

# **Bloodborne Pathogen Standard OSHA's Final Rule**

**William A. Rutala, Ph.D., M.P.H.**

**Director, Statewide Program for Infection Control and  
Epidemiology, Professor of Medicine, University of North  
Carolina (UNC)**

**Former Director, Hospital Epidemiology, Occupational  
Health and Safety Program, UNC Health Care, Chapel Hill  
(1979-2017)**

October 2024

## OSHA's Mandate

- OSHA's mission is to protect the healthcare worker
- OSHA has no mandate over patient care, how it is delivered or patient outcomes (unlike TJC or NC Division of Health Service Regulations)
- OSHA Rule is required compliance under Federal Law (1991)
- Fines (maximum)-\$13,260 violation, \$132,598 willful

## Occupational Exposure to Bloodborne Pathogen Standard, 1991



# OSHA INSTRUCTION

U.S. DEPARTMENT OF LABOR

Occupational Safety and Health Administration

**DIRECTIVES NUMBER:** CPL 2-2.69

**EFFECTIVE DATE:** November 27, 2001

**SUBJECT:** Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens

### ABSTRACT

**Purpose:** This instruction establishes policies and provides clarification to ensure uniform inspection procedures are followed when conducting inspections to enforce the Occupational Exposure to Bloodborne Pathogens Standard.

**Scope:** This instruction applies OSHA-wide.

**References:** 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens  
OSHA Instruction CPL 2.103, Field Inspection Reference Manual

**Cancellations:** This instruction cancels CPL 2-2.44D

## Revised CPL Enforcement Document - 2001

# BBP Standard Scope and Application

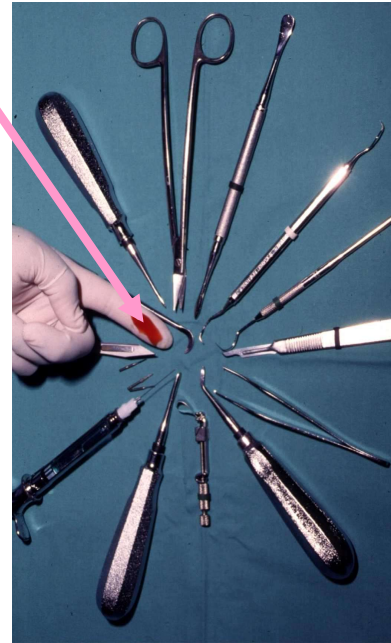
- Applies to **all employees** with occupational exposure to blood or other potentially infectious materials (OPIM) and includes:
  - All private sector employees
  - All public sector employees
  - Students receiving compensation (teaching/graduate assistants, internships)
- Does not include:
  - Self-employed persons
    - ◆ Includes sole practitioners and partners
  - Students not receiving compensation
  - Other employees covered by other federal statutes

## Employees Potentially At Risk

- Physicians and surgeons
- Nurses
- Phlebotomists
- Medical examiners
- Dentists and dental workers
- Clinical/diagnostic laboratory workers
- Medical technologists
- Nursing home personnel
- Dialysis personnel
- Laundry and housekeeping employees

## Types of Occupational Exposures to Bloodborne Pathogens

- Percutaneous injury (PI)
- Mucous membrane
- Non-intact skin



# Infection Control Program Components

---

Develop written institutional Exposure Control Plan

- Exposure Determination
- Control Methods
  - Universal (Standard) Precautions
  - Engineering Controls
  - Work Practice Controls
  - Personal Protective Equipment

## Infection Control Program Components (cont)

- HBV Vaccination
- Post-Exposure Evaluation and Follow-up
- Regulated Waste Disposal
- Tags, Labels, and Bags
- Housekeeping Practices
- Laundry Practices
- Training and Education of Employees
- Record Keeping



# Exposure Determination

---

## Considerations

- Employer shall identify all employees who are directly exposed or whose jobs have the likelihood of exposures to blood or other potentially infectious materials (OPIM)
- Employer shall make an exposure determination without regard to use of personal protective equipment (PPE)

## Fluids Recognized by CDC as Directly Linked to Transmission of HBV and/or HIV

blood

bloody body fluids

semen

vaginal secretions

amniotic fluid

saliva in dental settings

cerebrospinal fluid

synovial fluid

pleural fluid

peritoneal fluid

pericardial fluid

# Bloodborne Pathogens

- Pathogenic organisms that are present in human blood, *and*
  - Can cause disease in humans
- ***Includes but not limited to:***
  - Hepatitis B virus (HBV)
  - Hepatitis C virus (HCV)
  - Human immunodeficiency virus (HIV)

# Other Bloodborne Pathogens

(linked to blood exposures)

- Malaria
- Syphilis
- Babesiosis (protozoan)
- Brucellosis
- Leptospirosis
- *Staphylococcus aureus*
- Arboviral infections (spread by mosquitoes and ticks-West Nile)
- Relapsing fever-tickborne
- Human T-Lymphotropic Virus Type 1 and 2
- Viral hemorrhagic fevers (includes Ebola, Marburg, Lassa fever, yellow fever viruses)

# OSHA Enforcement Revisions - Provider Services

- Shared responsibility between the contract provider and the host employer to ensure compliance with OSHA standards.
- Contract provider (who send their employees to work at other facilities to be employers) is responsible for providing:
  - General bloodborne pathogen training
  - Appropriate vaccinations
  - Follow-up evaluations to exposure incidents
- Host employer is responsible for providing:
  - Site-specific training
  - Personal protective equipment (PPE)
  - Control of potential hazards and exposure conditions

## OSHA Enforcement Revision – Exposure Control Plan

- Reviewed and updated annually\* (new or modified tasks, procedures, equipment)
- Procedure to evaluate circumstances surrounding exposure incidents
- Use of Body Substance Isolation or **Standard Precautions is acceptable** as long as all provisions of standard are adhered to.

