



ALBANY MEDICAL CENTER

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29 October, 2009

Progress Report

Project Title: "Source Reduction Demonstration Project"

EPA-OPPT-06-008 / CDA 66.717

EPA Grant # X9-97256506-0

Project Period: 8/1/2007-7/31/2009

PI: Russell F. Mankes, PhD

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The project, ending July 31, 2009, evaluated strategies for source reduction of pharmaceutical waste from a hospital into the environment, primarily through waterborne disposal (flushing) of drugs, reduction in use and wastage of hazardous medications (such as propofol), development of educational tools to improve compliance by patient care staff, and finally to disseminate this information and lessons learnt to the 550 hospitals in New York State and to the regulatory community.

The project was an unqualified success. We were able to develop a training program which was embraced by patient care staff. We significantly reduced maldisposals and initiated a "no-flush" policy. We collected unique data on dispensing as well as wasting practices, noting a wide variation in "wasting" percentages of drugs. Some drugs having 0 waste yet others exceeding 50% of all drug dispensed. These data provide unique opportunities for process improvement as well as healthcare cost containment.

We provided onsite tours for facilities from Canada to Puerto Rico to see and touch the program as well as talk to nursing staff regarding the acceptance of the program. These tours were extremely well received (85% positive) and sixty-one percent indicated the tours were an impetus for change at their institutions.

As indicated in our initial grant application, we intended to use this knowledge gained in the pilot project as an entryway into the program expansion to the main (631 bed) hospital campus. As noted in the attached final report, we have begun the roll out at the main hospital, with interesting results. This roll out would not have been possible without the knowledge gained from the present pilot project.

Albany Medical Center

**Pharmaceutical waste management:
A 2 year pilot project**

Russell F. Mankes, PhD
Associate Professor, Center for
Neuropharmacology and Neuroscience and
Center for Immunology and Microbial Disease

10/13/2009

Albany Medical Center
Pharmaceutical waste management: A 2 year pilot project
Funded by US EPA grant X9-97256506-0
In collaboration with HANYS (Healthcare Association of New York State) and the New York State
Department of Environmental Conservation
Russell F. Mankes, PhD
Associate Professor, Center for
Neuropharmacology and Neuroscience and
Center for Immunology and Microbial Disease

Participants



- Albany Medical Center – Albany Medical College
 - Russell F. Mankes, PhD Associate Professor, PI
 - Timothy Duffey, Hospital Director Albany Medical Center South Clinical Campus
 - Michael Murphy, RN Director of Patient Care South Clinical Campus
 - Elena Cioppa, RPH Director of Pharmacy South Clinical Campus
 - Brenda Streeter, CIH Director Environmental Health & Safety
 - Laurie DeWeerd, Chemical Hygiene Officer AMC
 - Peter Gorman, Asst Chemical Hygiene Officer AMC
- Healthcare Association of New York State
 - Karen Roach, Director governmental Affairs
- New York State Department of Environmental Conservation
 - Alan Woodard, PhD
 - Dennis Lucia

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Healthcare Association of New York State - Karen Roach, Director governmental Affairs
New York State Department of Environmental Conservation - Alan Woodard, PhD, Dennis Lucia, Resa Dimino
New York State Department of Health, Bureau of Narcotic Enforcement – Paula Grogan; Victoria Hanson, RPH
New York State Department of Education
Stericycle Inc (Contractor) – Maureen Guice Major Account Executive, Dan Fadgen Rx Formulary

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Planning

- Maldi-disposals of Pharmaceuticals from OR
– “Houston we have a problem”



Controlled drugs in trash (cocaine - fentanyl): March, 2005
Glass vials with regulated drugs in trash: May, 2005

Pharmaceutical maldi-disposals became a significant issue for AMC in 2005. As shown above, controlled drugs and regulated substances were haphazardly disposed in cardboard boxes and regulated medical waste (white buckets) making drug diversion likely. Additionally, many of the regulated drugs were not handled in accord with State or federal regulations (RCRA). No consistent guidance for pharmacists or medical practitioners was available and staff were pretty much “left on their own”. Regulatory control and guidance from the US EPA and NY DEC was focused upon the professional waste managers for healthcare facilities (Environmental Health & Safety) and statewide enforcement inspections of hospitals by both EPA and DEC in 2003 had resulted in significant penalties. This had not translated into guidance or process improvements to handling of pharmaceutical waste by the ultimate caregivers (pharmacy / patient care staff).

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Pharmaceutical Waste

- Goals
 - Compliance
 - Avoid water wasting and discharge.
 - Reduce drug diversion
 - Improve medication management practices
 - New regulations on pharmaceutical waste (universal wastes).

Goals: Improve compliance with Joint Commission, State, Federal and Local restrictions on discharge of pharmaceutical waste to water supplies.

Improve compliance with Controlled Substance (Narcotics) regulations and avoidance of diversion.

Improve medication management practices in collaboration with HANYS (AMC - National Model).

Position AMC for compliance with new State and federal regulations on limiting waste water discharge of pharmaceutical waste (Universal wastes).

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What's Changed?

- New Joint Commission standards.
- Increased compliance 274 currently regulated drugs.
- Anticipated new regulations on discharge of pharmaceuticals to waste waters affecting 2,426 not currently regulated drugs.
- Publication of CCL3 (Third drinking water Contaminant Candidate List).

New Joint Commission standards.

(EC.02.20.01; MM.02.01.01; MM.03.01.01; MM.05.01.11; MM.05.01.19)
Increased compliance action on 274 currently regulated pharmaceuticals by OSHA; US EPA; NYS DoH; NYS DEC and Albany County Sewer District e.g., Chemotherapy drugs, epinephrine, fentanyl, aerosol containers.
Anticipated new federal and state regulations on discharge of pharmaceuticals to waste waters affecting 2,426 not currently regulated drugs. Mood altering drugs – prozac, antiviral drug, endocrine drugs, heart medications digoxin and antiinflammatory drugs – ibuprofen and cholesterol lowering drugs – lipitor.
Publication (September, 2009) Third Drinking Water Contaminant Candidate List (CCL3) including estrogens, formaldehyde, ethylene glycol and nitroglycerine.

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2009 Joint Commission Standards

Environment of Care Standard (EC.02.02.01): manage risks

Elements of Performance:

- Minimize risk disposing of hazardous medications.
- Minimize risk managing hazardous medications.

Medication Management Standard (MM.02.01.01): select, procure medications.

Elements of Performance

- Maintain formulary (strength and dosage).
- Formulary readily available.
- Reviewed at least annually.

Joint Commission Standards 2009 Applicable to Pharmaceuticals Waste Management
Environment of Care Standard (EC.02.02.01)

The [organization] manages risks related to hazardous materials and waste.

Elements of Performance for EC.02.02.01

The hospital minimizes risks associated with disposing hazardous medications. (See also MM.01.01.03, EP 4).

MM.01.01.03 (4): A, 3 The hospital minimizes risks associated with managing hazardous medications. (See also EC.02.02.01, EP 8)

**Medication Management Standard
(MM.03.01.01): safe storage**

- Maintain integrity
- Promote availability
- Reduce diversion and dispensing errors.
- A written policy to control medications from receipt to administration.
- Label all medications and components with contents, expiration date, and warnings.
- Expired, damaged, and/or contaminated medications are removed and stored separately.
- Periodically inspect medication storage areas.

