Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities

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Goals for Today’s Program

- To develop a better understanding of the regulatory and environmental reasons for managing pharmaceutical waste more stringently
- To review the Ten Step Blueprint for Managing Pharmaceutical Waste
- To understand how federal hazardous waste rules impact pharmaceutical waste management in hospitals
- To consider specific state requirements Kentucky
- To explore models for implementing a pharmaceutical waste management program
Introduction to Pharmaceutical Waste
Pop Quiz

- Is pharmaceutical waste ending up in red sharps containers in your patient care units?

- Are any unused IVs or other compounded prescriptions being disposed of down the drain?
Pop Quiz

- Are waste pharmaceuticals like warfarin and lindane, considered hazardous by EPA, being combined with non-hazardous pharmaceutical waste?

- What about items containing 24% alcohol?

- Or any items that contain mercury preservatives, such as vaccines, or eye and ear preparations?

- Are vials and IVs containing unused chemotherapy agents like Cytoxan being disposed of in chemo waste containers?
Compliance – Why Now?

- US Geological Survey Studies (USGS)
- US Environmental Protection Agency (EPA)
- State Regulatory Agencies
- The Joint Commission (TJC)
USGS Water Studies

- First nationwide reconnaissance of occurrence of pharmaceuticals, hormones, other organic wastewater contaminants - March 2002
- 139 Streams in 30 states, analyzed for 95 different OWCs
- 82 of 95 detected in at least one sample
- One or more OWCs found in 80% of stream samples
- 13% of sites had more than 20 OWCs
The Faroes Statement

- 200 environmental scientists from five continents met at the Faroes Islands in the North Atlantic – May 24, 2007
- Warned of fetal exposure to toxic substances resulting in “fetal programming” to the 2nd and 3rd generation
- Lifelong effects: obesity, diabetes, cancers, ADHD, Parkinson’s, Alzheimer’s, reduced immune system
- “The dose makes the poison” replaced by “The timing makes the poison”
- New approach to testing of chemicals strongly advocated; 80% of major chemicals never tested for damage to early development
- **5-month inquiry** discovered that drugs were detected in the drinking water supplies of 24 major metropolitan areas

- Reported that there are no sewage treatment systems engineered to remove pharmaceuticals

- Indicated drugs pose a unique danger, unlike pollutants, because they were crafted to act on the human body.

- Acknowledged continuous low-level exposure to chemo drugs, hormones, anti-depressants, antibiotics, and seizure meds found in our water could be impacting human health.
EPA Increasing Focus Pharmaceutical Waste

- EPA’s Clean Water Act Review
  - Focus includes unused or expired pharmaceutical discharges to municipal wastewater treatment plants from hospitals, long-term care facilities, and veterinarians

- Revising the blueprint for pharmaceutical management developed by H2E and funded by the EPA
  - Scheduled for release Mid-2008

- Pressure from Congress and the public based on AP reports on drugs in the water (March, 2008)
  - Senate and House hearings possible
  - Calls for more oversight
Species at Risk
Effects of Chronic Exposure to Prozac

- Developmental delays in forelimb formation and tail resorption
- Increased time to metamorphosis
- Increased mortality

Black, MC; Rogers, ED; Henry, RB. Endocrine Effects Of Selective Serotonin Reuptake Inhibitors (SSRIs) on Aquatic Organisms

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Below the Dose/Response Curve: Endocrine Disruptors

- Endocrine Disruptors: chemicals that interfere with the normal function of the endocrine system (glands including thyroid, adrenals, ovaries, testicles)
- Mimic hormone, trigger identical response, block a hormone
- Do not follow the normal dose/response curve
- Active at much lower doses, especially in the fetus and newborn
- Estradiols, progesterone, testosterone
- Lindane
Lower human male sperm counts (50% reduction since 1939)
Increased infertility
Increased genital deformities
Increased hormonally triggered human cancers
Associated with neurological disorders in children
  • Hyperactivity, attention deficit
  • Lowered IQ, rage reaction
www.ourstolenfuture.org
The Precautionary Principle

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.” Wingspread Conference, Racine, WI 1998
Applying the Precautionary Principle to Rx Waste Management

Three aspects of Rx waste management:

- Management of regulated hazardous pharmaceutical waste
- Management of non-regulated hazardous pharmaceutical waste applying BMPs
- Minimization of pharmaceutical waste

Applying the Precautionary Principle should encourage conservative management of ALL pharmaceutical waste
Practice GreenHealth
(Formerly Hospitals for a Healthy Environment)

- Enhanced focus on hazardous waste and pharmaceutical waste
  - [http://cms.h2e-online.org/ee/hazmat/](http://cms.h2e-online.org/ee/hazmat/)