\* Annual = 365 days from last review

## Control Measures Universal Precautions

---

“Universal (standard-used for all patients) precautions” refers to a method of infection control in which all human blood and OPIM are treated as if known to be infectious with HIV and HBV. Universal precautions does not apply to feces, nasal secretions, sputum, sweat, tears, urine or vomitus unless they contain visible blood.

# Control Measures

## Engineering Controls

---

Use of available technology and devices to isolate or remove hazards from the worker

Considerations: Engineering Controls

- should be used in preference to other control methods
- must be examined and maintained or replaced on a regular scheduled basis to ensure their effectiveness



## Examples of Engineering Controls

(only acceptable reason for not choosing a safety device is patient safety; must be evaluated by HCF to replace non-safety devices)

- Needleless IV systems
- Lasers (in place of scalpels), staples (not sutures)
- One-way cardiopulmonary resuscitation (CPR) airway-masks
- Handwashing facilities placement
- Sharps containers (do not have to walk for disposal)
- Self-sheathing needles
- Blunted sutures/sutureless products when appropriate (e.g., blunt safety needles cannot be used safely on surgery of all types)
- Safety scalpel that are disposal

## OSHA Enforcement Revision – Evaluation of Devices

- The employer must:
  - Review and evaluate available and new engineering control devices on an annual basis
  - Train employees on safe use and disposal
  - Implement use of appropriate engineering controls and devices
  - Document evaluation and implementation in the exposure control plan (ECP)

## Needlestick Safety and Prevention Act

### November 2002

---

- Directs OSHA to revise BBP standard to clarify requirement for employers to evaluate safer needles and involve employees in identifying and choosing devices
- **Requires** documentation of frontline provider participation in the evaluation of **safety devices** and decision making in product purchasing.
- Required to document any difficulties in implementing safety devices such as interference with medical procedures or not available

## OSHA Enforcement Revision - Action List

- Collect data on device-related injuries including how exposure occurred . . .
  - type (puncture vs cut) and brand of device
  - circumstances of injury (what time of day, location)
  - job category of injured provider
- Purpose is to use information on injuries to guide the selection and implementation of safety devices for your facility

# Control Measures

## Work Practice Controls

---

Alterations in the manner in which a task is performed to reduce likelihood of exposure

Considerations: Work Practice

- Handwashing ASAP after glove removal or contact with body fluids
- All PPE removed ASAP after leaving work area and placed in designated container for storage, decontamination, or disposal
- Used needles and sharps shall not be sheared, bent, broken, recapped or resheathed by hand.



## **NEVER:**

**Recapped By Hand**

**Removed From  
Disposable Syringes**

**Bent, Cut Or Broken  
By Hand**

# Control Measures

## Work Practice Controls

---

### Considerations: Work Practice (cont)

- All procedures performed to minimize splashing and spraying
- Prohibit eating, drinking, smoking, applying cosmetics or lip balm in work areas where reasonable chance of exposure
- Prohibit storage of food and drink in refrigerators or freezers, shelves, cabinets or countertops or benchtops where blood or OPIM are present

# Personal Protective Equipment (PPE)



- PPE is the last in the hierarchy of control measures.
- Gloves, masks, protective eyewear



# Personal Protective Equipment

Specialized clothing or equipment used by workers to protect themselves from direct exposure to blood or OPIM

Considerations: PPE

- Employer shall provide and assure employee use of appropriate PPE such as gloves, gowns, laboratory coats, fluid resistant aprons, face shields, or masks, eye protection and mouthpieces, resuscitation bags, pocket masks or other ventilation devices
- Change if visibly soiled

“Assure”-policy in place for disciplinary action: first offense-warning; second offense-re-education; third offense-affect merit raise; fourth offense-termination

## Personal Protective Equipment (cont)

- Equipment shall be available in a variety of sizes and readily accessible
- Employer provides for the cleaning, laundering or disposal of all PPE
- Disposable gloves replaced when visibly soiled, torn, or punctured, and shall not be washed or disinfected for reuse.
- Utility gloves may be cleaned and disinfected for reuse if they show no signs of deterioration

## Recommendations for Gloving

Remove gloves that are torn, cut or punctured



Do not wash, disinfect or sterilize gloves for reuse

# Gloves

- Gloves are worn for three reasons:
  - To minimize the risk of health care personnel acquiring infections from patients.
  - To prevent pathogenic organisms from being transmitted from health care personnel to patients.
  - To reduce contamination of health care personnel's hands by organisms that can be transmitted from one patient to another

## Protective Face Masks, Surgical Masks, and Eye Guards

- Required when contamination of mucous membranes of eyes, nose and mouth with body fluids may occur through splashes or aerosolization of these fluids.
- Prescription glasses may be used as protective eyewear as long as they are equipped with solid side shields.
- If protective eyewear is chosen over the use of a face shield, the eyewear must be worn in combination with a mask to protect the nose and mouth.