Medication Management Standard (MM.03.01.01)

The [organization] safely stores medications.

Rationale for MM.03.01.01

Medication storage is designed to assist in maintaining medication integrity, promote the availability of medications when needed, minimize the risk of medication diversion, and reduce potential dispensing errors.

Law and regulation and manufacturers' guidelines further define the [organization]'s approach to medication storage.

Elements of Performance for MM.03.01.01

The hospital stores controlled (scheduled) medications to prevent diversion, in accordance with law and regulation.

The hospital has a written policy addressing the control of medication between receipt by an individual health care provider and administration of the medication, including safe storage, handling, security, disposition, and return to storage.

All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.

The hospital removes all expired, damaged, and/or contaminated medications and stores them separately from medications available for administration.

The hospital periodically inspects all medication storage areas.

**Medication Management Standard
(MM.05.01.11): dispense medication**

- Practices and recordkeeping include antidiversion strategies.
- Medications dispensed in ready-to-administer or unit doses.

**Medication Management Standard (MM.05.01.19):
manage returns.**

- Medications are returned when allowed.
- Returns are accounted, controlled, and disposed to keep patients safe and prevent diversion.
 - The hospital determines if and when outside sources are used for destruction of medications.
 - The hospital implements its process for managing unused, expired, or returned medications

Medication Management Standard (MM.05.01.11)

The [organization] safely dispenses medications.

Elements of Performance for MM.05.01.11

The hospital dispenses medications and maintains records in accordance with law and regulation, licensure, and professional standards of practice.

Note: Dispensing practices and recordkeeping include antidiversion strategies.

Medications are dispensed in the most ready-to-administer forms commercially available, and, if feasible, in unit doses that have been repackaged by the pharmacy or licensed repackager.

Medication Management Standard (MM.05.01.19) manages returned medications.

Rationale for MM.05.01.19

Medications may be returned to the [organization] when allowed by law or regulation and organization policy.

Previously dispensed but unused, expired, or returned medications in the [organization] must be accounted for, controlled, and disposed of in order to keep patients safe and prevent diversion.

The hospital determines under what circumstances unused, expired, or returned medications will be managed by the pharmacy or the hospital.

When the hospital accepts unused, expired, or returned medications, it has a process for returning medications to the pharmacy's control, that includes procedures for preventing diversion.

The hospital determines if and when outside sources are used for destruction of medications.

The hospital implements its process for managing unused, expired, or returned medications

Implement

Grant Awarded

- Stage 1: Months 1-6; Baseline Data Collection, Education & Roll Out.
- Stage 2: Months 7 – 18: Program Implementation, Refinement and Data Collection
- Stage 3: Post Mortem Analysis & Decision Making for Full Scale Roll Out

Grant Awarded

Stage 1: Months 1-6; Baseline Data Collection, Education & Roll Out.

Stage 2: Months 7 – 18: Program Implementation, Refinement and Data Collection

Stage 3: Post Mortem Analysis & Decision Making for Full Scale Roll Out

Stage 1

- Baseline Metrics (see attached graphs)
- Award Contract for Pharmaceutical Waste Services
 - ✓ **Stericycle**
 - Triumvirate
 - PharmEcology
- Design Education Program

Stage 1: baseline data on weight and cost of pharmaceutical waste disposal was collected from AMC's Main campus and South Clinical Campus. Additional data from the AMC Pharmacies returns program was collected.

The AMC Formulary (some 2,700 items) was assembled by NDC in preparation for formulary characterization by an outside contractor.

Three outside contractors were solicited to provide bids for a subcontract under the EPA Grant. The sub contractor would provide formulary characterization and support, supplementary training, reusable waste containers and labels, and disposal of Non-RCRA Regulated pharmaceuticals. PharmEcology Inc requested not to be considered as a subcontractor for business reasons. Stericycle Inc., was awarded the sub contract by AMC.

The AMC Department of Education and Development designed an educational program focused upon the AMC caregiver. During this time, popular press reports of drinking water contamination by pharmaceuticals were appearing daily, so advantage was made of this confluence of events and flyers & Posters touting “What’s in Your Water” were distributed to the AMCH South Clinical patient care staff well in advance of the program’s kick off.

In addition to AMC’s education program, Stericycle provided a number of handouts and flyers targeting Environmental Services Staff and Nursing Staff based on other operating programs. AMC modified these for use at the South Clinical Campus. Stericycle also provided a 4 day train the trainer program just prior to placement of the pharmaceutical containers. AMC Facilities Maintenance had mounted the distinctive carriers and posters but had not placed any containers until the training was completed.

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Overview of Pharmaceutical Waste Management at AMC

- Management fragmentary and driven by competing regulations and practices
- Controlled substances (CS)
- Vaccines, biologicals and mixed wastes (regulated medical waste – RMW)
- Antineoplastic and cytotoxic drug wastes
- Radiopharmaceuticals
- Dyes and contrast agents (Barium)
- Shielding for radiotherapy

Controlled substances (CS)

Bedside wasting vs drug destruction

Most common toilet or sink wasting

Fentanyl patches must be put in sharps containers

Some CS are RCRA regulated (Chloral Hydrate / Paraldehyde)

Vaccines, biologicals and mixed wastes (regulated medical waste – RMW)

Red bag vs sharps containers

Sharps are not always incinerated!

Reusable sharps container systems.

Autoclave and shredding of sharps.

Sterile chemical wastes which are land filled!

Preservatives for vaccines, biologicals, human insulin. are hazardous wastes

Antineoplastic and cytotoxic drug wastes

Special handling and identification due to risk to employees (OSHA / NIOSH) during administration and clean up

Trace vs Residual waste

Radiopharmaceuticals

Decay in storage vs RCRA time limits

Mixed (radioactive – chemical) wastes

Dyes and contrast agents (Barium)

TCLP?

Shielding for radiotherapy

Heavy metal molding for directed beam procedures.

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Point of Generation?

- When drawn up?
- When partially administered?
- When returned to pharmacy?
- Floor stocks vs unit dosing?
- PYXIS® automated dispensing – return drawer
- Research, Investigational and patient's own medications

When drawn up?

When partially administered?

When returned to pharmacy?

Floor stocks vs unit dosing?

PYXIS® automated dispensing – return drawer

All transactions for all drugs recorded or just some?

Controlled substance wasting, returned to stock, etc.