- EPA grant to H2E to develop a pharmaceutical waste management blueprint
  - [http://www.h2e-online.org/docs/h2epharma-blueprint41506.pdf](http://www.h2e-online.org/docs/h2epharma-blueprint41506.pdf)

- EPA grant to H2E to train TJC surveyors on environmental issues
Increasing USEPA Regulatory Activity

- **Region 1 (New England):**
  - Veterans Administration Hospital, White River, Vermont, August 5th, 2005 cited and fined $372,254 for hazardous waste violations

- **Region 2 (NY, NJ):**
  - North Shore University Hospital, Manhasset, NY fined $40,000 (July 2003)
  - Nassau University Medical Center, East Meadow, NY fined $279,900 (Oct. 2003)
  - Mountainside Hospital, Montclair, NJ fined $64,349 (Nov. 2003)
  - Memorial Sloan Kettering Cancer Center, New York, NY, fined $214,420
Healthcare RCRA Violations

Breakout of RCRA Violations from Hospital Disclosures

- Generator Requirements 12%
- ID of HW 23%
- Universal Waste 18%
- General Facility Standards 16%
- Accumulation Time 2%
- Manifest 6%
- UST 2%
- Container Management 21%

Slide courtesy of John Gorman, USEPA Region 2

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2008
New Initiatives at TJC

- Adding healthcare engineers to survey teams
- Beginning to ask questions about waste disposal
Relationship to The Joint Commission Standards: Medication Management

- **Standard MM.4.80**
  - Medications returned to the pharmacy are appropriately managed.

- **Elements of Performance MM.4.80**
  - 3. The organization has a process in place that addresses how outside sources, if any, are used for destruction of medications.
Relationship to The Joint Commission Standards: Environment of Care

- **Standard EC.3.10**
- *The organization manages its hazardous materials and waste*[^1] *risks.*

[^1] Hazardous materials (HAZMAT) and waste: Materials whose handling, use, and storage are guided or regulated by local, state, or federal regulation. Examples include OSHA’s Regulations for Bloodborne Pathogens (regarding the blood, other infectious materials, contaminated items which would release blood or other infectious materials, or contaminated sharps), the Nuclear Regulatory Commission's regulations for handling and disposal of radioactive waste, management of hazardous vapors (such as glutaraldehyde, ethylene oxide, and nitrous oxide), *chemicals regulated by the EPA, Department of Transportation requirements,* and hazardous energy sources (for example, ionizing or non-ionizing radiation, lasers, microwaves, and ultrasound.)
Relationship to The Joint Commission Standards: Environment of Care

- **Rationale for EC.3.10**
  - *Organizations must identify materials they use that need special handling and implement processes to minimize the risks of their unsafe use and improper disposal.*
Elements of Performance for EC.3.10

1. Written management plan to effectively manage hazardous materials and wastes.

2. Inventory that identifies hazardous materials and waste

3. Selection, handling, storage, transportation, use, and disposal of hazardous materials and waste from receipt or generation through use and/or final disposal, including managing the following:
   - Chemicals
   - Chemotherapeutic materials
OSHA Hazardous Drugs

- **NIOSH Hazardous Drug Alert**
  - Hazardous drugs as defined by OSHA/NIOSH intersect but are not the same as EPA hazardous wastes

- **ASHP Guidelines on Handling Hazardous Drugs**
  - Deal primarily with OSHA employee exposure issues but also refer to required or recommended hazardous pharmaceutical waste management practices
Hazardous Drugs vs. Hazardous Waste
Where OSHA & EPA Meet

- Genotoxicity
- Teratogenicity
- Reproductive toxicity
- Carcinogenicity
- Organ toxicity at low doses

Examples:
- Chemotherapy agents
- Endocrine disruptors

OSHA HAZARDOUS DRUGS

EPA TOXIC HAZARDOUS DRUG EXAMPLES
- Arsenic trioxide
- Cyclophosphamide
- Mitomycin
- Melphalan

EPA IGNITABLE HAZARDOUS DRUG EXAMPLES
- Paclitaxel
- Valrubicin
- Etoposide

EPA HAZARDOUS WASTE
P&U Listed Examples:
- Epinephrine
- Warfarin
- Nicotine

Characteristic Examples:
- Formulations containing greater than or equal to 24% alcohol
- Formulations containing heavy metals
- Strong acids & bases
Ten Steps to Successful Implementation

- Navigating the Blueprint
- Step 1: Getting Started
- Step 2: Understanding the Regulations
- Step 3: Considering BMPs for Non-Regulated Pharmaceutical Waste
- Step 4: Performing a Drug Inventory Review
- Step 5: Minimizing Pharmaceutical Waste
Ten Steps to Successful Implementation