## HBV Vaccination

- HBV vaccination shall be offered, at no cost, after training and within 10 days of initial job assignment, to all employees whose jobs include risk of directly contacting blood or OPIM
- Vaccinations shall be given according to recommendations for standard medical practice
- A declination form must be signed by employee who refuses the HBV vaccination (including those who do not complete the 3 shot series)



## Post-Exposure Management Program

- Clear policies and procedures on how to manage employees
- Education of healthcare workers including principles of post-exposure management, importance of prompt reporting, PEP efficacy/toxicity
- Resources for rapid access to
  - Clinical care
  - Post-exposure prophylaxis (PEP) within 72 hours
  - Testing of source patients/HCP



## Post-Exposure Evaluation and Follow-up

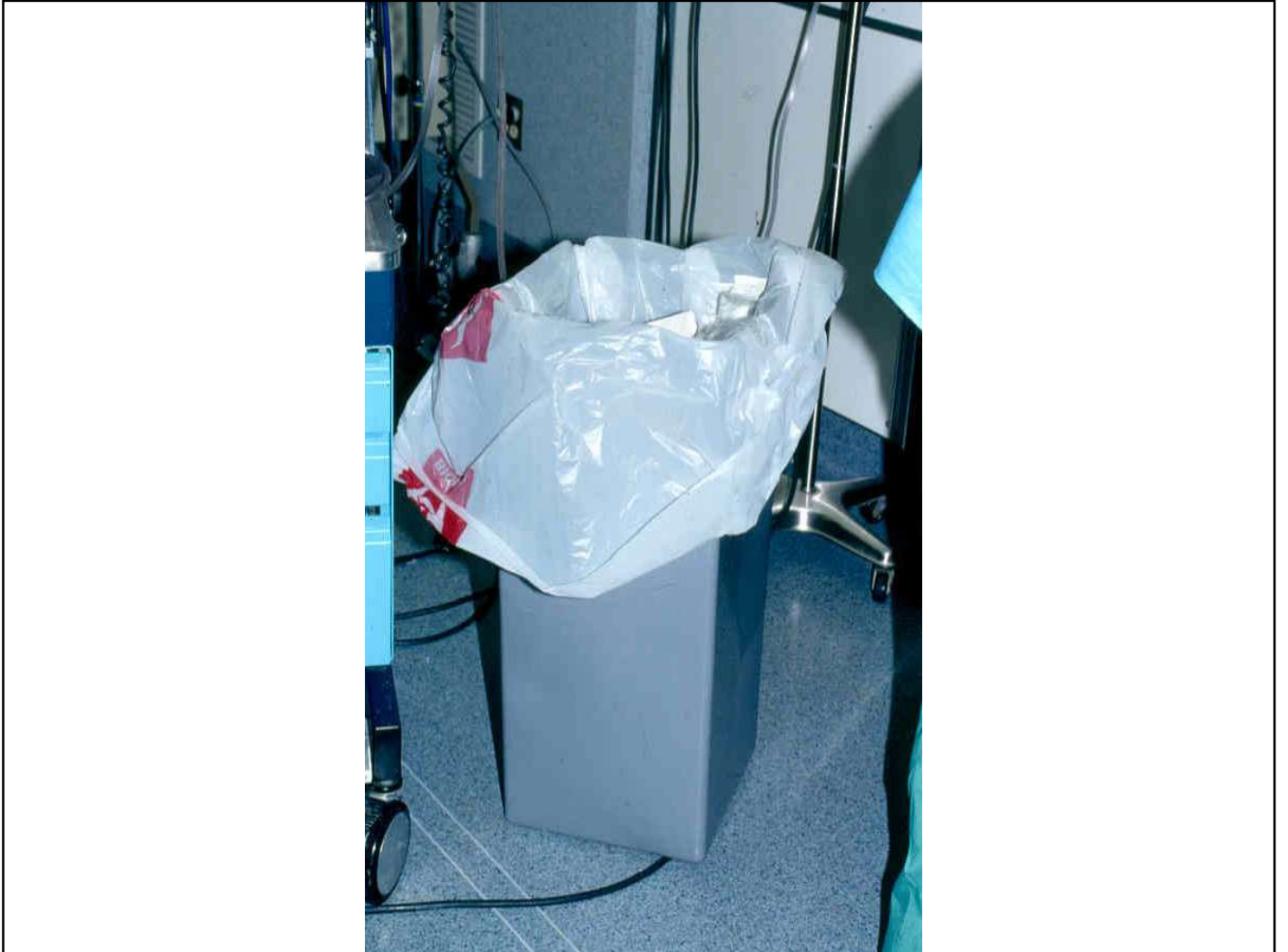
- Within 15 days following report of an exposure incident, the employer shall make available to employee a confidential medical evaluation and follow-up
- Employer shall document the route of exposure, HBV and HIV status of the source patient, if known, and the circumstances under which the exposure occurred
- Employer shall notify the source patient of the incident, obtain consent if necessary and test the source for HIV or HBV unless known positive