Outdated stock

Research, Investigational and patient's own medications

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Metrics
Pharmaceutical Waste Generation – “Trace” vs “Residual”

MONTH	TRACE PHARM WASTE Lbs	RESIDUAL PHARM WASTE Lbs	TOTAL PHARM WASTE Lbs	TRACE PHARM \$	RESIDUAL PHARM \$	TOTAL PHARM \$
Jan-07	1,095	86	1,181	\$ 285	\$ 685	\$ 970
Feb-07	914	-	914	\$ 238	-	\$ 238
Mar-07	992	-	992	\$ 258	-	\$ 258
Apr-07	975	186	1,161	\$ 254	\$ 810	\$ 1,064
May-07	654	-	654	\$ 170	-	\$ 170
Jun-07	884	-	884	\$ 230	-	\$ 230
Jul-07	1,018	22	1,040	\$ 265	\$ 210	\$ 475
Aug-07	1,076	-	1,076	\$ 280	-	\$ 280
Sep-07	842	226	1,168	\$ 245	\$ 660	\$ 905
Oct-07	1,021	-	1,021	\$ 252	-	\$ 252
Nov-07	989	-	989	\$ 257	-	\$ 257
Dec-07	803	-	803	\$ 257	-	\$ 257
Jan-08	997	97	1,094	\$ 233	\$ 420	\$ 653
Feb-08	1,144	-	1,144	\$ 298	-	\$ 298
Mar-08	2,906	-	2,906	\$ 756	-	\$ 756
Apr-08	1,017	242	1,259	\$ 264	\$ 708	\$ 972
May-08	1,139	-	1,139	\$ 296	-	\$ 296
Jun-08	1,146	-	1,146	\$ 298	-	\$ 298
Jul-08	802	298	1,100	\$ 209	\$ 1,280	\$ 1,489
Aug-08	1,290	103	1,394	\$ 335	\$ 38	\$ 373
Sep-08	937	257	1,193	\$ 244	\$ 1,094	\$ 1,338
Oct-08	1,028	108	1,136	\$ 267	\$ 38	\$ 305
Nov-08	1,140	55	1,194	\$ 296	\$ 19	\$ 315
Dec-08	737	107	844	\$ 192	\$ 38	\$ 229
Jan-09	1,257	331	1,588	\$ 327	\$ 1,236	\$ 1,563
Feb-09	901	110	1,011	\$ 234	\$ 38	\$ 272
Mar-09	891	53	944	\$ 232	\$ 19	\$ 251
Apr-09	1,880	291	2,171	\$ 489	\$ 1,299	\$ 1,787
May-09	1,013	54	1,067	\$ 263	\$ 19	\$ 282
Jun-09	965	52	1,017	\$ 251	\$ 19	\$ 270
Jul-09	1,076	271	1,347	\$ 230	\$ 832	\$ 1,112
Aug-09	1,149	53	1,202	\$ 299	\$ 19	\$ 318
Sep-09	-	52	52	\$ -	\$ 19	\$ 19
TOTALS 2007	11,363	520	11,883	\$ 2,989	\$ 2,364	\$ 5,353
TOTALS 2008	14,184	1,266	15,450	\$ 3,688	\$ 3,634	\$ 7,322
TOTALS 2009	9,132	1,267	10,399	\$ 2,374	\$ 3,499	\$ 5,873
GRAND TOTAL	34,678	3,053	37,732	\$ 9,061	\$ 9,497	\$ 18,559

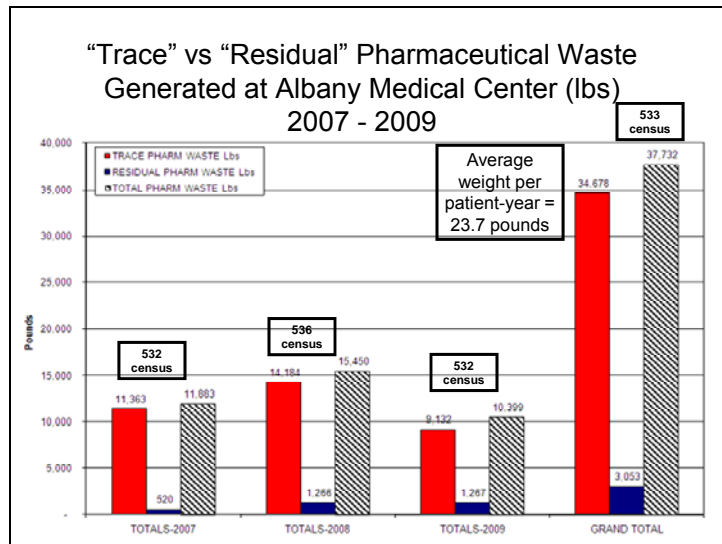
Stage 1: baseline data on weight and cost of pharmaceutical waste disposal was collected from AMC’s Main campus and South Clinical Campus. Additional data from the AMC Pharmacies returns program was collected.

“Trace” pharmaceutical waste refers to materials characteristic of regulated medical waste that have come into contact with regulated pharmaceuticals during administration. The most common example is trace contaminated materials from the administration of antimetabolite – antineoplastic drugs “Chemo”. These are labeled “CHEMO INCINERATE ONLY”

“Residual” pharmaceutical waste refers to both RCRA and Non-RCRA pharmaceutical wastes shipped for disposal by a commercial hazardous waste hauler.

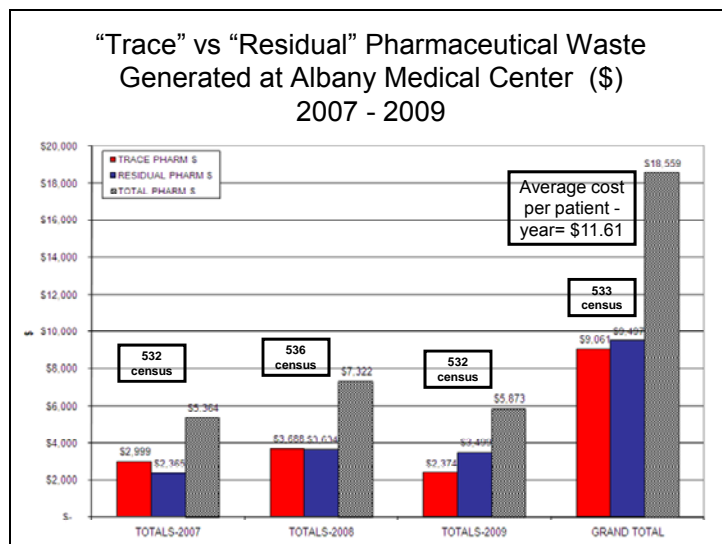
Despite the increased focus on pharmaceutical waste management and disposal, AMC experienced very modest increases in weight and cost of disposal of pharmaceutical wastes from January 2007 to the present. AMC’s pharmacy returns program also maintained a stable return for credit weight and cost. This program accounted for the bulk of returned medications.

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Graphical display of baseline data for “trace” and “residual” pharmaceutical waste generated at the Albany Medical Center’s Main Campus and South Clinical Campus from 2007 through 2009. The above amounts do not include pharmaceuticals returned for credit under AMC’s guaranteed returns program. During the project period, residual pharmaceutical waste (e.g., recognizable drug waste, partial vials, tablets, etc) doubled from about 500 pounds / year to over 1,000 pounds, yet overall waste generation was not significantly changed. Hospital occupancy levels remained relatively constant at 532, 536 and 532 patients per day. These data also provide some expectations for other facilities which wish to embark on pharmaceutical waste collection programs, allowing for rough projection of 23.7 pounds (21.6 pounds “trace” and 1.9 pounds “residual”) of drug waste generated per patient-year.