- Step 6: Assessing Current Practices
- Step 7: Taking On the Communication/Labeling Challenge
- Step 8: Considering the Management Options
  - Models of Implementation
- Step 9: Getting Ready for Implementation
- Step 10: Launching the Program
- Next Steps
Navigating the Blueprint

- The Ten Steps are not all consecutive. Some will occur in parallel and some will probably be referenced throughout your process.
- Due to the length and detail of the Blueprint, consider it as a reference tool.
- The primary “champions” of the process should read the Blueprint in its entirety to gain a complete picture of the process and how the steps work together.
Step One: Getting Started

- Recognition of highly interdisciplinary process
- Obtain support from senior management
- Establish a committee of stakeholders that will meet regularly
- Committee must include managers of: pharmacy, environmental services, safety, nursing, education, and infection control
Step One: Getting Started

- Others to consider: Facilities/engineering, administration, laboratory, purchasing/materials management

- Recognize that increased costs involved in compliant Rx waste disposal are off-set by reduced risk of enforcement, violations, fines, TJC citations, and negative publicity
Step 2: Understanding the Regulations

- USEPA Resource Conservation and Recovery Act (RCRA)
- State environmental protection agencies may be stricter
- Defines hazardous waste for businesses in the US, including healthcare facilities
RCRA: The Defining Regulation

- Resource Conservation & Recovery Act
  - Enacted in 1976, enforced by the EPA
  - Federal regulation of the disposal of solid wastes
  - Encourages the minimization of waste generation
- Defines “hazardous waste”
- “Cradle to Grave” tracking of hazardous waste
RCRA Risk Management & Liability

- Civil and criminal liability
  - Civil: State/USEPA enforcement
  - Criminal: FBI, Attorney General, Grand Jury
    - Significant environmental harm
    - Culpable conduct
- Corporate fines: Up to $32,500 per violation/day
- Personal liability: fines and/or imprisonment
- No statute of limitations
- Managers up through CEO liable
Potential Liability for Rx Hazardous Waste Management

- Board of Trustees
- CEO
- COO
- VP of Finance
- VP of Nursing
- VP of Clinical Services
- VP of Ambulatory Services
- VP of Facility Planning & Maintenance
- Director of Radiology
- Director of Pharmacy
- Director of Laboratory Medicine
- Director of Dietary & Nutritional Services
- Director of Environmental Services
- Director of Safety
- Director of Maintenance & Grounds

= POTENTIALLY LIABLE
Criminal Case Selection Process

- Significant Environmental Harm: Factor 4

When certain illegal conduct appears to represent a trend or common attitude within the regulated community, criminal investigation may provide a significant deterrent effect incommensurate with its singular environmental impact. While the single violation being considered may have a relatively insignificant impact on human health or the environment, such violations, if multiplied by the numbers in a cross-section of the regulated community, would result in significant environmental harm.

Translation: EPA can make an example of an organization regardless of the amount of actual pollution

Criminal Case Selection Process

- **Culpable conduct**
  - Factor 1: *History of repeated violations*
  - Factor 2: Deliberate misconduct resulting in violation
  - Factor 3: Concealment of misconduct or falsification of required records
  - Factor 4: Tampering with monitoring or control equipment
  - Factor 5: Business operation of pollution-related activities *without a permit, license, manifest or other required documentation*

- **EXAMPLE:** If hazardous Rx waste is not being identified, segregated, and managed as hazardous waste, no manifest will exist which can be considered a repeated violation.
Which Discarded Drugs Become Hazardous Waste?

- **P-listed chemicals**
  - Sole active ingredient, unused

- **U-listed chemicals**
  - Sole active ingredient, unused

- **Characteristic of hazardous waste**
  - Ignitability
  - Toxicity
  - Corrosivity
  - Reactivity
Hazardous Waste Segregation Can be FUN!

- Mix and Match opportunity to apply hazardous waste information to real life simulations
- Keep an eye out for the “All Seeing Eye”
- Watch for **BOLDED ITEMS**
Examples of P-Listed Pharmaceutical Waste

- **Arsenic trioxide** P012
- **Epinephrine base*** P042
- Nicotine P075
- **Nitroglycerin** (weak) P081
- Phentermine (CIV) P046
- Physostigmine P204
- Physostigmine Salicylate P188
- Warfarin >0.3% P001

*Salts excluded federally as of Oct. 15th, 2007; Kentucky has accepted this position.