## Post-Exposure and Evaluation Follow-up

- Employer shall offer to collect a blood sample from the exposed worker ASAP to test for HIV and or HBV status (if requested, must hold for 90 days)
- Employer shall offer HIV testing of baseline, 6 weeks, and 6 months after exposure
- Follow-up shall include counseling, medical evaluation of any febrile illness that occurs within 12 weeks
- Post-exposure prophylaxis when indicated, as recommended by US Public Health Service (PEP for HIV ASAP, must be <72 hours)

## OSHA's Definition of Medical Waste

OSHA states “regulated waste” is (1) liquid or semi-liquid blood or other potentially infectious material; (2) contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; (3) items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; (4) contaminated sharps; and (5) pathological and microbiological wastes containing blood or OPIM







## Regulated Medical Waste (RMW) Disposal

---

- Disposal of RMW shall be in accordance with all applicable federal, state, and local regulations
- All RMW shall be placed in closable, leakproof containers, or bags that are color-coded, labeled or tagged
- Disposable syringes, needles, scalpel blades and other sharp items shall be placed in puncture-resistant containers for disposal

## Regulated Medical Waste Disposal (cont)

- Puncture-resistant sharps containers shall be easily accessible to workers and located in areas where they are commonly used
- Double-bagging prior to handling, storing, and/or transporting is necessary if the outside of the bag is contaminated
- Lab specimens of body fluids shall be transported in a container that will prevent leaking and disposed of in accordance with institutional policies and regulatory requirements





## Tags, Labels, and Bags

---

- Tags that are orange-red in color with a contrasting background are acceptable
- Tags shall contain the word “BIOHAZARD” or the biological hazard symbol and
- State the specific hazardous condition or the instructions to be communicated
- Word and message must be understandable to all

## Tags, Labels, and Bags (cont)

---

- Label tags may be part of container or affixed as closely as possible by wire or adhesive to prevent their loss
- Red bags or red containers may be substituted for labels on containers of Regulated Medical Waste
- All employees must be informed of meaning of labels/tags

# Handling Specimens

---

- Employers may avoid labeling only if all employees who have contact with specimen containers can recognize them as requiring Universal Precautions and the employees have been trained to follow Universal Precautions
- Employers must label or color-code specimen containers whenever they leave the facility

# Housekeeping Practices

- Employer shall assure that the worksite is maintained in a clean and sanitary condition
- Employer shall determine and implement an appropriate cleaning schedule for rooms where BBP are depending on the site, type of surface, and amount of soil present
- Employer shall ensure that housekeepers wear appropriate PPE including general purpose utility gloves during all cleaning of BBP and decontamination procedures

## Housekeeping Practices (cont)

- Initial clean-up of blood or OPIM shall be followed with the use of an EPA-approved hospital disinfectant chemical germicide that has either a tuberculocidal or HIV/HBV label claim or a solution of 5.25% sodium hypochlorite (household bleach) diluted between 1:10 and 1:100 with water
- Equipment contaminated with blood or OPIM shall be decontaminated if possible prior to servicing or shipping



# Laundry Practices

- The employer shall ensure that laundry workers wear protective gloves and other appropriate PPE during handling and sorting of linen.
- Contaminated laundry shall be bagged at the location of use and not sorted or rinsed in patient areas.
- Contaminated laundry shall be placed and transported in bags that are labeled or color-coded that prevent leakage.
- When a facility uses UP in the handling of all soiled laundry, alternative labeling is acceptable if recognizable by all workers.



# Provider Education and Training



- Strategies to prevent occupational exposure to blood
- Importance of reporting exposure incidents
- New employee orientation
- Annual inservices
- New procedure or equipment

# Training

- Employers must train at-risk employee at no cost and on paid time
- Must train at time of initial assignment and at least annually thereafter, or if new occupational exposure

## Training (cont)

- Training program must include
  - accessible copy of regulatory text of standard and explanation
  - general epidemiology and symptoms of BBP
  - explanation of modes of transmission
  - explanation of employer's exposure control plan and how to get a copy

## Training (cont)

- Training program must include
  - explanation of appropriate methods for recognizing tasks that may involve exposure
  - explanation of the use and limitations of methods to prevent exposures
  - info on types, use, locations, removal, handling of PPE
  - explanation of basis for selection of PPE

## Training (cont)

- Training program must include
  - info on actions and persons to contact for exposure to BBP
  - method for reporting on exposure incidents
  - info on post-exposure evaluation and follow-up
  - explanation of signs and labels
  - opportunity to question trainer about standard; therefore, training cannot be totally by videotape

# Recordkeeping

- The employer must **keep training records** with the following information:
  - The dates of the training session
  - The contents or a summary of the training session
  - The names and qualifications of the persons conducting the training
  - The names and job titles of all persons attending the training sessions
- **Employers must keep these records for 3 years from the date of the training session**

