Surface Monitoring Recommendations for Hazardous Drugs: Does Health System Size or Location Matter?

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View faculty bios at
ashpadvantage.com/surfacemonitoring

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1.5 contact hours (0.15 CEUs)
Application-based

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The following person in control of this activity's content has a relevant financial relationship:

Patricia Kienle – BD: Stock owner

All other persons in control of content do not have any relevant financial relationships with an ineligible company.

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Learning Objectives

At the conclusion of this educational activity, participants should be able to

- Summarize the status of USP Chapter <800> and other guidelines and consensus recommendations pertaining to the safe handling and monitoring of hazardous drugs (HDs) in the drug-use process
- Apply strategies for implementing safe handling recommendations and HD monitoring
- List surfaces that should be monitored for HD contamination
- Develop an action plan for routine monitoring of surfaces for HD contamination and post-spill analysis based on the surface monitoring results

Where Are We Now? Reflections on Domestic and International Guidelines for Monitoring Hazardous Drug Contamination

Patricia C. Kienle, M.P.A., BCSCP, FASHP

The Issues

- Why should surface monitoring be considered?
- Who does this?
- Where should it be done?
- How should it be done?

Primum non nocere

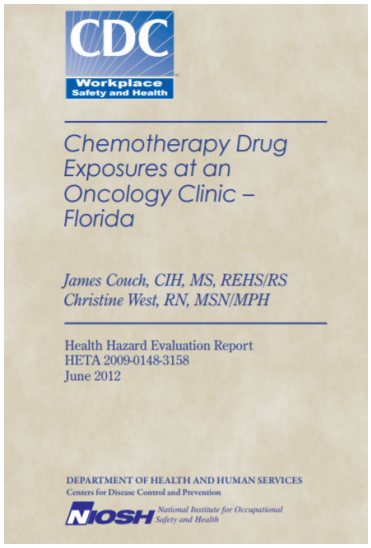
- Clearly refers to our responsibility to patients, but also means we need to remain safe
- Limiting exposure to hazardous drugs (HDs) is a key safety step
  - Minimize contamination
  - Monitor to detect contamination

Primum non nocere = first, do no harm

Is There a Problem?

- Years of research concerning contamination
  - 1980s: Association between exposure to antineoplastics and adverse reproductive effects
    - Miscarriages, congenital malformations, low birth weight, and infertility
  - 1990s: Link between cancer in healthcare workers and their exposure to antineoplastic agents

Resources



- Roussel C. et al. Meta-analysis of chromosomal aberrations as a biomarker of exposure in healthcare workers occupationally exposed to antineoplastic drugs. Mutation Research/Reviews in Mutation Research (2017)
- NIOSH Health Hazard Evaluation: Chemotherapy Drug Exposures at an Oncology Clinic (June 2012) https://www.cdc.gov/niosh/hhe/reports/pdfs/2009-0148-3158.pdf

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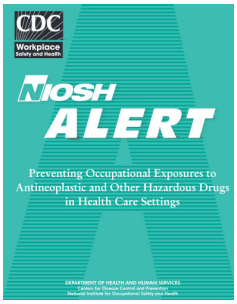
Standards and Guidance



Practice Guideline > Am J Health Syst Pharm. 2018 Dec 15;75(24):1996-2031.
doi: 10.2146/ajhp180564. Epub 2018 Oct 16.

ASHP Guidelines on Handling Hazardous Drugs

Luci A Power [1], Joseph W Coyne [2]

USP Chapter <800>
Hazardous Drugs – Handling in Healthcare Settings

ISOPP
Standards of Practice

Safe Handling of Cytotoxics

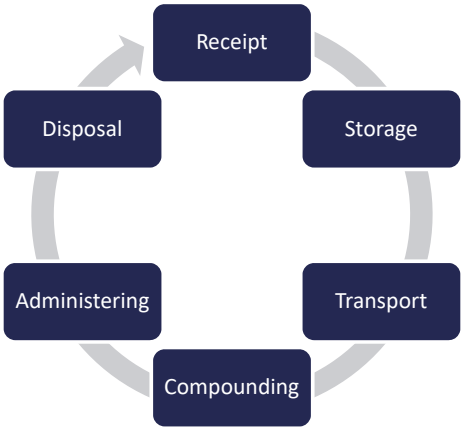
NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations

ISOPP = International Society of Oncology Pharmacy Practitioners
NAPRA = National Association of Pharmacy Regulatory Authorities

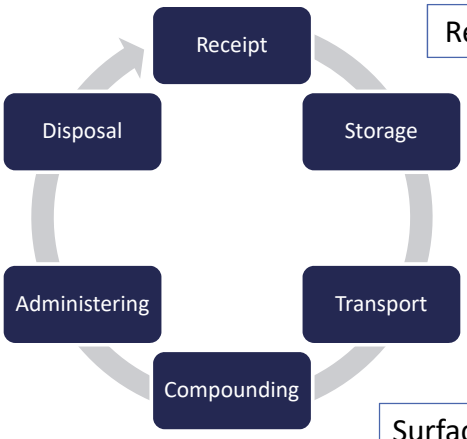
Environmental Monitoring

- USP chapter <797> requirements for microbial monitoring
- Frequency allows multiple data points
- Why don't we use the same logic for HDs?