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As noted earlier, the cost per pound of disposal of “residual” (RCRA) pharmaceutical waste is markedly higher than for “trace” (RMW) contaminated drug waste for incineration only. Current RMW rates average between \$0.26 - \$0.45 per pound, depending on contractor. RCRA (“residual”) disposal rates may range as high as \$156 per pound for acutely toxic (P –listed) drug wastes. The above graph clearly indicates the necessity for careful waste segregation into appropriate streams as a small increase in RCRA waste can translate into a large increase in cost with no significant environmental benefit. Per patient-year costs for drug waste disposal over the baseline period 2007 – 2009 were \$11.61 (\$5.67 “trace” and \$5.94 “residual” – RCRA).

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Metrics

AMC-SCC Formulary characterization

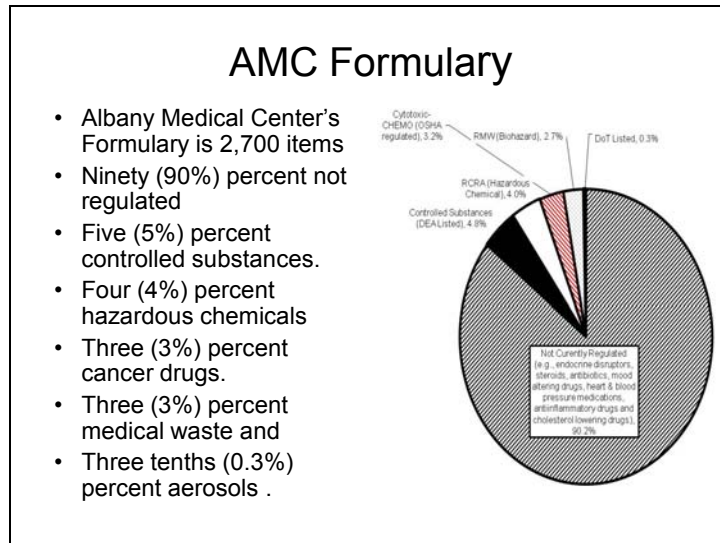
TOTAL	2,700	100%
Scheduled drugs (DEA or NYS regulated)	129	4.8%
RCRA	109	4.0%
Characteristic (D)	72	2.7%
Ignitable (D001)	38	1.4%
Mercury D009)	11	0.4%
Acutely Toxic (P) Note 3 of the 36 are epinephrine salts regulated by NY but Not US EPA*	31	1.1%
Listed (U)	6	0.2%
DoT listed (aerosols)	9	0.3%
Cytotoxic - Chemo (EPA/OSHA & NY DEC) Includes U & P listed	87	3.2%
RMW (biohazards)	73	2.7%
Not Currently Regulated (e.g., endocrine disrupters, steroids, antibiotics, antipsychotics, depressants, etc)	2,435	90%

*Nine drugs removed from RCRA Hazardous by US EPA & NY DEC:

1. Cyclophosphamide injection -U058; 10019095701
2. Cytoxan ® injection - U058, 00015050641
3. Epinephrine injection - 1mg/mL - P042, 66860002001
4. Epinephrine HCL - 1mg/mL - P042, 00548331600
5. Epinephrine HCL- 1mg/mL - P042, 00409724101
6. Mitomycin injection 40mg - U010 - 55390045301
7. Mitomycin injection 5mg- U010 - 55390045101
8. Physostigmine salicylate injection 1 mg/mL - P188, 11098051002
9. Trisenox - P012, 1459060010

The formulary for AMC is representative of most hospitals which have between two and three thousand individual items. If a drug is not on the formulary, it is normally not available unless by special order. Characterization of the hospital formulary is the first step in RCRA and Joint Commission compliance. A facility without a formulary (or “drug list”) will not know what medications are either available for administration or what solid wastes are generated, thus failing the first test in “cradle to grave” RCRA compliance. Furthermore, the facility is unable to determine its generator status under RCRA, any manifesting, notification or training requirements which may apply. AMC’s South Clinical Campus maintained its status as a Conditionally Exempt Small Quantity Generator (CESQG) despite generating small amounts of the P listed waste - epinephrine. In April, 2009, The New York State Department of Environmental Conservation concurred with an earlier determination by the US EPA to delist epinephrine salts (epinephrine is insoluble in water so medical epinephrine for drug use is converted to the hydrochloride salt for administration). This ruling also affected other P and U (but not characteristic – D) listed wastes in syringes and needles. Because of this recent clarification and the rather standardized formularies in use, most healthcare facilities should now find themselves as CESQG status.

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Of the 2,700 pharmaceuticals (unique NDC's) which comprise the Albany Medical Center's Formulary, ninety percent are not currently regulated (e.g., endocrine disruptors, steroids, antibiotics, mood altering drugs, heart & blood pressure medications, anti-inflammatory and cholesterol lowering drugs).

Five percent are controlled substances, regulated by the US DEA or New York State.

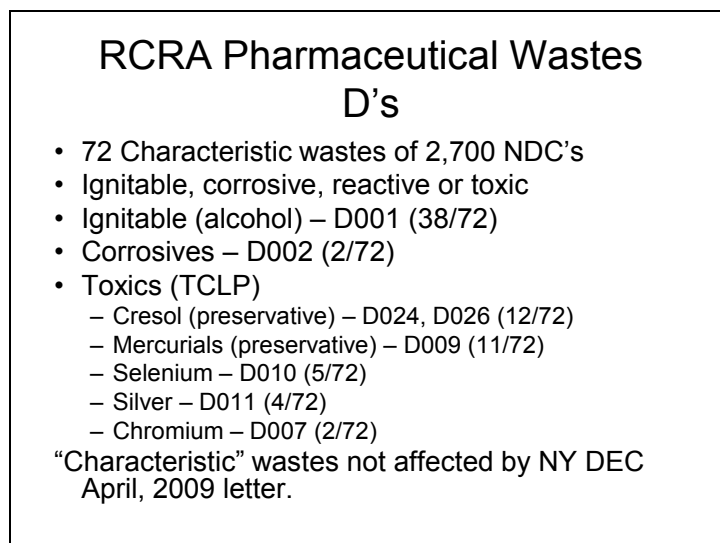
Four percent (April, 2009) were regulated as hazardous chemical wastes (N.B. the US EPA and New York State have since deregulated epinephrine salts and syringes with listed wastes).

Three percent are OSHA / NIOSH regulated cytotoxic drugs.

Three percent are medical waste (biohazardous); and

three tenths of a percent are aerosols regulated by the US Department of Transportation.

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Examples of characteristic drug wastes:

Ignitable – Aromatic ammonia, argatroban, benzoin tincture, clindamycin, collodion, dexamethasone, etoposide, iodine tincture, kaletra, mastisol, nitroglycerine injection, norvir, paclitaxel, trileptal;

Corrosive – Trichlor liquid;

Reactive – none; and

Toxicity (D004 – D043) – Multitrac-4 injectable concentrate, Tab-a-vite, Thera vitamin (D007); Bio Glo, flurbiprofen, Genesal solution, nasal decongestant, neomycin/polymyxin/gramacidin ophthalmic solution, Neo-syneprine spray, oxymetazoline solution, trifluridine ophthalmic solution (D009), Adqadeks liquid, selenious acid injection, selenium sulfide lotion/shampoo (D010), silver nitrate applicator, SSD cream, thermazine cream (D011); Apidra injectable, Humalin®, lantus, Novolin N injectable (D024), and clobetasol cream, Humalog, Novolin 70/30, Novolog (D026).