## Exposure Control Plan Requirements

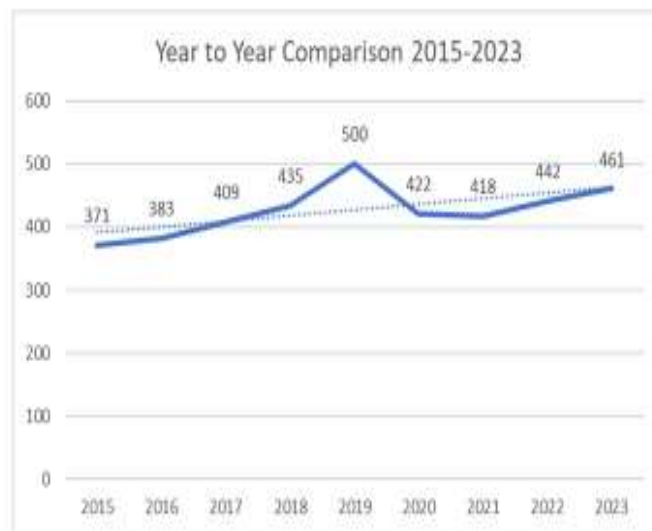
- In annual review of ECP employers must consider innovations in procedure or technological developments that reduce the risk of sharps exposure.
- Must state methods used to evaluate and justification for decisions on safety devices.

## Federal Legislation on Needle Safety

- Bloodborne Pathogens Standard amended with Needlestick Law requirements (Federal Register January 18, 2001)
  - Defining “engineering controls”
  - Exposure control plan requirements
  - Soliciting employee input
  - Recordkeeping