HD Surface Contamination



HD Surface Contamination



Residue on packages

Disposal and spills

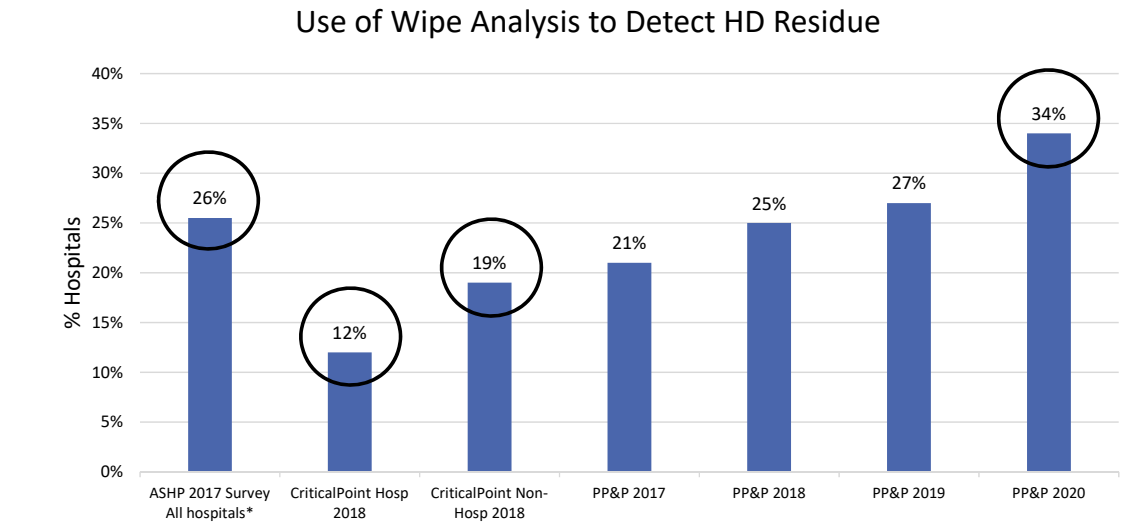
Breakage

Surface contamination on patient chairs, IV pumps, toilets, and sinks

Surface contamination in hoods and rooms

Development Process in the US

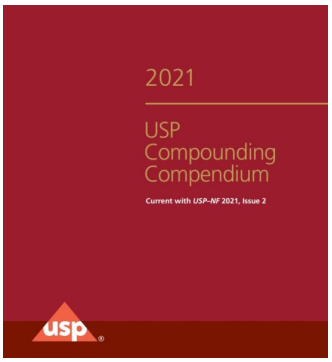
Information from Surveys



PP&P = Pharmacy Purchasing & Products

Documents

- NIOSH
  - 2020 Draft: Managing Hazardous Drug Exposures: Information for Healthcare Settings
- USP chapter <800>
  - Hazardous Drugs: Handling in Healthcare Settings



Graphic courtesy of USP.

Our Spanish Society Colleagues

- Valero-Garcia S, Gonzalez-Haba E, Gorgas-Tomer et al. Monitoring contamination of hazardous drug compounding surfaces at hospital pharmacy departments: a consensus statement. Practice guidelines of the Spanish Society of Hospital Pharmacists (SEFH). *Farm Hosp.* 2021; 45(2):96-107.

Why Isn't Wipe Sampling Done?

- No specific US regulation requiring it
- But there is organizational oversight
  - Occupational Safety and Health Administration (OSHA)
  - Scientific publications
  - Risk tolerance

Image used with permission.

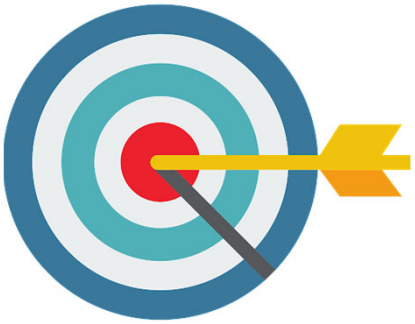
Dealing with Barriers to Detection of Containment

- Potential barriers
  - Cost
  - Fear of results
- Sources of help
  - Risk Management
  - Employee Health

Image used with permission.