** Excluded from the P list federally and in Kentucky
Examples of P-Listed Pharmaceuticals
Examples of U-listed Pharmaceutical Waste

- Chlortal Hydrate (CIV) U034
- Chlorambucil U035
- Cyclophosphamide U058
- Daunomycin U059
- Diethylstilbestrol U089
- Melphalan U150
- Mitomycin C U010
- Streptozotocin U206
- Lindane U129
- Saccharin U202
- Selenium Sulfide U205
- Uracil Mustard U237
- Warfarin <0.3% U248
Examples of U-Listed Pharmaceuticals

- **LEUKERAN** (chlorambucil) Tablets
- **CYTOXAN** (cyclophosphamide) Injection
- **ALKERAN** (melphalan hydrochloride) for Injection
- **Reserpine Tablets, USP** 0.25 mg
- **LINDANE LOTION, USP 1%**
Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point < 140° F
- Non-aqueous solutions with flash points < 140 ° F
- Oxidizers
- Flammable aerosols
- Hazardous Waste Number: D001
- Rubbing Alcohol
- Topical Preparations
- Injections
Characteristics of Corrosivity

- An aqueous solution having a pH $\leq 2$ or $\geq 12.5$
- Examples: Primarily compounding chemicals
  - Glacial Acetic Acid
  - Sodium Hydroxide
- Hazardous waste number: D002
Characteristic of Toxicity

- 40 chemicals which must be below specific leaching concentrations
- Must pass the Toxicity Characteristic Leaching Procedure (TCLP)
- Must evaluate IVs, such as TPN – may come out of regulation due to dilution
- Examples of potential toxic pharmaceuticals:
  - Arsenic
  - Barium
  - Cadmium
  - Chromium
  - Lindane
  - m-Cresol
  - Mercury (thimerosal, phenylmercuric acetate)
  - Selenium
  - Silver
Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Heavy Metals: Selenium, Chromium and Silver

Preservatives: thimerosal & m-cresol
Meet eight separate criteria identifying certain explosive and water reactive wastes.

Nitroglycerin formulations may be considered excluded federally from the P081 listing as non-reactive as of August 14, 2001, unless they exhibit another characteristics, such as ignitability.

Kentucky has adopted the federal exclusion for nitroglycerin.

Hazardous Waste Number for reactives: D003
Chemotherapy Agents: Many Are Not Regulated by RCRA

- About 100 chemotherapy agents not regulated by EPA
- Examples:
  - Alkylating agents: Cisplatin, Thiotepa
  - Antimetabolites: Fluorouracil, Methotrexate
  - Hormonal (antiandrogen): Lupron® (leuprolide)
  - Hormonal (antiestrogen): Tamoxifen
  - Mitotic Inhibitor: Taxol® (paclitaxel)
Two Types of Chemotherapy Waste

- Trace Chemotherapy Waste (yellow)
  - Medical waste hauler protocols for “Chemo Waste”
  - Empty vials, syringes, IV’s, gowns, gloves, ziplock bags
  - Treated as infectious medical waste through regulated medical waste incineration

- “Bulk” Chemotherapy Waste (black)
  - If not empty, should be placed into Hazardous Pharmaceutical Waste container

- Spill Clean-up
  - RCRA Hazardous Waste
Definition of “Empty”

- “P” Listed Waste
  Containers of “P” listed chemicals are considered hazardous waste, unless they have been rinsed three times and the rinsate discarded as hazardous waste. Never done in healthcare settings, therefore containers are also hazardous waste.

- “U” Listed and Characteristic Waste
  Containers of “U” listed chemicals and characteristic wastes are empty only when
  - All contents removed that can be removed through normal means
  - And no more than 3% by weight remains
  - Example: “Empty” Cytoxan vial would be “trace” chemotherapy
What Is PharmE Hazardous® Waste?

- Drugs which may cause harm to human health or the environment and need to be managed according to BMPs
  - NIOSH Hazardous Drug Alert Appendix A
  - Drugs with LD50s at or below 50mg/kg
  - Endocrine disruptors
- Identified as PharmE Hazardous® in Inventory Analysis
- BMP recommendation is to segregate at least chemo agents into RCRA toxic hazardous waste containers and to dispose of other agents through incineration
Hazardous Waste Incinerators

- Permitted by USEPA, known as a Treatment, Storage and Disposal Facility (TSDF)
- High temperature, molecular bonds broken
- Pollutants scrubbed, emits only water vapor, ash stored in a lined, hazardous waste landfill
- Authorized to accept the “worst of the worst” hazardous chemicals, shipped on a 5-part manifest

Examples:
- Veolia
- Clean Harbors
- Heritage
How Should Non-hazardous Drugs be Handled, Stored and Disposed?