## Year to Year Comparison 2015-2023

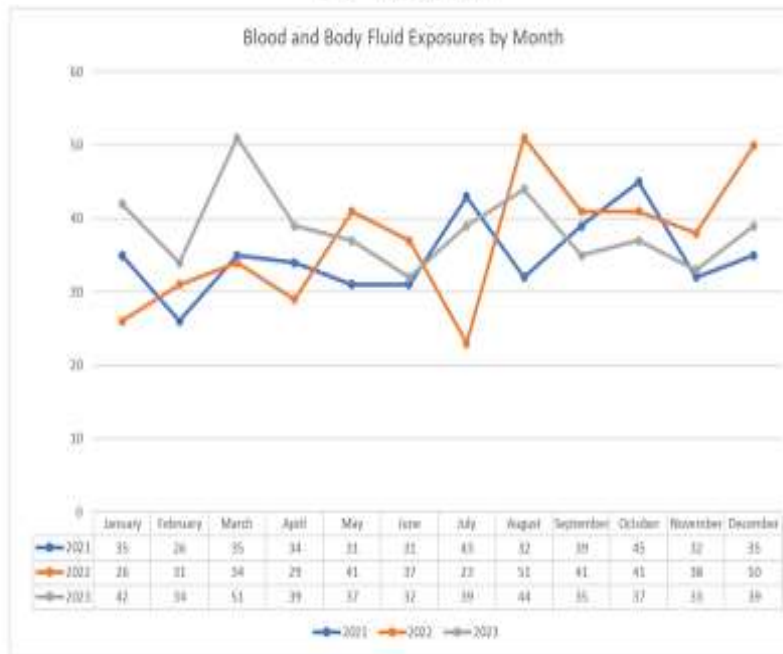


**Total for 2023: 461\*\***  
Blood: 446  
Other fluid: 27  
Two-way: 20  
Employee to patient: 1

\*Some exposures had multiple types of fluid

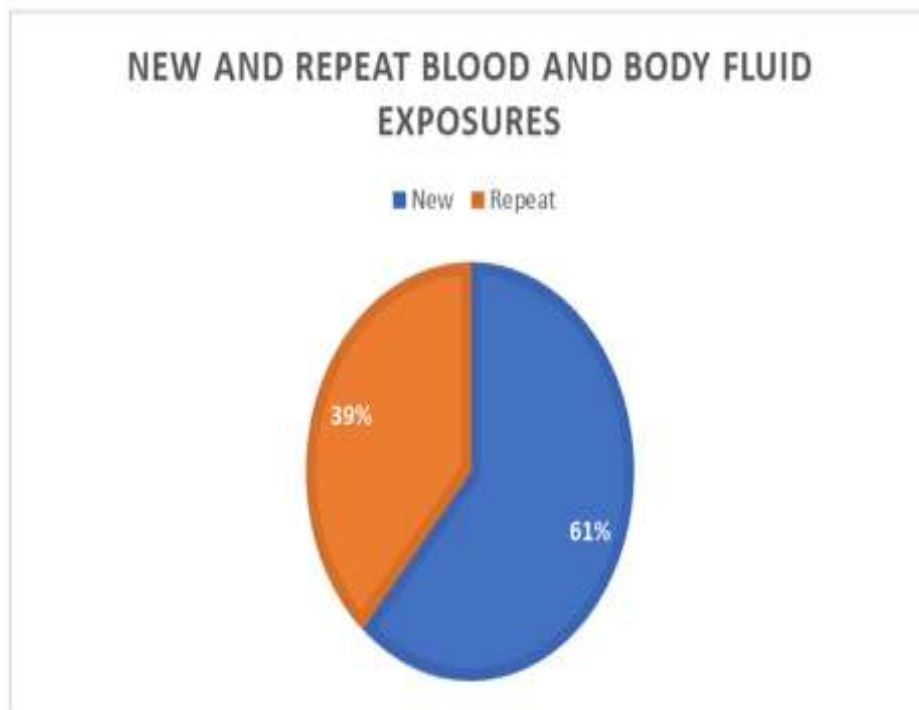
**\*\*As of January 2024.**

## 2021, 2022, and 2023: Blood and Body Fluid Exposures by Month

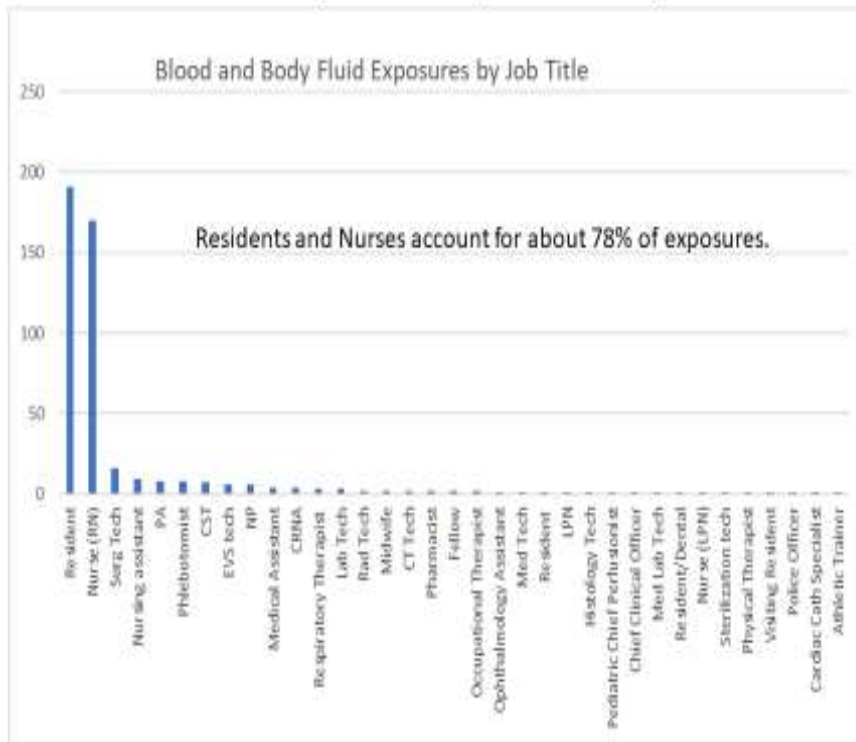


Total for Year as of  
January 2024: 461

## New vs. Repeat

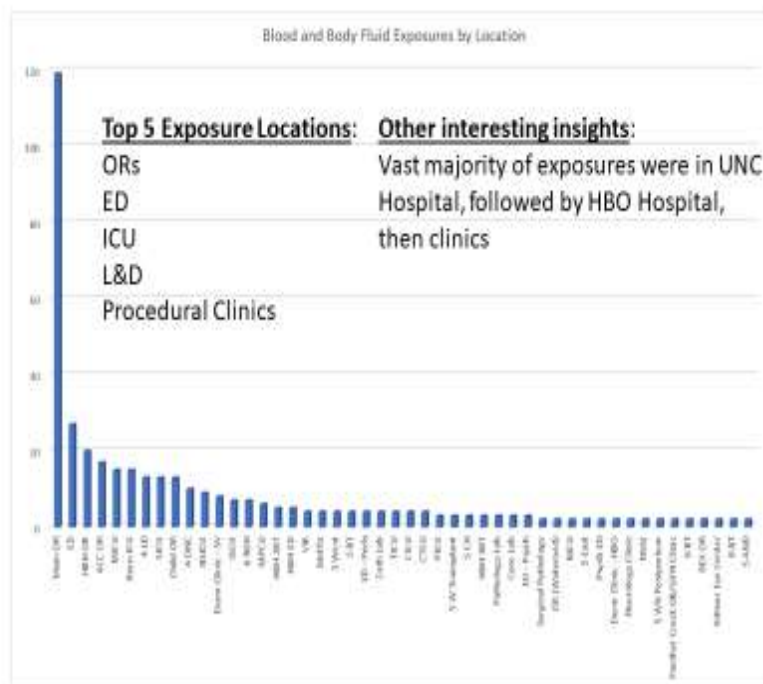


## Blood and Body Fluid Exposures by Job Title



# Blood and Body Fluid Exposures by Location

Areas with >1 exposure



## Blood and Body Fluid Exposures by Location

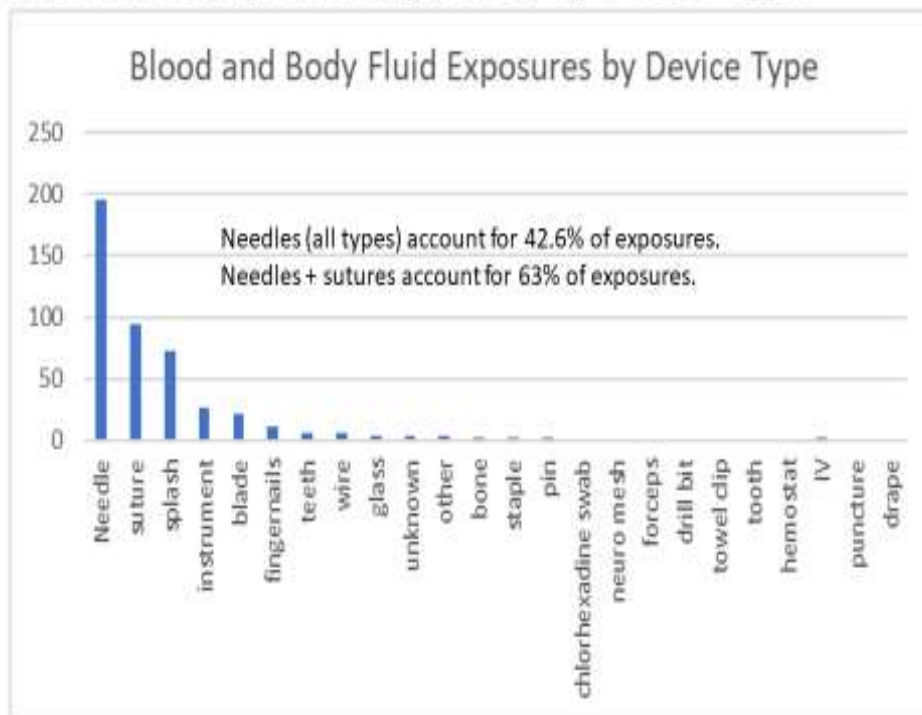
### Areas with 1 exposure

5 Neurosciences
Dental Clinic
OPT Oncology Infusion
Eastowne - Endo
Dental School
Eastowne - Same Day Clinic
CT Radiology
3 WH
Ortho Clinic - ACC
Children's Speciality Clinic CPill
Pre -Op
5 WH Nursery
Surgery Clinic
Wound Care Clinic - Meadowmont
4 Womens
WSU (Women's Speciality Unit)
Central Sterile
ENT Nelson Hwy
Cysto
Fam Med Clinic - Carroway
PACU
Fluoro
Ped Hem/Onc
GI Procedures

Rehab
GYN/Onc Clinic
4 Women's
Children's Speciality Clinic in CH
4W L&D
Children's Speciality Clinic in Raleigh
Morgue