Triage Your Needs

- HDs used
- Locations to test



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Testing Location Suggestions

- HD storage areas
- Compounding areas
  - In front of BSC
  - Door, refrigerator, and pass-through handles
  - Staging areas
- Patient care areas
  - Infusion chairs
  - IV pumps
  - Patient toilet rooms

BSC = biological safety cabinet

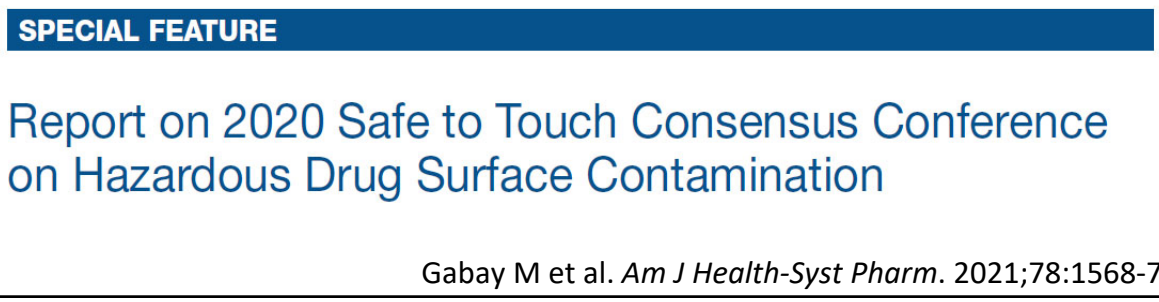
Image used with permission

When to Test?

- Baseline
  - Before initial use of facility or equipment
  - As a starting point
- Routine
  - At the end of the workday, before decontamination and cleaning
- After spill cleanup

Safe to Touch Seminar

- Participation by individuals and stakeholder organizations in September 2020
- Development of consensus statements



Gabay M et al. *Am J Health-Syst Pharm*. 2021;78:1568-75.

Consensus Statements …

- Establish administrative control
  - Create an effective surface monitoring program
  - Recognize barriers to HD surface monitoring programs
  - Establish surface-monitoring policy for all sites where HDs are handled
  - Develop setting-specific sampling plan
- Improve work practices
  - Reduce occurrence of HD surface contamination
- Monitor
  - Use both qualitative and quantitative tests
  - Report results in standardized format

Gabay M et al. *Am J Health-Syst Pharm*. 2021;78:1568-75.

… Consensus Statements

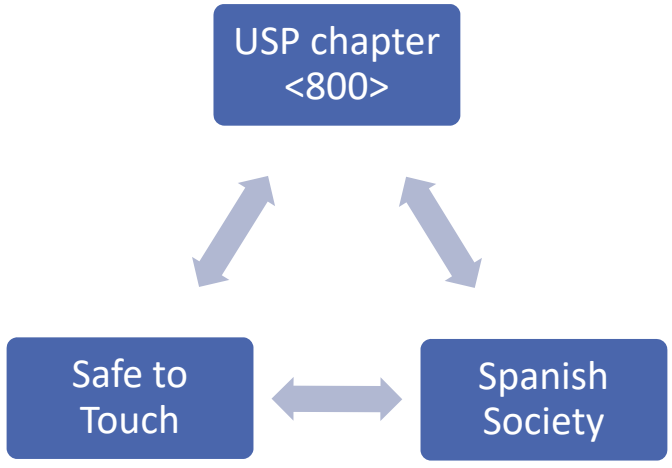
- React to results
  - Mitigate HD spills and commit to decontamination
  - Implement safety practices related to HD preparation and administration
  - Collaborate to highlight importance and increase scope of HD surface monitoring
- Improve practice
  - Conduct more research on HD surface contamination

Gabay M et al. *Am J Health-Syst Pharm*. 2021;78:1568-75.

Testing Systems

Traditional Technology	Lateral Flow Immunoassay
Sample sent to specialized laboratory	Sample inserted into reader at practice site
Reports provided for selected panel of agents	Detects specific agent
Laboratory returns report in several weeks	Results available within an hour

Comparing Recommendations



Valero-Garcia S et al. *Farm Hosp.* 2021;45(2):96-107; United States Pharmacopeial (USP) Convention. https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare (accessed 2021 Oct 7); Gabay M et al. *Am J Health-Syst Pharm*. 2021;78:1568-75.

When HD Contamination is Detected

- Evaluate the site and potential sources of contamination
- Decontaminate, clean, and disinfect the area
- Retest to determine success of mitigation

Sample Approach to Detecting Contamination

LOCATION	CONTAMINATION RISK	FREQUENCY OF HD MANIPULATION		
		VERY COMMON	MODERATE FREQUENCY	RARE
		≥ 5 times/week	1-4 times/week	<1 times/week
C-PEC surface	HIGH	Monthly	Every 3 months	Every 6 months
Floor in front of C-PEC	HIGH	Monthly	Every 3 months	Every 6 months
Carts and counters	MEDIUM	Every 3 months	Every 6 months	Every 6 months
C-SEC door	MEDIUM	Every 3 months	Every 6 months	Every 6 months
Preparation areas	LOW	Every 6 months	Every 6 months	Every 6 months

C-SEC = containment secondary engineering control

Adapted from Valero-Garcia S et al. *Farm Hosp.* 2021;45(2):96-107.