TCLP – Toxic constituent leaching potential as expressed as mg/L (40 CFR 261.24)

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RCRA Pharmaceutical Wastes

P's (Acutely Toxic)

- 31 of 2,700 NDC's
- Generator status – 1 kg, includes container weight
- Included:
 - Warfarin / Coumadin – P001- solid (tablet) dosage form only.
 - Nicotine – P075 (gum, patches)
- Excluded:
 - Epinephrine (salts) – July 15, 2009
 - Physostigmine Salicylate – injection residual
 - Trisenox ® arsenic trioxide – injection residual

Examples of non-excluded P listed pharmaceutical wastes:

Coumadin tablets 2-10 mg, Jantoven tablets 2-10 mg, Warfarin tablet 2-10 mg (P001); and Nicorelief, nicotine transdermal (P075)

Affects generator status – 1 kg (2.2 pounds) generated in any one month or accumulate 1 kg (2.2 pounds) of P waste at any time.

FULLY REGULATED - LARGE QUANTITY GENERATOR!!

2.2 POUNDS INCLUDES WEIGHT OF EMPTY CONTAINER!!!!!!!

Excluded:

Epinephrine (salts) – Delisted by New York, July 15, 2009 for salts of epinephrine and injection residuals (syringes, vials, sharps, etc).

Physostigmine Salicylate – P188 injection residuals (syringes, vials, sharps, etc).

Trisenox ® arsenic trioxide – P012 injection residual (syringes, vials, sharps, etc).

RCRA Pharmaceutical Wastes

U's

- 10 of 2,700 NDC's
- Discarded virgin product not in syringe / needle
- Sole active ingredient
- Chemo / Cytotoxic
 - Mitomycin C – U010
 - Cyclophosphamide – U058
- Shampoo – Selenium Sulfide U205
- Throat Spray – Phenol U188
- Warfarin / Coumadin – U248 (1 mg tablet)

Examples of non-excluded U listed pharmaceutical wastes (virgin discarded product, sole active ingredient only, not in sharps or syringe - injectable): Sore throat spray cherry (U205), selenium sulfide lotion and shampoo (U205); coumadin 1 mg tablet, Jantoven tablet 1 mg, Warfarin tablet 1 mg (U248)

Antineoplastic / Cytotoxic Drugs

- | | |
|--------------------|-------------------|
| • 5 fluoro Uracil | • Danorubicin |
| • Arsenic trioxide | • Daunomycin |
| • Azaserine | • Doxorubicin |
| • Azathioprim | • Lomustine |
| • Bleomycin | • Mechlorethamine |
| • Busulfan | • Melphalan |
| • Carmustine | • Mercaptopurine |
| • Chlorambucil | • Methotrexate |
| • Cyclophosphamide | • Mithramycin |
| • Chlornaphazin | • Mitomycin |
| • Cisplatin | • Mitomycin C |
| • Cytarabine | • Procarbazine |
| • Dicarbazine | • Uracil Mustard |
| • Dactinomycin | |

In 1987, an EPA policy letter clarified that waste contaminated with trace residues of chemotherapy agents would be considered non-hazardous waste if it meets the “empty container” criteria. OSWER Directive 9441.1987(45) (policy directive from J. Sales, Chief, Regulation Development Section, EPA), U.S. Environmental Protection Agency, June 16, 1987; cited in W. L. Turnberg, loc. cit. “Empty containers” are containers from which chemotherapy agents have been removed and no more than 1

inch of residue or no more than 3% by weight of residue remains in the container. The EPA recommends that materials such as vials, syringes, gloves, etc. contaminated with these chemicals not be handled after use to minimize exposure.

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Not Currently Regulated Drugs (2,426)

- Antibiotic/antiviral drugs – 250 (10.3%)
 - Examples: amoxicillin, ketoconazole, miconazole, levofloxacin
- Antipsychotic/antidepressant drugs – 109 (4.5%)
 - Examples: haloperidol, clozapine, imipramine
- Endocrine disruptors/hormones – 100 (4.1%)
 - Examples: bromocriptine, estradiol, megestrol, tamoxifen
- Heart/blood pressure drugs – 71 (2.9%)
 - Examples: amiodarone, propranolol
- Antiarthritic / antiinflammatory drugs – 55 (2.9%)
 - Examples: allopurinol, aspirin, ketoprofen

Non-regulated does not mean not harmful. In December 2008, The US EPA proposed to extend the universal waste rule to hazardous (RCRA regulated) pharmaceuticals “Amendment to the Universal Waste Rule: Addition of Pharmaceuticals” 73 FR 73519-73544 Dec 2, 2008. The EPA specifically encouraged (but did not mandate) healthcare facilities to manage all pharmaceutical wastes (hazardous and non-hazardous) as universal wastes under this new proposed rule. An area left unresolved was the handling of RCRA regulated controlled substances. Neither RCRA nor the proposed rulemaking supersede the requirements of the Controlled Substances Act and DEA regulations for the disposal of controlled substances. Thus, any entity generating, collecting, handling or managing a RCRA hazardous pharmaceutical waste that is also a controlled substance in Schedule II-V \43\ must abide by RCRA as well as the requirements of the Controlled Substances Act and DEA regulations. Three examples of listed hazardous wastes that are also controlled substances are phentermine (alpha, alpha-dimethyl- benzenethanamine, P046), chloral hydrate (U034), and paraldehyde (U182).

Additional pharmaceuticals were listed by the US EPA to the Contaminant Candidate List 3 (CCL3) on September 22, 2009. These included 9 endocrine disruptors/hormones: 17 alpha estradiol, 17 beta estradiol; 17 alpha ethynyl estradiol, estriol, estrone, mestranol, equilenin, equilin, 19 norethisterone, and 1 antibiotic: erythromycin.

Slide 23

Examples of Environmentally Harmful but Non-Regulated Drugs of Concern*

Pharmaceutical	PBT <small>(persistence, bioaccumulation, toxicity)</small>	Risk of Bioaccumulation	Pharmaceutical	PBT <small>(persistence, bioaccumulation, toxicity)</small>	Risk of Bioaccumulation
acitretin	9	N/A	diazepam**	6	N/A
allopurinol	6	moderate	docetaxel	9	cannot be excluded
amiodarone	9	N/A	drospirenone	8	cannot be excluded
amoxicillin**	6	moderate	dutasteride	8	cannot be excluded
atovaquone	9	N/A	efavirenz	9	insignificant
beclomethasone	9	cannot be excluded	escitalopram	9	insignificant
bromocriptine	9	N/A	estradiol	9	high
budesonide	8	insignificant	ethinyl estradiol	9	high
carvedilol	9	insignificant	etonogestrel	8	insignificant
citalopram	9	insignificant	felodipine	9	low
clemastine	9	N/A	fentanyl**	7	N/A
clozapine	9	insignificant	haloperidol	8	insignificant
cyproterone	8	cannot be excluded	imipramine	9	N/A
dasatinib	9	insignificant	isradipine	9	insignificant
desogestrel	8	insignificant	ketoconazole	9	moderate
dextropropoxyphene	8	cannot be excluded	ketotifen	9	N/A
dydrogesterone	8	cannot be excluded	leflunomide	8	N/A
levofloxacin	8	insignificant	megestrol	9	N/A
miconazole	9	N/A	ofloxacin	9	insignificant
propofol	9	N/A	propranolol	3	moderate
tamoxifen	9	N/A	telithromycin	9	insignificant

*Those with a PBT (persistence, bioaccumulation and toxicity) score of 8/9 or 9/9 and/or a moderate or high risk (high production/use or high environmental measurement) as reported by "Environmental Classification of Pharmaceuticals in www.fass.se". **Included in list due to high production, usage and environmental release.