- BMPs strongly discourage sewering and landfilling of non-hazardous drugs
- Organization can minimize risks by adopting BMPs
- Possible exception: controlled substances due to difficulty in rendering non-recoverable under Drug Enforcement Administration (DEA) regulations
- Consider segregating into white container with blue top (used extensively in California)
- Label “Incinerate Only”
- Dispose at a regulated medical waste incinerator or municipal incinerator that is permitted to accept non-hazardous pharmaceutical waste
Municipal and Regulated Medical Waste Incinerators

- **Municipal Incinerator**
  - Permitted to burn municipal “garbage”
  - Usually not permitted to handle infectious waste
  - May be permitted to handle non-hazardous pharmaceuticals, with certain volume restrictions

- **Regulated Medical Waste Incinerator**
  - Permitted by USEPA and the state to accept pathology waste, red bag and red sharps waste, trace chemo waste
  - May be permitted to accept non-hazardous pharmaceutical waste
  - Regulated under the Clean Air Act
  - Lower temperature, less controls than TSDF
  - Ash disposed of in a municipal (non-hazardous) landfill; may or may not be lined
## Common But Inappropriate Pharmaceutical Waste Stream Management

<table>
<thead>
<tr>
<th>Type of Waste Container</th>
<th>Color code</th>
<th>Contents</th>
<th>Treatment Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red bag (non-pathology)</td>
<td>Red</td>
<td>Biohazardous (RMW) + Rx</td>
<td>Autoclave/Landfill</td>
</tr>
<tr>
<td>Red sharps/needlebox</td>
<td>Red</td>
<td>Biohazardous; needles, etc. + Rx</td>
<td>Autoclave/Landfill</td>
</tr>
<tr>
<td>Trace chemo Rx</td>
<td>Yellow or White</td>
<td>Bulk &amp; Trace Chemo</td>
<td>RMW Incineration</td>
</tr>
<tr>
<td>Sewer</td>
<td></td>
<td>Unused IVs, tablets, etc.</td>
<td>Wastewater Treatment Plant</td>
</tr>
<tr>
<td>Municipal Trash</td>
<td></td>
<td>Unused ointments, inhalers, etc</td>
<td>Landfill</td>
</tr>
</tbody>
</table>
## Pharmaceutical Waste Management Recommendations

<table>
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<td>Biohazardous &amp; Trace Chemo</td>
<td>RMW Incineration</td>
</tr>
<tr>
<td>RCRA Toxic Hazardous Rx</td>
<td>Blue or Black</td>
<td>RCRA, bulk chemo, &amp; BMP Hazardous Rx</td>
<td>RCRA TSDF</td>
</tr>
<tr>
<td>RCRA Ignitable Hazardous Rx</td>
<td>Blue or Black</td>
<td>RCRA ignitable Hazardous Rx</td>
<td>RCRA TSDF</td>
</tr>
<tr>
<td>Non-hazardous Rx Waste</td>
<td>White/Blue or Purple top</td>
<td>Non-hazardous Rx Waste</td>
<td>Municipal/RMW Incineration</td>
</tr>
</tbody>
</table>
Step 4: Performing a Drug Inventory Review

- Perform initial inventory review
  - Obtain drug specific data from purchasing records
  - Identify ingredients
  - Determine RCRA hazardous waste code
  - Make Best Management Practice determinations

- Document decision making process
- Keep the review current
Reformulations and Compounded Items

- Hazardous waste designation for re-formulations and compounded items may not be the same as for original formulation
  - Paclitaxel contains ~ 50% alcohol in original vial
    - Manage residue in vial as ignitable hazardous waste
  - Alcohol < 24% when diluted in IV
    - Apply BMP and discard unused IV as “bulk” chemotherapy hazardous waste
Managing Specialty Wastes

- Controlled substances:
  - May be handled by some hazardous waste vendors as a transfer between DEA registrants
  - Can be shipped to a reverse distributor as a transfer between registrants (non-hazardous waste)
  - Sewering still the most economical until a system for rendering the controlled substances non-recoverable can be developed

- Hazardous/RMW wastes:
  - Some hazardous waste vendors can accept dual hazardous and infectious waste
DHMC Waste Characterization Summary*

84%

11%

5%

*Performed for Dartmouth Hitchcock Medical Center by PharmEcology Associates, LLC

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DHMC Inventory Review

- Antimicrobial Agents
- Biologicals
- Biologics
- Antineoplastic Agents
- Cardiovascular Agents
- Respiratory Agents
- Gastrointestinal Agents
- Genitourinary Agents
- Analgesics and Anesthetics
- Neurological System Drugs
- Nutritional Products
- Hematological Drugs
- Neuromuscular Agents
- Topical Products
- Miscellaneous Products

Legend:
- Non Hazardous
- BMP Hazardous
- Federally Hazardous
<table>
<thead>
<tr>
<th>Drug</th>
<th>Waste Code</th>
<th>Units</th>
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<tr>
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<td>HSCU</td>
</tr>
<tr>
<td>Epinephrine</td>
<td>P042</td>
<td>ED</td>
</tr>
<tr>
<td>Chlortal Hydrate</td>
<td>U034</td>
<td>Psych Care</td>
</tr>
<tr>
<td>Oxymetazoline Nasal Spray</td>
<td>D009 (Hg Preservative)</td>
<td>Med/Surg.</td>
</tr>
</tbody>
</table>