HBH 4 BT
CRC Phys Med & Rehab Clinic
6 Memorial
ACC PACU
HBH Lab
OHS/Employee Health
4 West
Adams School of Dentistry
HBH VIR
OR/LD (Wakemed)
ID clinic
Ortho Clinic - Panther Creek
Img & Spine Center
Pain Mgmt Clinic- Quadrangle dr.
Infusion Clinic
Antepartum
Carolina Vascular Access Clinic

Blood Bank
7 CH
Dental Clinic - Peds
4 MICU
REX Cath Lab
Lobby
Rockingham Hosp OPT Infusion Ctr
7 NSH
Surg Onc Clinic
3 AND
Main Preop
Urology Clinic
5 Children's
MIGS Clinic
Inpatient Hospice House
2 NSIU
ED (Wakemed)
ISCU

## Blood and Body Fluid Exposures by Device Type



### Type of Blood-Borne Virus: Source Patient

	HIV	Hepatitis B	Hepatitis C	Unknown
JANUARY	1	0	0	4
FEBRUARY	0	0	1	4
MARCH	0	0	1	3
APRIL	0	0	1	4
MAY	1	0	0	2
JUNE	0	0	1	6
JULY	0	0	1	5
AUGUST	2	2	0	5
SEPTEMBER	3	1	0	3
OCTOBER	1	0	0	5
NOVEMBER	1	0	0	6
DECEMBER	2	1	0	2
<b>TOTALS</b>	<b>11</b>	<b>4</b>	<b>5</b>	<b>49</b>

2.38% of exposures

0.87% of exposures

1.08% of exposures

10.61% of exposures



## Care After Viral Exposure

Care by OHS	Number of Employees
Employees sent to the ED after hours	22
Employees given PEP	38
Employees who declined PEP	7
Employees given HBIG	5 *most have had Hep B shot
Employees who declined HBIG	0
Employees offered serial monitoring for Hepatitis C	41