The table was abstracted from “Environmental Classification of Pharmaceuticals in www.fass.se”. Additional pharmaceuticals with lower PBT scores were included because of high production, usage and environmental release (e.g., amoxicillin, diazepam, fentanyl).

PBT (persistence, bioaccumulation, toxicity) were assigned as 1 to 3 individually and multiplied to give an overall ranking from 1 to 9. Risk of Bioaccumulation was assessed as the drug concentration in the environment compared to the expected drug concentration based on drug production / usage (e.g. a drug with a moderate score would have a greater than expected environmental concentration as compared to a drug with an insignificant score which would have a lower than expected concentration in the environment).

Antibiotic/antiviral drugs – 250 (10.3%): amoxicillin - PBT 6, moderate bioaccumulation; atovaquone – PBT 9, no data available for bioaccumulation; efavirenz - PBT 9, insignificant bioaccumulation; levofloxacin - PBT 8, insignificant bioaccumulation; miconazole – PBT 9, no data available for bioaccumulation; ketoconazole – PBT 9, moderate bioaccumulation; ofloxacin – PBT 9, insignificant bioaccumulation; telithromycin – PBT 9, insignificant bioaccumulation.

Antipsychotic/antidepressant drugs – 109 (4.5%): citalopram - PBT 9, insignificant bioaccumulation; clozapine - PBT 9, insignificant bioaccumulation; escitalopram - PBT 9, insignificant bioaccumulation; haloperidol – PBT 8, insignificant bioaccumulation; imipramine – PBT 9, , no data available for bioaccumulation;

Endocrine disruptors/hormones – 100 (4.1%): cyproterone - PBT 8, cannot be excluded from bioaccumulation; desogestrel - PBT 8, insignificant bioaccumulation; dydrogesterone - PBT 8, cannot be excluded from bioaccumulation; tamoxifen - PBT 9, no data available for bioaccumulation; drospirenone - PBT 8, cannot be excluded from bioaccumulation; dutasteride - PBT 8, cannot be excluded from bioaccumulation; estradiol – PBT 9, high bioaccumulation (CCL3 listed); ethinyl estradiol – PBT 9, high bioaccumulation (CCL3 listed); etonogestrel – PBT 8, insignificant bioaccumulation; megestrol – PBT 9, no data available for bioaccumulation;

Heart/blood pressure drugs – 71 (2.9%): amiodarone - PBT 9, no data available for bioaccumulation; carvedilol- PBT 9, insignificant bioaccumulation; felodipine – PBT 9, low bioaccumulation; isradipine – PBT 9, insignificant bioaccumulation; propranolol – PBT 3, moderate bioaccumulation;

Antiarthritic/antoinflammatory drugs – 55 (2.9%): allopurinol – PBT 6, moderate bioaccumulation; leflunomide - PBT 8, no data available for bioaccumulation; beclomethasone – PBT 9, cannot be excluded from bioaccumulation; ketoprofen – PBT 7, cannot be excluded from bioaccumulation.

Slide 24

AMC Pharmacy Reverse Distribution

- Vendor: Guaranteed Returns, Holbrook, NY
- Quarterly pickups.
- 539 items were returned (March 10, 2009) for a credit of \$89,375.19
- 487 items were sent to vendor and not credited due to various reasons – charged \$35,105.34
- 50 “Hazardous Materials” were returned for a credit of \$1,868.92
- 8 Controlled substances were returned for a credit of \$283.99
- Net credit to AMC \$56,422.76 - March 10, 2009.

AMC Pharmacy Reverse Distribution

Vendor: Guaranteed Returns, Holbrook, NY; Quarterly pickups. Representative data from March, 2009.

539 items returned (March 10, 2009) for a credit of \$89,375.19. These were quite varied. Only 4 drugs had from 7 to 9 returns each. The most frequently returned were flumazenil (9 items - \$3,924); Abilify® - 8 items – \$95.12; Coreg® tablets – 8 items - \$1,293.89; Ceftin suspension – 7 items - \$456.42;

487 items were sent to vendor and not credited due to various reasons – Guaranteed Returns charged \$35,105.34 for these non-returnable items.

50 “Hazardous Materials” were returned for a credit of \$1,868.92. These included insulin (21 returns – Humulin®, Novolin® - \$1,583.79) ; epinephrine (8 returns - \$50.10); influenza vaccine (2 returns - Fluarix® - \$86.13) and one each physostigmine (\$36.45), alcohol (98% - \$81.25), nicotine transdermal (\$25.99) and amyl nitrate (\$5.21).

8 Controlled substances were returned for a net credit of \$283.99

Slide 25

What Have We Done?

- Received 2 year grant from US EPA for pharmaceutical waste pilot program at South Clinical Campus.
 - Program implemented at SCC & extended to all offsite and practice sites.
 - Collection of ALL pharmaceutical waste and on site sorting.
- AMC Pharmacy uses reverse distributor and take back of unopened or outdated drugs.
- Participated in formation of a State program “Do Not Flush Your Drugs”
- State Program expands to drug take back days in each region.
- Main campus pilot program implemented.
 - Authorized for 4 patient care areas.
 - Focused on controlled substances (narcotics) wasting.
 - Culture change from bedside wasting into toilets and sinks by patient care staff.

What Have We Done?

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Program implemented at SCC & extended to all offsite and practice sites.

Collection of ALL pharmaceutical waste and on site sorting.

AMC Pharmacy uses reverse distributor and take back of unopened or outdated drugs (NO WASTES ACCEPTED).

Participated in formation (<http://www.dec.ny.gov/press/45813.html>) of a State program “Do Not Flush Your Drugs” http://www.dec.ny.gov/docs/administration_pdf/0409dontflush.pdf

State Program expands to drug take back days in each region Statewide Household Pharmaceutical Collections -- October 19 -24, 2009 <http://www.dec.ny.gov/chemical/45083.html>

AMC’s pilot project provided model for protection of New York City Watershed – Office of the NYC Watershed Inspector General.

Main campus pilot program implemented.

Authorized for 4 patient care areas.

Focused on controlled substances (narcotics) wasting.

Culture change from bedside wasting into toilets and sinks by patient care staff.

