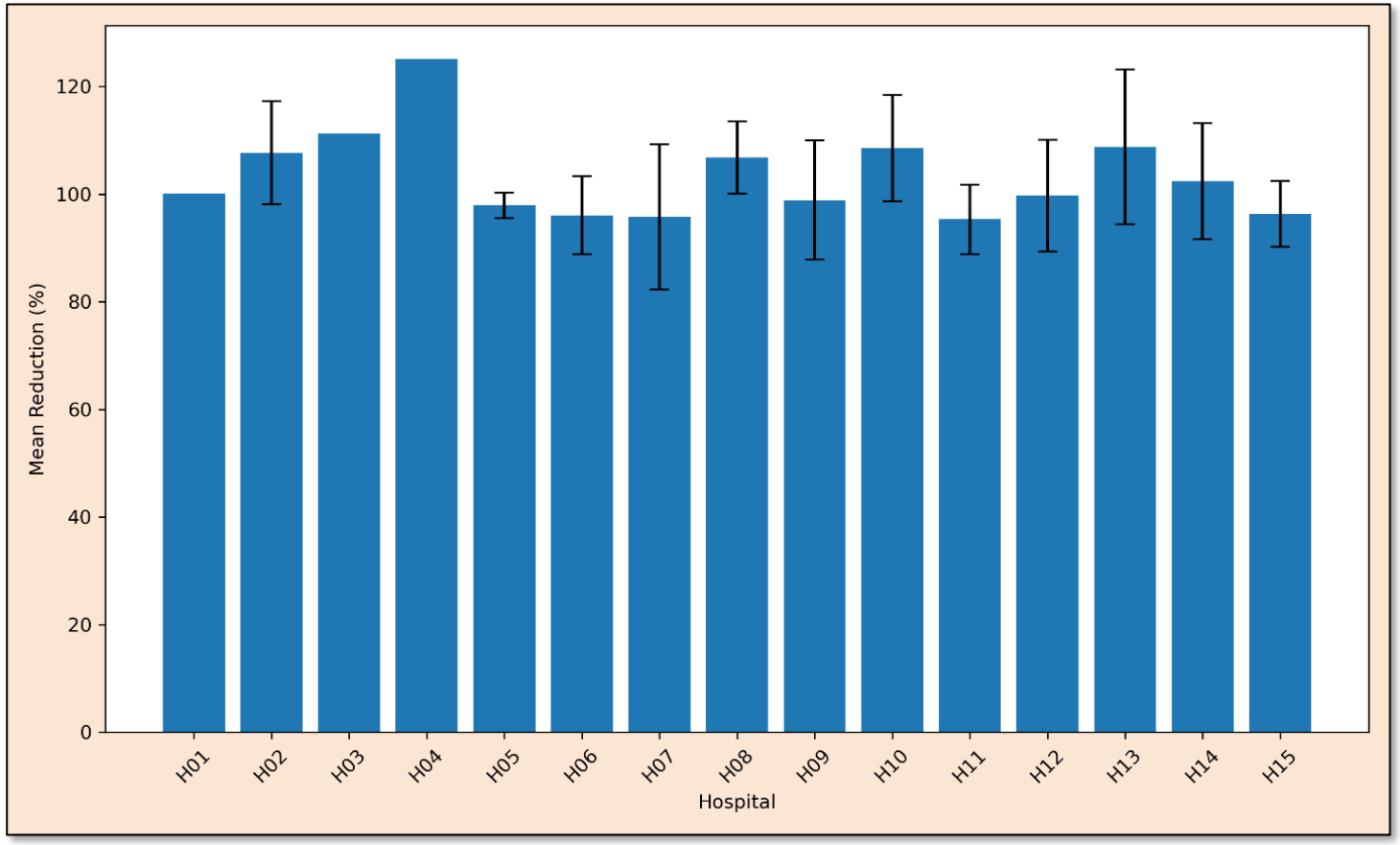
To cite this article: Seth Eisenberg & Changjie Cai (01 Oct 2024): Reducing the particles generated by flushing institutional toilets. Part II: Assessing a portable and reusable toilet cover in U.S. hospitals, Journal of Occupational and Environmental Hygiene, DOI: 10.1080/15459624.2024.2398752

To link to this article: https://doi.org/10.1080/15459624.2024.2398752

Published online: 01 Oct 2024.

2024 MULTI-CENTER STUDY

- Covering the toilet with a portable, solid, reusable cover demonstrated a mean reduction of 99.98% (p<.0002).



BARRIERS TO COMPLIANCE

AND WHAT TO DO ABOUT THEM

BARRIERS TO COMPLIANCE

- Perceived immunity to risk.

  “It’s only a little chemo. I’ve been exposed and I’m fine!”

It’s not just about you.

Seth Eisenberg, *Oncology Nursing Lecturer, USA. Brussels March7th, 2025*

BARRIERS TO COMPLIANCE

- “We’re short staffed and I don’t have time.”