Contamination Detected

- Decontaminate and clean
- Present results to staff
- Attempt to identify the cause
- Evaluate testing frequency
  - High level – increase frequency
  - Medium level – consider increasing frequency
  - Low level – maintain frequency

Standards and Guidance Documents

- National Institute for Occupational Safety and Health (NIOSH) – www.cdc.gov/niosh
  - NIOSH Alert (2004)
  - NIOSH List of Hazardous Drugs (2016)
  - Draft updates (2020)
- United States Pharmacopeial (USP) Convention, <800> Hazardous Drugs – Handling in Healthcare Settings (2016) – www.usp.org/compounding
- American Society of Health-System Pharmacists (ASHP), Guidelines for Handling Hazardous Drugs (2018) – www.ashp.org
- Oncology Nursing Society (ONS) and Hematology/Oncology Pharmacy Association (HOPA), Ensuring Healthcare Worker Safety When Handling Hazardous Drugs (2019) – www.ons.org
- Infusion Nursing Society (INS), Infusion Therapy Standards of Practice (2021) – www.ins1.org

Other Resources

- ASHP National Survey (published every year), www.ajhp.org
- Pedersen CA, Schneider PJ, Scheckelhoff DJ. *Am J Health-Syst Pharm*. 2018; 75:1203-26.
- ASHP On-Demand CE: Best Practices for Monitoring Surfaces for Hazardous Drug Contamination: Consensus Conference Recommendations and Next Steps, https://symposia.ashp.org/lms/content/safesurfaces/ (exp. 2/1/2022)
- CriticalPoint LLC 800 Gap Analysis, https://www.criticalpoint.info/tools-resources/gap-analysis/
- Pharmacy Purchasing and Products, Halvorsen D. 2020; 17(7 suppl):S2-8. https://www.pppmag.com/article/pppv17n7s1

Key Takeaways

- Evidence concerning risks for those working with hazardous drugs has been published since the 1970s
- Guidance documents and testing methods are available
- Risk of hazardous drug contamination occurs in sites of all sizes and includes patient care areas

Telling Our Story: Practical Approaches to Monitoring Surfaces for Hazardous Drug Contamination

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Clinton L. Meachum, CPhT, CSPT

CONE HEALTH®

- Over **1,200** acute care beds
- **5** acute care hospitals
- **6** cancer centers
- **4** outpatient pharmacies
- **2** surgical centers
- Women's and Children's Center
- Stand alone emergency center
- Urgent care facilities
- Specialty clinics
- Physicians' offices

Images courtesy of Cone Health

Moses H. Cone Memorial Hospital

Alamance Regional Medical Center

236 beds

Wesley Long Hospital

175 beds

Annie Penn Hospital

110 beds

Behavioral Health Hospital

80 beds

CONE HEALTH®

Department of Pharmacy Statistics

- 20+ pharmacy locations (inpatient/outpatient)
- Over 350 employees (technicians/pharmacists)
- Six outpatient cancer centers
  - 75 infusion chairs
  - 5,300 outpatient visits per month
- 5 acute care hospitals
- Approximately **36,000** chemo compounded sterile preparations (CSPs) per year
- **6** Hazardous drug cleanrooms
- 15 Biological safety cabinets (used for HDs)
- 2 Hazardous drug IV robots

Cancer Center Location(s)

35

Timeline

2017
- Established USP Chapter <800> Implementation Task Force
- Established Hazardous Drug Committee
- Initiated cleanroom renovations

2018
- Installed IV robotics and gravimetric compounding equipment for hazardous and nonhazardous preparations
- Implemented closed-system transfer devices (CSTDs) system wide

2019 – 2020
- Completed cleanroom renovations
- Hired Pharmacy Regulatory Coordinator
- Insourced terminal cleaning
- Implemented Gemba
- COVID-19

2021
- Reestablished Hazardous Drug Committee
- Required additional training and certification for CSPs
- Initiated environmental sampling program

USP Chapter <800> Implementation Task Force

- Launched early 2017
- **Broad** representation across Cone Health
  - Pharmacy
  - Nursing
  - Quality Improvement
  - Environmental Services & Facilities
  - Accreditation

Goal=Full compliance by end of calendar year 2021

Hazardous Drug Committee

- Priority list….
  - Facilities and engineering controls
  - Controls and alternative containment strategies
  - Standard operating procedures (receipt ➡ disposal)
  - Personal protective equipment
  - Deactivating, decontaminating, cleaning, and disinfecting protocol
  - Environmental and surface monitoring
  - Gap analysis

Speedbump in Our Journey

- Establishing a budget
  - Capital vs. departmental
  - Strategic multi-year commitment
- FTE commitment and turnover
- Informatics System integration
- Organizational commitment
  - Champion across all stakeholders
- Education (non-chemo HDs)
- COVID-19

The Virus in the Room

See official NCBOP Statement Monday, September 23, 2019

"Board staff will not begin inspecting for compliance with USP chapter <800> standards in compounding activities on December 1, 2019."

"…Board staff will begin inspecting for compliance with chapter <800> standards at such time as the revised chapters [for <795> and <797>] go into effect."