Results - AMC South Clinical Campus

- Project period runs May 9, 2008 – August 27, 2009 (475 days)
- 226 containers from 8 OR's Post-Op; Pre-Op, MRI, Patient care floor and a Surgical practice site
- 0.008 lbs/container/day
- Total weight 851.7 pounds
- 17.2 pounds (2.0%) RCRA
- 717.2 pounds (84%) Non-RCRA
- 191.4 pounds of propofol, the most common (27% - by weight includes container weight) non-RCRA medication.
- 662 sharps
- 760 antibiotics (30.1 pounds – 4.2%)
- 178 controlled substances (2.2 pounds – 0.3%)
- Costs per pound (RCRA contractor):
 - RCRA pharmaceutical waste \$156 - \$3.52;
 - RCRA chemotherapeutic waste \$6.07;
 - Non-RCRA pharmaceutical waste for incineration only \$4.37 – \$2.23.
- Stericycle = \$0.36/lb (Incinerate only).
- 113 hr for labor in waste sorting (2 persons)

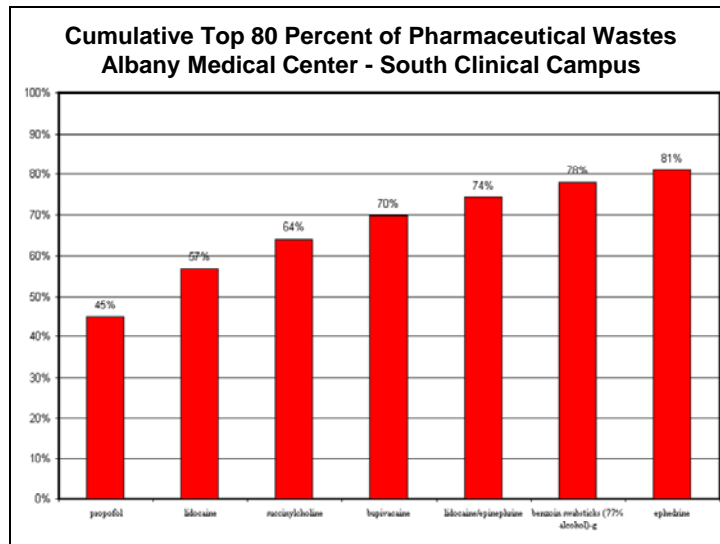
Results – AMC South Clinical Campus

From May 9, 2008 – August 27, 2009 (475 days) 226 containers were collected from 8 operating rooms (8,000 surgical cases per year), Post-Op; Pre-Op, Post Anesthesia Care Unit (PACU), Magnetic Resonance Imaging and Radiology, one patient care floor (20 beds – 23 hour stay) and a Surgical practice site. This averaged 0.008 lbs/container/day from a total weight collected of 851.7 pounds, only 17.2 pounds (2.0%) was RCRA regulated pharmaceutical waste. Non-RCRA pharmaceutical waste constituted 84% of the collected material or 717.2 pounds. Propofol, a non-narcotic lipid soluble anesthetic was the most common (27% - by weight includes container weight) non-RCRA medication accounting for 191.4 pounds of drug waste. During the course of the pilot program propofol waste management was targeted for a process improvement and propofol waste declined from 43% of initial waste collections from the operating rooms to less than 20% by weight. Other non-RCRA drug wastes included 760 antibiotics (30.1 pounds – 4.2%) and 178 controlled substances (2.2 pounds – 0.3%).

662 sharps including broken glass vials, uncapped needles with or without syringes and ampoules were removed during sorting and resulted in maldisposal reports to the Director of Patient Care Services.

Costs per pound (RCRA contractor): RCRA pharmaceutical waste \$156 - \$3.52; RCRA chemotherapeutic waste \$6.07; Non-RCRA pharmaceutical waste for incineration only \$4.37 – \$2.23. Stericycle® provided disposal under contract for Non-RCRA pharmaceutical waste by incineration only at a cost of \$19.00 for a 4.0 Cu.Ft. cardboard box (55 pounds Maximum weight). Labor for sorting required 113 hr for 2 persons. Refer to the sorting video for a more detailed review of the process of drug waste sorting.

Slide 27



Graphical representation of cumulative “80/20” data from pharmaceutical wastes collected at the AMC South Clinical Campus from May, 2008 – August, 2009. Of the 2,700 drugs in the AMC Formulary, seven account for over 80% of the drug wastage. Forty-five percent of the drug waste collected was one drug - Propofol (Diprivan®) waste. This wastage was markedly decreased by restricting the size available for dispensing from 50 and 100 mL vials to only 20 mL vials. The other 6 drug wastes were non-RCRA, non-controlled drugs used primarily in surgical procedures (anesthetics – lidocaine, bupivacaine, lidocaine/epinephrine; pressors – ephedrine; a neuromuscular blocker – succinylcholine; and a topical antimicrobial – benzoin swab sticks, 77% alcohol)

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Typical drugs collected:

1. propofol	13. omnipaque
2. lidocaine	14. lidocaine/marcaine
3. succinylcholine	15. bacitracin-g
4. bupivacaine	16. phenylephrine
5. lidocaine/epinephrine	17. dye
6. benzoin swabsticks (77% alcohol)-g	18. vancomycin-g
7. ephedrine 81%	19. heparin
8. epinephrine	20. neostigmine
9. bupivacaine/epinephrine	21. gadodiamide
10. atracurium	22. lidocaine jelly
11. proparacaine	23. cefazolin
12. atropine	24. diatrizoate meglumine
	25. oxymetazoline 95%

Listing of the top 25 (of 2,700 formulary drugs) wasted drugs from the South Clinical Campus from May, 2008 through August, 2009. Note that RCRA regulated drugs were a very minor component of the drug waste (epinephrine, dye, oxymetazoline – RCRA) and no controlled substances were among the top 25 (95% cumulative percent).

Slide 29

Drugs Disposed in Pharmaceutical Waste Containers (top 85%):			
Drug	Cum Pct	Percents	Total Of Total
Totals	100%	100%	50,150
propofol	45%	45%	22,515
lidocaine	57%	12%	6,052
succinylcholine	64%	7%	3,531
bupivacaine	70%	6%	2,922
lidocaine/epinephrine	74%	5%	2,307
benzoin swabsticks (77% alcohol)-g	78%	4%	1,818
ephedrine	81%	3%	1,524
epinephrine	83%	2%	854
bupivacaine/epinephrine	84%	2%	770

Cumulative data table for cumulative drug waste from May, 2008 through August, 2009. Cumulative totals based upon units (mL unless otherwise specified – e.g., benzoin swabsticks –grams not mL). Note of 50,150 units total waste collected only 854 mL of epinephrine was collected as waste.

Slide 30

Program Highlights
<ul style="list-style-type: none"> • SCC program operating 2 years. <ul style="list-style-type: none"> – Good compliance – low maldisposal rate. – Developed educational materials. – Reduced opportunity for diversion • Process Improvements & Cost Savings – SCC <ul style="list-style-type: none"> – Propofol wasting from surgery reduced. – Est \$100,000 in annual savings (8,000 surgical case/yr) • Offsite & Practices. <ul style="list-style-type: none"> – Excellent compliance. – Minimal maldisposals. – Increased compliance

Highlights.

SCC program operating 2 years.

Good compliance low maldisposal rate. Developed educational materials. Significantly reduced opportunity for diversion of controlled substances (narcotics – morphine, fentanyl, midazolam)

Process Improvements & Cost Savings – SCC

Propofol wasting from surgery reduced by changing sizes dispensed to 20cc only. Translates to \$100,000 in annual savings based on 8,000 surgical case load.