# Impact of Safety-Engineered Devices on the Incidence of BBP Exposures at UNC Hospitals

Kanamori et al. ICHE. Feb 2016

Overall BBP exposures and incidence of percutaneous injuries reduced

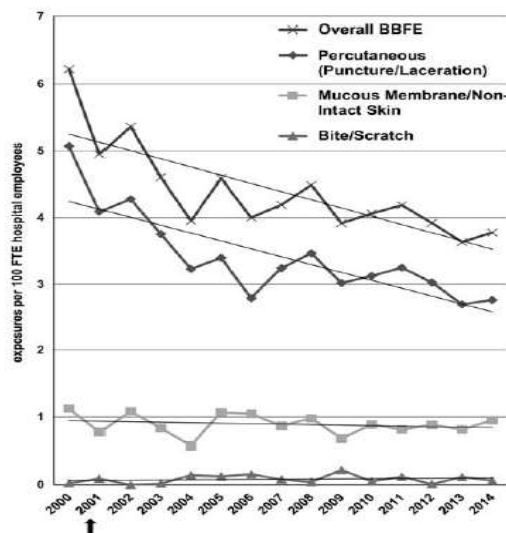
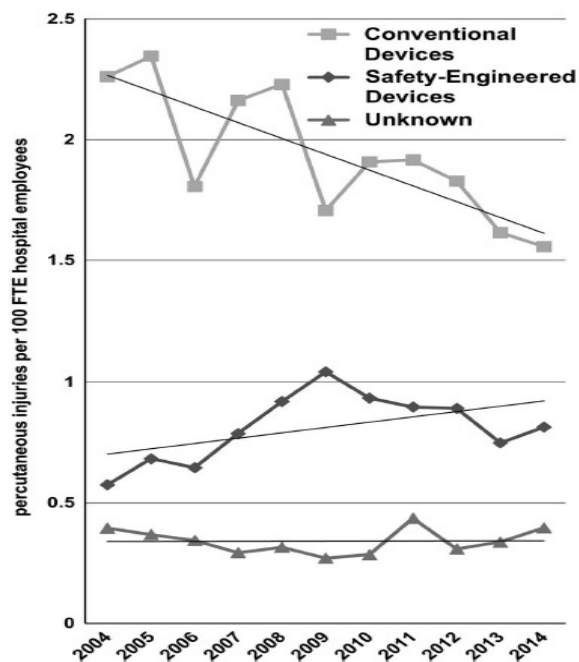


FIGURE 1. Incidences of blood and body fluid exposures (BBFE) by nature of injury among healthcare personnel, University of North Carolina Hospitals, 2000–2014. Arrow shows the year 2001 of the Needlestick Safety and Prevention Act. FTE, full-time equivalents.

# Impact of Safety-Engineered Devices on the Incidence of BBP Exposures at UNC Hospitals

Kanamori et al. ICHE. Feb 2016

Incidence rate associated with percutaneous devices significantly reduced and percutaneous injuries associated with safety-engineered devices increased



# Impact of Safety-Engineered Devices on the Incidence of BBP Exposures at UNC Hospitals

Kanamori et al. ICHE. Feb 2016

The incidence rate for overall BBP was significantly reduced

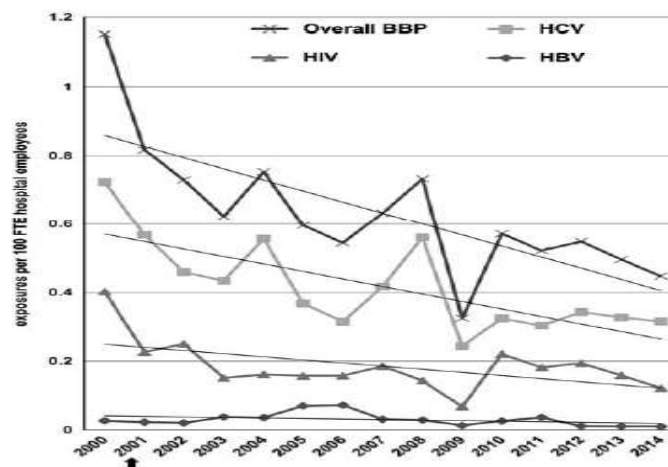


FIGURE 3. Incidences of blood and body fluid exposures by source positive for bloodborne pathogens (BBP) among healthcare personnel, University of North Carolina Hospitals, 2000–2014. Arrow shows the year 2001 of the Needlestick Safety and Prevention Act. FTE, full-time equivalents. HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus.

## Soliciting Employee Input

- Employers must invite participation of non-managerial employees who are potentially exposed to sharps injuries to participate in identification, evaluation and selection of engineering and work practice controls.
- Explain in exposure control plan how employer solicited employee participation.

## OSHA Enforcement Revisions - Home Health

The American Dental Association v. Martin decision upheld the bloodborne pathogen standard but restricted its application in home health services provided in private homes.

- . . . feasibility of off-site control not appropriate
- . . . OSHA may not cite employers when hazard is site-specific (housekeeping requirements such as clean and sanitary worksite, handling and disposal of regulated waste, ensuring use of PPE, engineering controls and handwashing)

## OSHA Enforcement Revision - Home Health (cont)

- The employer will be held responsible for all non-site specific requirements of the exposure control plan
  - hepatitis B vaccination
  - post-exposure evaluation and follow-up
  - recordkeeping
  - generic training requirements
  - appropriate supply of PPE

## OSHA's Mandate

---

- OSHA's mission is to protect the healthcare worker
- OSHA Rule is required compliance under Federal Law