Unit: Neuro, ED, CCU, ICU, CTIC, ICCU, Psych Med, ED
Sample Guidance Poster

Proper Waste Disposal in Hematology/Oncology

Infectious Waste: Red Bucket/Tan Bag
- Materials not exposed to chemo that are saturated with blood or body fluids (i.e., could get at least a drip out by squeezing or flicking).
- Containers of blood products or other potentially infectious materials.
- Absorbent materials not saturated with blood should be disposed as ordinary trash.

Trace Chemo and Combined Chemo/Infectious: Yellow Bucket
- EMTV chemo containers (IV bags, tubing, vials, syringes, ziplock bags).
- IV sets that have held chemo and remain attached to catheter or other bloody material.
- Gloves, gowns, ziplock bags, other paraphernalia used to administer chemo but NOT VISIBLY CONTAMINATED with chemo.
- Linens containing trash or items of chemo patients.

EPA-Regulated Chemo Waste: Blue Bucket
- Chemo containers that are NOT EMTV and have NO CATHETER attached.
- Paraphernalia (e.g., gloves, gowns) that HAVE BEEN VISIBLY CONTAMINATED with chemo.
- Materials used to clean up a chemo spill.
- All aerosol trioxide sets (separate from port; dispose port in yellow).

Ordinary Trash: Clear Bag
- Materials not exposed to chemo and not saturated with blood or body fluids (i.e., could not get a drip out by squeezing or flicking).
- Examples: non-chemo IV bags, packaging, food waste.

Sharps: Sharps Container
- All sharp objects that have not been exposed to chemo.

Articulated on premises & landfilled
- Sent to medical waste incinerator
- Sent to hazardous waste incinerator
- Sent to municipal landfill
- Ground, incinerated, and landfilled; container is cleaned and reused

*Empty = Less than 3% of contents remaining
Capturing New Drugs

- **Establish systems to:**
  - Capture new drugs added to the formulary and non-formulary purchases at least quarterly
  - Manage discarded physicians’ samples
  - Discard personal medication left by patients appropriately

- **PharmE® Waste Wizard used in study**
  - Online search engine
  - Over 170,000 drug products updated weekly
Public Access to Resources and FAQS at www.pharmecology.com
Regulated as federal hazardous waste:
P001-Warfarin (conc. greater 0.3%)

Handle as hazardous waste:
Toxic
WARFARIN

Warfarin is defined by USEPA as a P-listed, acutely hazardous waste when present as the sole active ingredient in concentrations greater than 0.3% (P001). All manufactured dosage forms exceed the 0.3% criteria.

All containers that have held P-listed waste must be managed as hazardous waste unless triple rinsed. If triple rinsed, all rinsate must also be treated as hazardous waste. The rinsed RCRA-empty container may then be disposed of as non-hazardous waste.

If present as the sole active ingredient in concentrations equal to or less than 0.3%, warfarin is a U-listed hazardous waste (U248).

For additional information, refer to:
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?
c=ecfr&sid=3814ba269b3466ca3675c45c3e6956f6&rgn=dent8&view=text&node=40.25.0.1.1.2
Step 5: Minimizing Pharmaceutical Waste

- Limitations on less hazardous drug substitution
  - Hazardous nature of drug often provides therapeutic effect

- Always ask:
  - What pharmaceuticals are being wasted?
  - Why are they being wasted?
  - How can wasting be minimized?
How Can Hazardous RX Waste Generation Be Minimized?

- Inherent limitations on substitution of a less hazardous drug since the hazardous nature of the chemical often provides the therapeutic effect.

- Tighter inventory control to reduce outdate generation, both original manufacturers’ containers and repacks.

- Pre-labeling of multi-dose items such as ointments, inhalers, as take-home meds – works best in smaller, primary care hospitals.

- Single dose vials vs. multiple dose vials.

- Patient specific oral syringes vs. 10 cc. repacks (e.g. choral hydrate for pediatric use).
Step 6: Assessing Current Practices

- Performing department reviews
  - Quantitative volumes/weights of discarded drugs difficult to obtain
  - Informal but well documented interview process in pharmacy and nursing units can determine current medication disposal practices

- Schedule units in advance
  - Emphasize “no wrong answer” approach

- Utilize data from automated dispensing machines

- Conduct a frequency analysis, especially for drugs which become hazardous waste
Federal Hazardous Waste Generator Status

- Large Quantity Generator (LQG): generates more than 1000 kg/month of hazardous waste or >1 kg/month “P” listed waste.