NCBOP = North Carolina Board of Pharmacy

February 2020: Pandemic Strikes

- COVID-19 pandemic response became the singular focus of the health system
  - All system resources and strategic planning were diverted to pandemic response
- Q2 2020 Pharmacy tasked with cost-saving opportunities to offset loss of business

Compounding Regulatory Coordinator

- Monthly sporicidal cleaning and ad hoc cleaning
- Safety and regulatory audits and inspections
- Standardization of compounding practices and daily environmental monitoring
- Correction Action & Preventive Action (CAPA)
- Environmental sampling
  - Microbiological surface sampling
  - Hazardous wipe sampling

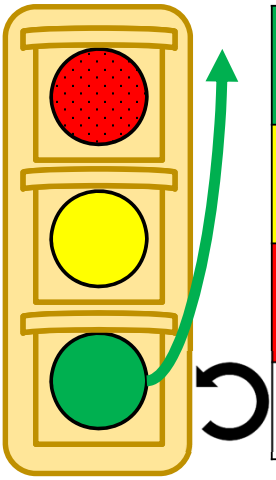
Renewed Call to Action

- Groups began to pick up the pieces
- Pharmacy expanded quality initiatives
- Dedicated and trained observer uncovered variability across practices
  - Inconsistent training
  - Misinterpretation of regulatory requirements
  - Incomplete response to breakdown in environmental controls
  - Potentially (?) ineffective containment strategies

Reengaging Key Stakeholders

1. Updated USP Chapter <800> project charter to reflect new timeline
2. Reengaged or enrolled new Hazardous Drug Committee team members and champions
3. Streamlined efforts of involved groups to accomplish our baseline practice enhancement with the option to expand enrollment as necessary

Follow Me if You Want To Gemba



	GEMBA Communication to Staff	Examples
AWESOME (*continue*)	Celebrate what is going well and reinforce good behaviors/practices	• Environmental monitoring within limits and clearly documented • All multi-dose vials appropriately dated and stored once punctured
OK (*reminders*)	Inconsistencies found; opportunity to provide reminders to improve behaviors/practices	• Mopping under equipment is vital to remove all debris and ensure all surfaces are appropriately disinfected • Monitor equipment for failure or loss of integrity (rust, pitting, etc.)
POOR (*actions required*)	Noncompliant areas requiring immediate actions	• Post warning about handwashing antisepsis step missing from garbing procedure per USP <797> requirements • Observed cell phone use in sterile product compounding area
RESEARCH (*opportunities*)	Review of opportunities to research and implement ideas to improve processes	• Dedicate a safe spot to don gloves in the anteroom to ensure consistent garbing practices • Identify hands free options for

Let's Recap our Journey so far...

Complete	In Progress	Outstanding
• Build an interprofessional coalition • Update all facilities for the receiving, storage, and compounding of HDs	• Expand role of Compounding Regulatory Coordinator • Integrate surface sampling with departmental quality initiatives	• Initiate HD surface sampling • Share results with the organization • Ensure long-term success of surface sampling program

Assessing HD Wipe Sampling Options

Analytical method and source	LFIA (HD Check, BD)	UPLC-MSMS (ChemoAlert, Bureau Veritas)	UPLC-MSMS (ChemoGLO, ChemoGLO, LLC)	UPLC-MSMS (SafeChemo, American Analytics, Inc)
Number of antineoplastic drugs tested	3	1 4	1 7	18
Samples per kit	1 – 20	1 – 10	6	1 – 12
Time to obtain results	<10 minutes	10 – 15 working days	5-7 working days	10 – 15 working days
Relative price	$$	$$$	$$$	$$$
Sampling period (suggested)	Before cleaning	Before or after cleaning	Before or after cleaning	Before or after cleaning

Understanding Your Risk

Hazard

Exposure

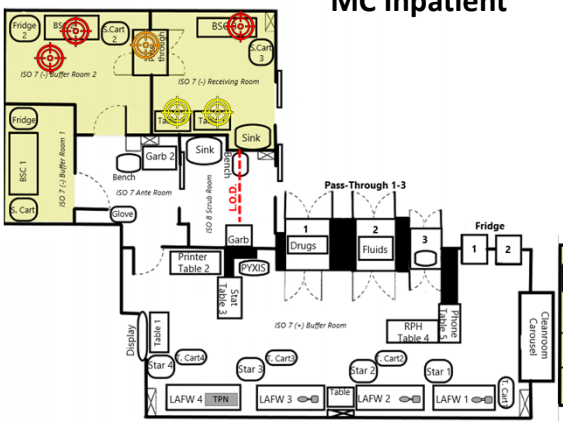
Risk

Photos courtesy of Cone Health.