Seth Eisenberg, *Oncology Nursing Lecturer, USA. Brussels March7th, 2025*

SAFETY CULTURE

- Yes, safe practices can add time.

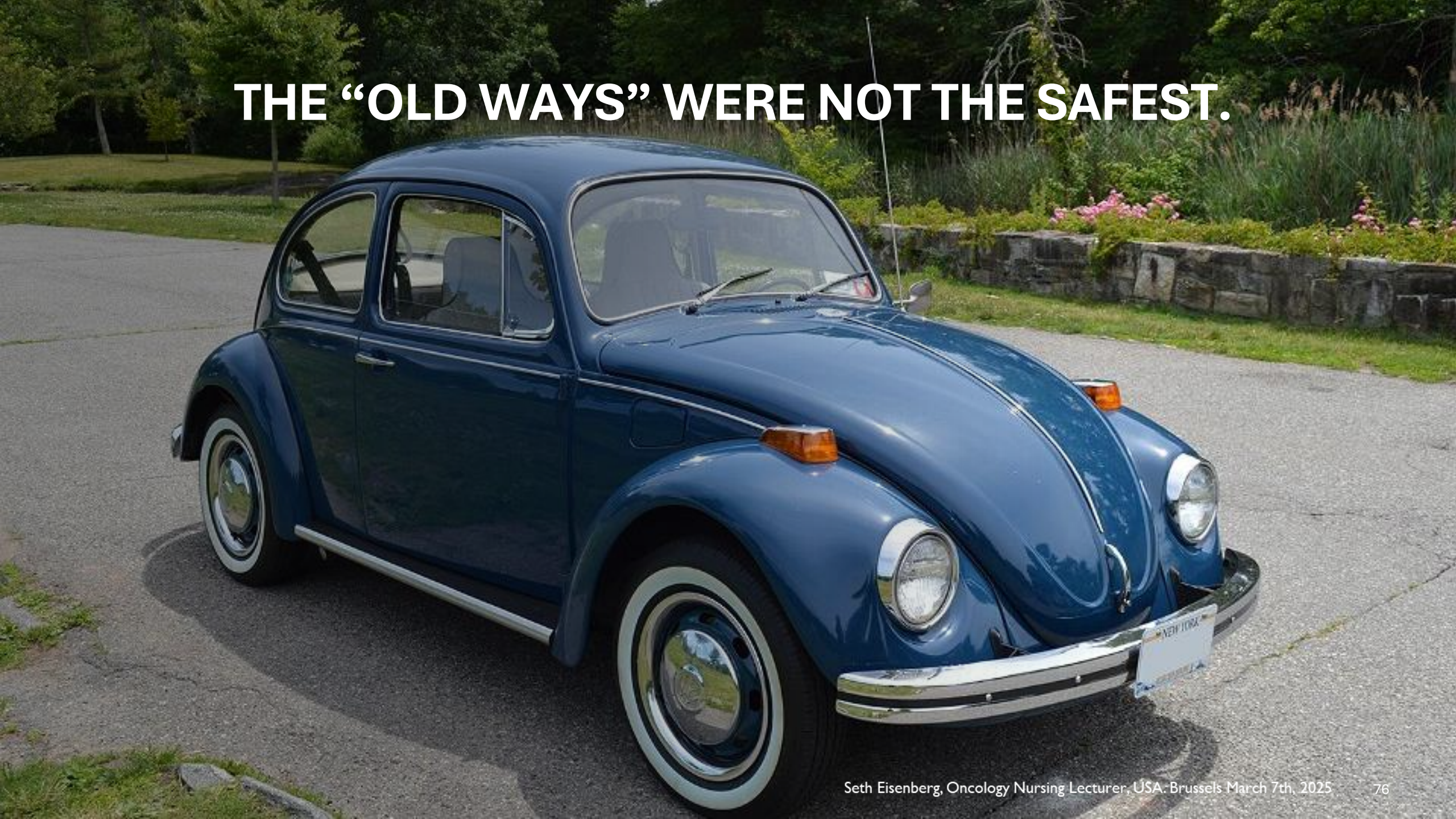
"Poor staffing is not an excuse for poor safety."

Seth Eisenberg, *Oncology Nursing Lecturer, USA. Brussels March7th, 2025*

SAFETY CULTURE

What about your hospital's culture?

THE “OLD WAYS” WERE NOT THE SAFEST.



CHANGING THE SAFETY CULTURE REQUIRES:

- Leadership support.
- Bedside champions.
- Without those, it’s an uphill climb.

Seth Eisenberg, *Oncology Nursing Lecturer, USA. Brussels March7th, 2025*

SAFETY CULTURE

Understimate the power of peer pressure,
you must not!

IN CLOSING:

- **Administrators:**
  - What is the value of protecting your employees?

- **Nurses and Pharmacists:**
  - Advocate for your safety.

And remember, change takes time.

QUESTIONS

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