- Small Quantity Generator (SQG): Generates <1000 kg/month but >100 kg/month of hazardous waste & < or = 1 kg/month “P” listed waste.

- Conditionally Exempt Small Quantity Generator (CESQG): Generates < or = 100 kg haz waste/month, < or = 1kg P listed waste/month
Documenting Your Hazardous Waste Generator Status

- Large quantity generator: no need to record P waste separately.

- Small or very small quantity generator: need to segregate all P-listed including empty containers and document weights per calendar month

- Cannot exceed 1 kg or 2.2 lbs/month for any given month
Step 7: Taking On the Communication/Labeling Challenge

- Determine an acceptable label that indicates the item is a toxic or ignitable hazardous waste
  - Special Disposal Required
  - HW-T (for toxic)
  - HW – T Full or Empty (for P-listed waste)
  - HW-I (for ignitable)
Labeling in the Pharmacy and Nursing Units

- Shelf-stickers in the pharmacy
- Automating the labeling process for nursing units
  - Incorporating disposition data into dispensing software
    - Must include all possible labeling scenarios: unit dosed items, IV admixtures, re-formulated items, robot dispensed labels
  - Inserting disposition data on barcodes
    - Must be bedside barcode enabled
- Manually labeling in the pharmacy for nursing units
Step 8: Considering the Management Options

- **Model I: Segregating at the Point of Generation**
  - Option A: Automatic Sorting Device
    - In beta testing
  - Option B: Data Applied to Dispensing Software
  - Option C: Stickers Applied Manually

- **Model II: Centralizing Segregation**

- **Model III: Managing All Drug Waste As Hazardous**
Model I Option A: Automatic Sorting Device

- Vestara’s EcoRex®
  - Proprietary database of 170,000+ NDCs
  - Integrated IT network
  - Omni-directional barcode scanner
  - Cart and wall configuration
  - Tamper-proof reusable containers
  - Scan, dispose and close
Pros and Cons

Pros:
- Lower training costs
- One-time inventory analysis
- Reduction in human error
- Automatically updated weekly
- Locked stations located anywhere

Cons:
- Pharmacy must be bar-code enabled
- Equipment must be acquired
Model I Option B: Data Applied to Dispensing Label Software

- Entire inventory is analyzed
- Shelf stickers in pharmacy
- Data is entered into the dispensing software at the NDC or “pneumonic” level
- Label prints with pre-determined code
  - HW1, RCRA1, Black Bin, etc.
- Nursing staff are trained on waste segregation based on codes
- Black “satellite accumulation” containers in soiled utility rooms; restricted entry black containers in patient rooms
- Hybrid Model: North Memorial Health Care
  - Programmed automated dispensing machines (e.g., Pyxis)
Pros and Cons

Pros:
- Eliminates manual stickering of dispensed items
- Reduces opportunity for human error

Cons:
- Must have dispensing software that is flexible and can accept message
- Must still sticker pharmacy shelves to alert pharmacy staff
- Printed message may not show up as well as stickers
- System must be maintained by pharmacy staff
Model I Option C: Manual Labeling of Hazardous Waste

- Entire inventory is analyzed
- Shelf stickers are applied
- Items are stickered upon dispensing
- Nursing staff are trained on waste segregation based on stickers
- Black “satellite accumulation” containers in soiled utility rooms
- Model program: North Memorial Health Care
North Memorial Health Care
Robbinsdale, MN

SPECIAL DISPOSAL REQUIRED

Photos courtesy of North Memorial Health Care
Pros & Cons

Pros:
- Relatively easy to implement regardless of software
- No programming costs

Cons:
- Labor intensive and relies on consistent employee performance
- Higher training costs
- System must be maintained by pharmacy staff
Model II: Centralizing Segregation

- All pharmaceutical waste is collected in hazardous waste containers in the pharmacy and in the nursing units.

- The mixed waste is removed to the central hazardous waste storage accumulation area.

- Sorting is done by hazardous waste vendor or trained hospital staff based on an analysis of the inventory.

- Hazardous waste and related items are manifested and disposed as such.