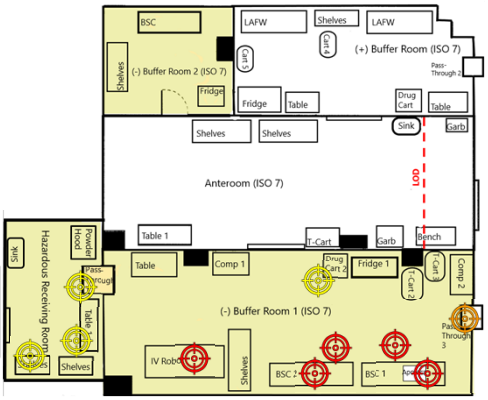
Back to the Gemba

Risk Levels
- Low – Semi-annually
- Medium - Quarterly
- High - Monthly

MC Inpatient



Wesley Long Cancer Center



Life Cycle

Receiving
↓
Storage
↓
Transport
↓
Compounding
↓
Administration
↓
Disposal

Analytics to Guide Strategy: LFIA

Location	Cyclophosphamide	Doxorubicin	Methotrexate
Cone Health Cancer Center			
Wesley Long & High Point MedCenter	High	High	Moderate
Alamance Regional Medical Center & Mebane MedCenter	Moderate	Moderate	Low
Annie Penn Cancer Clinic	Low	Moderate	No utilization
Cone Health Acute Hospitals			
Moses Cone Memorial Hospital	No utilization	No utilization	Moderate
Wesley Long Community Hospital	Low	Moderate	Low
Alamance Regional Medical Center	No utilization	No utilization	Low

*Based on utilization over the past 12 months

Analytics Guide Strategy: UPLC-MSMS

1. Analyze data for top 10 HDs per location
2. Cross check vendor assay compatibility
3. Omit infrequently used drugs
4. Represent all containment strategies

Pharmacy Location	Medication Name	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Total
ALAMANCE REGIONAL MEDICAL CEI	METHOTREXATE FOR ECTOPIC PREGNANCY KIT	1	2	1		1	1	1		3	2	2		14
ANNIE PENN HOSPITAL	FLUOROURACIL (5-FU) CHEMO IV INFUSION PUMP <5 GM	12	20	18	17	17	18	19	20	28	21	12	16	218
ANNIE PENN HOSPITAL	OXALIPLATIN CHEMO IV INFUSION	4	9	9	10	14	14	20	19	20	10	9	9	147
ANNIE PENN HOSPITAL	ETOPOSIDE CHEMO IV INFUSION (</=200 MG)	9	3	3	6	3	9	6	15	13	9	20	16	112
CONE HEALTH CANCER CENTER	PACLITAXEL CHEMO IV INFUSION < OR = 300 MG (</=80MG/M2	82	96	128	115	94	85	88	76	100	118	118	69	1,169
CONE HEALTH CANCER CENTER	GEMCITABINE CHEMO IV INFUSION IN 250 ML	88	73	94	93	79	85	82	86	95	95	63	52	985
CONE HEALTH CANCER CENTER	FLUOROURACIL (5-FU) CHEMO IV INFUSION PUMP <5 GM	92	87	90	66	66	73	80	73	75	78	82	90	952
CONE HEALTH CANCER CENTER	CARBOPLATIN CHEMO IV INFUSION (BY AUC) 400-800MG	71	65	65	67	66	84	88	79	81	78	76	86	906
CONE HEALTH CANCER CENTER	OXALIPLATIN CHEMO IV INFUSION	59	60	83	60	66	72	77	73	69	82	65	86	852
CONE HEALTH CANCER CENTER	CARBOPLATIN CHEMO IV INFUSION (BY AUC) <400 MG	60	64	71	62	53	58	64	52	83	99	102	77	845
CONE HEALTH CANCER CENTER	CYCLOPHOSPHAMIDE CHEMO IV INFUSION < 2 GM	74	82	94	64	52	60	49	50	77	53	61	64	780
CONE HEALTH CANCER CENTER	IRINOTECAN CHEMO IV INFUSION	61	57	72	54	54	56	54	41	40	37	47	54	627
CONE HEALTH CANCER CENTER	DOXORUBICIN HCL CHEMO IV INJECTION 2 MG/ML	43	63	64	37	38	46	42	36	46	29	28	39	511
CONE HEALTH CANCER CENTER	DOCETAXEL CHEMO IV INFUSION > OR = 75 MG	52	34	56	25	32	34	34	41	43	27	30	37	445
CONE HEALTH CANCER CENTER ALA	PACLITAXEL CHEMO IV INFUSION < OR = 300 MG (</=80MG/M2	39	33	45	33	41	49	27	28	33	45	27	36	436
CONE HEALTH CANCER CENTER ALA	CARBOPLATIN CHEMO IV INFUSION (BY AUC) <400 MG	31	30	26	20	31	32	20	17	19	27	16	23	292
CONE HEALTH CANCER CENTER ALA	OXALIPLATIN CHEMO IV INFUSION	10	13	22	24	25	31	24	20	33	25	28	24	279
CONE HEALTH CANCER CENTER ALA	FLUOROURACIL (5-FU) CHEMO IV INFUSION PUMP <5 GM	11	20	15	20	18	30	19	24	27	22	24	30	260
CONE HEALTH CANCER CENTER ALA	FLUOROURACIL (5-FU) CHEMO IV INFUSION PUMP 5-11 GM	10	13	20	16	18	19	17	14	21	19	25	18	210
CONE HEALTH CANCER CENTER ALA	ETOPOSIDE CHEMO IV INFUSION (</=200 MG)	18	12	30	12	18	28	11	11	16	20	13	15	204
CONE HEALTH CANCER CENTER ALA	CYCLOPHOSPHAMIDE CHEMO IV INFUSION < 2 GM	21	21	17	14	10	22	24	17	14	12	8	6	196

Program Design

	Baseline Assessment	Biannual Sampling	Monthly Sampling	Ad Hoc Sampling
Analytical Method	UPLC-MSMS **and** LFIA	UPLC-MSMS **and** LFIA	LFIA	UPLC-MSMS **or** LFIA
No. of drugs	5 + 3 = 8 + platinum analogues	5 + 3 = 8 + platinum analogues	3	Based on need
Location(s)	Cancer Centers and Acute (leverage analytics)	Cancer Centers and Acute (leverage analytics)	Rotate site(s) and surface(s) based on risk and analytics	TBD
Sampling Period	Before cleaning	Before and after cleaning	Before cleaning	TBD – Kit
Risk Level	High, Med, Low	High, Med, Low	High	High
Notes	Comprehensive assessment	Focused assessment based on risk	Assess containment strategies	Post-spill, training, new equipment, etc.

LFIA– CHCC Pharmacy

Department	Location	Cyclophosphamide	Doxorubicin	Methotrexate
CHCC – WLRX	CSP Surface #1	POS	ND	ND
CHCC – WLRX	CSP Surface #2	POS	ND	ND
CHCC – WLRX	Disp Prep Surface	POS	ND	ND
CHCC – WLRX	IV Robot Surface #1	POS	ND	ND
CHCC – WLRX	IV Robot Surface #2	POS	ND	ND
CHCC – WLRX	Pass-through	POS	ND	ND
CHCC – WLRX	Dumbwaiter	ND	ND	ND

POS = Contaminate detected
ND = No detection

UPLC-MSMS – CHCC Pharmacy

Department	Location	5-fluorouracil	Gemcitabine	Paclitaxel	Doxorubicin	Docetaxel	Platinum analogues
CHCC – WLRX	Apoteca PS Unit	POS (0.28 ng/cm^2)	ND	ND	ND	ND	ND
CHCC – WLRX	PEC 1 DCA	ND	ND	ND	ND	ND	ND
CHCC – WLRX	PEC 2 DCA	ND	ND	ND	ND	ND	POS (0.03 ng/cm^2)
CHCC – WLRX	PEC Floor (HD trace container)	ND	ND	ND	ND	ND	ND
CHCC – WLRX	IV Robot Surface #2	ND	ND	ND	ND	ND	ND
CHCC – WLRX	Pass-through	ND	ND	ND	ND	ND	ND
CHCC – WLRX	Dumbwaiter	ND	ND	ND	ND	ND	ND

POS = Contaminate detected
ND = No detection

LFIA – CHCC Nursing

Department	Location	Cyclophosphamide	Doxorubicin	Methotrexate
CHCC – WLRN	Dumbwaiter	ND	ND	ND
CHCC – WLRN	Med Room Surface #1	ND	ND	ND
CHCC – WLRN	Med Room Surface #2	ND	ND	ND
CHCC – WLRN	Infusion Chair	ND	ND	ND
CHCC – WLRN	RN Keyboard	ND	ND	ND

ND = No detection

UPLC-MSMS – CHCC Nursing

Department	Location	5-fluorouracil	Gemcitabine	Paclitaxel	Doxorubicin	Docetaxel	Platinum analogues
CHCC – WL- RN	Patient Bathroom #1 (Floor/toilet)	ND	ND	ND	ND	ND	ND
CHCC – WL- RN	Transport Bins (LMPQ)	POS (0.27 ng/cm^2)	ND	ND	ND	ND	ND
CHCC – WL- RN	Door Handle Med Room	ND	ND	ND	ND	ND	ND
CHCC – WL- RN	IV Pump Floor (Left)	ND	ND	ND	ND	ND	POS (0.04 ng/cm^2)
CHCC – WL- RN	Armchair (Pump Side)	ND	ND	ND	ND	ND	ND
CHCC – WL- RN	HD Waste Bin (floor)	ND	ND	ND	ND	ND	ND
CHCC – WL- RN	Med room Counter/Bin.	ND	ND	ND	ND	ND	ND

POS = Contaminate detected
ND = No detection

Interpreting Results

- What do the results tell you about your practice?
- Are there any differences based on the mode of preparation and delivery? (IVPB, pump, IV push)
- Are results reproducible?
  - Instant results allow for additional testing
  - Results from quantitative testing would take longer
- Understanding qualitative and quantitative results
- Is there an *acceptable* level of contamination?