- Model: Abbott Northwestern Hospital.
Pros & Cons

Pros:

- No time spent in pharmacy on stickering or maintaining software system
- Less time spent on training pharmacy and nursing personnel on segregation rules
- Less chance of error based on expertise of vendor

Cons:

- Still must analyze inventory and keep up-to-date with new items
- Increased cost of vendor for sorting time
Option III: Managing All Pharmaceutical Waste as Hazardous

- Easiest, most expensive
- May still need to sort out aerosols
- Still need to do analysis of inventory to determine waste codes for manifesting

Hybrid Model: UW Health, Madison, WI
- All tablets/capsules/solids hazardous
- IVs hazardous if RCRA, PharmE Hazardous™ (BMP)
Step 9: Getting Ready for Implementation

- Locating your satellite accumulation areas
  - Pharmacy
    - Clean rooms and all pharmacy dispensing areas
  - Nursing units
    - Soiled utility rooms
    - Patient rooms if restricted entry container used
Satellite Accumulation Requirements

- Label each container as “Hazardous Waste” with the appropriate waste stream noted
- No time limit to fill the container
- No more than 55 gallons of U listed and characteristic waste or 1 quart of P listed waste may be accumulated
- Must be moved to storage accumulation within three days after these quantities are reached
Tips for Satellite Accumulation

- Keep wastes in their original closed container
  - Do not squirt or drain liquids into the satellite container
  - Do not empty tablets or capsules into the satellite container

- If P waste escapes into the container, the entire container becomes contaminated P-listed waste
Evaluating Your Storage Accumulation Area

- Provides a safe and secure storage area for hazardous waste while it awaits shipping
- Same locked area as for xylene, formaldehyde, lab chemicals
- Maximum storage time: 90 or 180 days based on generator status
- May need a larger area or more frequent vendor pick-ups
Selecting the Right Vendor(s)

- For RCRA hazardous waste, vendor must be permitted by EPA as a treatment, storage and disposal facility (TSDF)
  - Request a copy of their notification

- Insure your current vendor can handle all new waste codes
  - Provide them with all P, U and D codes

- Ask for a waste profile to be generated to enable manifesting without documenting each item in each container
  - KY may require all waste codes to be listed on the container

- Ask if vendor can pre-certify the items and combine ignitables with toxics to simplify waste segregation

- Determine if you will have special needs, such as hazardous controlled substances or mixed hazardous/regulated medical waste streams
Reverse Distributors Are NOT Waste Management Services

- Most reverse distributors are generators of hazardous waste, not TSDFs
  - Not permitted to accept hazardous waste
  - May not be permitted to accept ANY waste

- Two letters to the industry from EPA specifically state that reverse distribution is NOT to be used as a waste management system
  - Don’t push the system
  - Send only potentially creditable outdated drugs to RDs
  - Kentucky requires that credit be given for the outdates – if not creditable, manage as waste at the facility
Conducting a Pilot Program

- Pilot the program in the pharmacy first
  - Requires shelf stickers on drugs that become hazardous waste
  - Introduces concept to pharmacy staff

- Consider inpatient and/or outpatient oncology

- Find nursing “champions” within the system
Develop Policies and Procedures

- Complete pilots to determine best methods to use

- Develop policies and procedures applicable to the entire facility
  - Be sure to involve all stakeholders

- Consider developing a pharmaceutical waste flow chart and/or pictorial diagrams for each area

- Be sure to update spill management plans to include non-chemo hazardous waste
Step 10: Launching the Program

- **Educating and training staff**
  - Notify the entire facility of the timetable for training and roll out
  - Train all shifts immediately before their units/department is to begin waste segregation
  - Stick with the timetable!

- Take advantage of Safety Fairs, Nursing Education Expos, or other hospital-wide events for a general introduction

- Involve nursing educators initially, with new hires, and for annual training
Hazardous Waste Manifests and Land Disposal Restriction Forms

- **Hazardous Waste Manifests**
  - Highly technical
  - Involve your hazardous waste vendor
  - Certification of all P, U and D codes simplifies the process
  - Universal Manifest required in September, 2006

- **Land Disposal Restriction Forms**
  - Indicates what wastes you are disposing and how they will be treated prior to land application
  - Hazardous waste requires high temperature incineration
  - Hazardous waste vendor should complete for you
Tracking, Measuring and Recording Progress

- Hazardous waste identification: document your process initially and how new drugs are evaluated

- Labeling: document consistency, especially with manual processes; re-evaluate processes annually

- Compliance: perform periodic surveys to determine if procedures are understood and followed

- Quantity: track the number, size, weight of hazardous waste containers generated

- Costs: track all costs involved

- JCAHO Performance Improvement Initiative: Document for next survey and H2E Award Opportunity: Identify goals and action plans; submit your efforts for annual recognition

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Best Management Practices: Managing to the Highest Standard

- Hazardous waste regulations have not kept pace with drug development

- Approximately 10% of the drugs that are not regulated are equally as hazardous

- Best management practices encourage managing drugs that are equally harmful as hazardous waste when discarded

- Best management practices also discourage sewage and landfilling of all drugs
Next Steps

- This Blueprint should be viewed as a beginning to addressing an emerging issue, not an end in itself.

- A great deal of national dialog needs to occur to determine the optimum management of waste pharmaceuticals, including household waste generation.

- You as healthcare leaders will be creating the optimum solutions of the future.