Sharing the Results

- A positive result should not result in *panic*
- Regardless of location or agent, it is an opportunity for improvement
- Response to testing
  - Praise the negative results
  - Investigate positive results
  - Review policies and procedures
  - Ensure appropriate equipment is available (e.g., CSTDs, personal protective equipment, cleaning supplies)
  - **Do Not** minimize impact of staffing shortages
- Create a corrective action plan for contamination results
- Repeat testing

Next Steps

- Expand testing strategy to additional locations
- Present trending data to Hazardous Drug Committee
- Modify testing strategy based on results
- Revisit budget to accommodate shifting strategy
- Determine long-term responsibility for sampling in patient care areas outside of Pharmacy
  - Inpatient, ambulatory, and retail

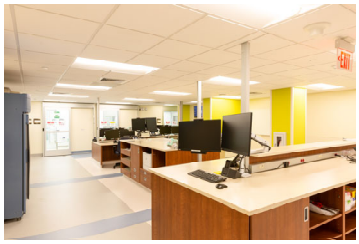
Long-Term Responsibility

Pharmacy
1. Cleanroom areas
2. Administration areas

Pharmacy Quality Personnel

Patient Care Areas
1. Inpatient nursing units
2. Ambulatory care areas

Industrial Hygienist



Photo(s) courtesy of Cone Health.

Key Takeaways

- Educate staff regarding potential for HD contamination of surfaces and continuous low-level HD exposure
- Build a coalition to address the problem within your organization
- Leverage monitoring data and GEMBA walks to identify surfaces that may evade routine containment strategies
- Research potential vendors to build your surface monitoring program based on their relative strengths and weaknesses
- Remember that, although costs must be considered, the results of testing for surface contamination are particularly valuable

How will you change your practice?

- Engage the interprofessional team, including the institution's leadership, in discussions about the necessity of doing surface monitoring on a regular basis
- Integrate surface monitoring programs with the health system's sterile compounding initiatives
- Identify specific surfaces to sample throughout the drug-use process, including patient treatment areas
- Develop an action plan for routine monitoring and post-spill analysis
- Ensure staff in all areas have procedures and resources to deal with hazardous drug spills of any size
- Follow my institution's procedures for handling hazardous drug spills and monitoring surfaces for contamination.

Take a moment to reflect on changes you would make based on what you learned today

Comparing Recommendations for Addressing Hazardous Drug Wipe Sampling

USP <800>: United States Pharmacopeial (USP) Convention. https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare (accessed 2021 Oct 18).

Safe to Touch: Gabay M et al. *Am J Health-Syst Pharm*. 2021; 78:1568-75.

Spanish Society of Hospital Pharmacists (SEFH): Valero-Garcia S et al. *Farm Hosp.* 2021; 45(2):96-107.

Recommendation	USP <800>	Safe to Touch	SEFH
Action plan	• Identify, document, and contain any measurable contamination • Repeat wipe sampling to confirm correction	• Develop a site-specific plan • Implement safety practices • Reduce the occurrence of HD surface contamination	Define a plan
Recognize barriers to implementation		Cost, reluctance, lack of regulatory requirements	
Drugs to monitor	Common markers include • cyclophosphamide • ifosfamide • methotrexate • fluorouracil		Cyclophosphamide and others

Recommendation	USP <800>	Safe to Touch	SEFH
	• platinum-containing drugs		
Areas to monitor	• Interior of BSC and equipment inside • Floor under front of C-PEC • Pass-through chamber • Staging or work area near C-PEC • Area immediate outside compounding room • Patient administration areas		• BSC central work area • Floor in front of BSC • Surface for final CSP inspection • Staging area • Door handle into compounding area
Sampling time			End of workday before cleaning
Assessing risk			Determine risk based on contamination risk (low, medium, high) and frequency of handling HDs (low, moderate, high), including a monitoring plan for different areas within the pharmacy based on risk and frequency

Recommendation	USP <800>	Safe to Touch	SEFH
Frequency of sampling	Benchmark and every 6 months		Establish frequency in policy based on assessment of risk • Monthly • Quarterly • Semi-annually May decrease frequency if 3 consecutive samples are negative
Analytical techniques		Employ both qualitative and quantitative methods	• Baseline: quantitative tandem mass spectrometry • Periodic: tandem mass spectrometry • Routine monitoring and when fast response is needed: lateral flow immunoassay
Contamination threshold	Cyclophosphamide greater than 1 ng/cm^2	Report results in a standardized format	Establish maximum allowable exposure limits based on historical controls, with levels above the 90th percentile (or 1 ng/cm^2 for cyclophosphamide) above

Recommendation	USP <800>	Safe to Touch	SEFH
			which procedures must be changed
Decontamination		Mitigate spills and emphasize decontamination	Include surface and correct removal to determine the product to use
Research		• Conduct research • Collaborate with stakeholders	

BSC = biological safety cabinet, C-PEC = containment primary engineering control, CSP = compounded sterile preparation, HD = hazardous drug