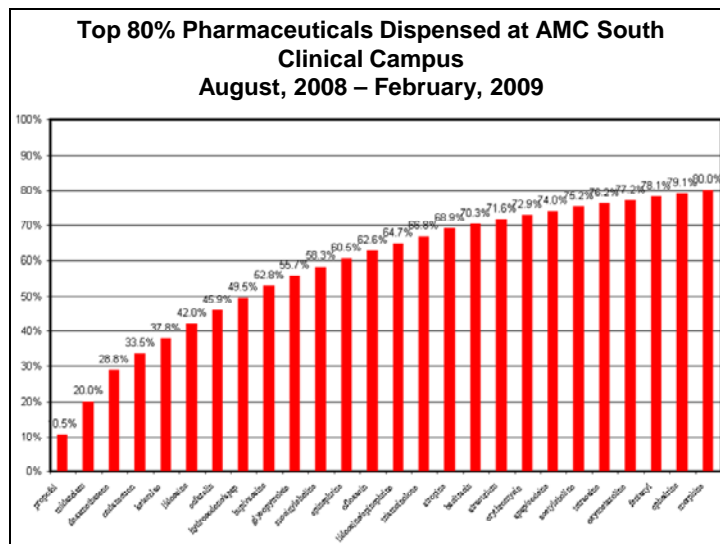
Offsite & Practices.

Excellent compliance. Minimal maldisposals. Increased compliance with hazardous waste laws and regulations.

Main campus pilot program.

Bedside wasting of liquid formulations common. Over 1/2 of drugs such as levofloxacin (antibiotic) or acetaminophen with codeine elixer (narcotic) are wasted into toilets and sinks. Eighty four percent of drugs dispensed at AMC (main campus) have a 0% wasting and are predominantly solid dosage forms dispensed as unit doses.

Slide 31



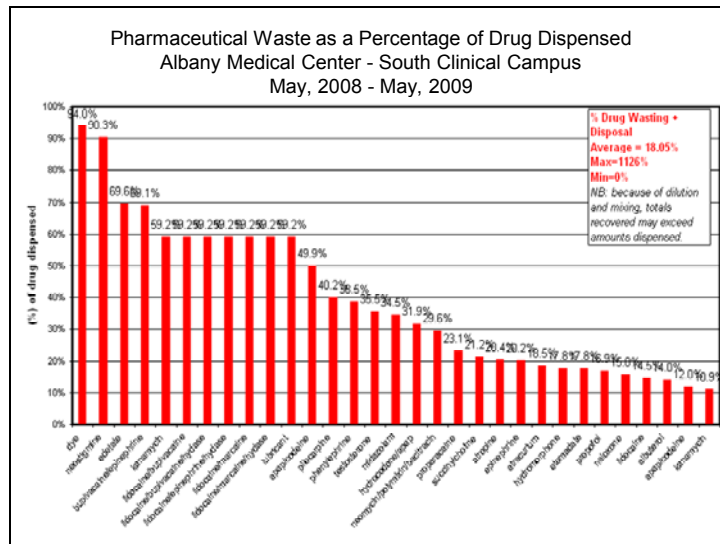
Graphical representation of cumulative dispensing data from PYXIS® automated dispensing machines at the AMC South Clinical Campus. Propofol, the most common waste, was also the most frequently dispensed medication. It however accounted for but 10.5% of the drugs dispensed as compared to 45% of the waste collected. Midazolam, a controlled drug, was next most frequently dispensed. Four controlled substances were among the 80% most dispensed drugs. Epinephrine and oxymetazoline were the only RCRA regulated (at that time) drugs which contributed to the top 80%.

Slide 32

Cumulative 80% Pharmaceuticals Dispensed at AMC South Clinical Campus						
August, 2008 – February, 2009						
Drug	Cum_pct (%)	Pct (%)	Out	Ret	Wst	Net
2/8/2009 - 190 days GRAND TOTAL	100%	100%	33,044	3,574	677	28,796
propofol	10.5%	10.5%	3,470	15	0	3,455
midazolam	20.0%	9.5%	3,135	37	520	2,579
dexamethasone	28.8%	8.8%	2,909	113	0	2,796
ondansetron	33.5%	4.7%	1,562	27	0	1,535
ketorolac	37.8%	4.3%	1,407	16	0	1,391
lidocaine	42.0%	4.2%	1,390	242	0	1,148
cefazolin	45.9%	4.0%	1,308	239	0	1,069
hydrocodone/apap	49.5%	3.5%	1,160	14	2	1,145
bupivacaine	52.8%	3.3%	1,106	293	0	813
glycopyrrolate	55.7%	2.9%	955	0	0	955
succinylcholine	58.3%	2.6%	864	1	0	863
epinephrine	60.5%	2.2%	720	216	0	504
ofloxacin	62.6%	2.2%	716	139	0	577
lidocaine/epinephrine	64.7%	2.1%	692	190	0	502
triamcinolone	66.8%	2.1%	688	200	0	488
atropine	68.9%	2.1%	688	50	0	638
baclofin	70.3%	1.4%	469	109	0	360
atracurium	71.6%	1.3%	426	9	0	426
erythromycin	72.9%	1.2%	409	108	0	301
apap/codeine	74.0%	1.2%	391	1	124	266
acetylcholine	75.2%	1.1%	374	128	0	246
tetracaine	76.2%	1.0%	344	172	0	172
oxymetazoline	77.2%	1.0%	319	86	0	233
fentanyl	78.1%	1.0%	318	1	0	317
ephedrine	79.1%	1.0%	318	1	0	317
morphine	80.0%	0.9%	311	14	29	269

Cumulative dispensing data from PYXIS® automated dispensing machines at AMC South Clinical Campus collected from August, 2008 – February, 2009. All data were downloaded weekly, stripped of patient identifiers and summarized by drug using Microsoft Excel and Microsoft Access. Out refers to number of drug units dispensed from the PYXIS®. Ret refers to the number of drug units recorded as returned to the PYXIS® machine. Wst refers to the number of drug units recorded as wasted in the PYXIS® records. Net refers to net drug units (out less returned and wasted). All units are the same for comparison and may be thought of as individual prescriptions. Of the 2,700 drugs in the AMC Formulary, 26 accounted for 80% of the drugs dispensed at the South Clinical Campus. As noted above, propofol was the most commonly dispensed medication. Five controlled substances (midazolam, hydrocodone/apap, apap/codeine, fentanyl and morphine); four local anesthetics (lidocaine, bupivacaine, lidocaine/epinephrine, tetracaine), three anti-inflammatory drugs (dexamethasone, ondansetron, ketorolac); vasopressors; muscle relaxants; and antibiotics rounded out the 26 dispensed medications

Slide 33



Graphical representation of drug wasting as a percentage of drug dispensed from PYXIS® automated dispensing machines. Great variability was noted in the percentage of wasting which averaged 18.05%. Ninety four percent of all dyes (RCRA regulated) dispensed were collected in the pharmaceutical waste. Neostigmine (90.3%), edetate (69.9%), bupivacaine/epinephrine (68.1%) exceeded 60% wasting. Eleven drugs exceeded 50% wasting. Refer to next slide for details on individual drug wasting.

Slide 34

Collection of Dispensed Medications as Pharmaceutical Waste at South Clinical Campus

We are collecting an average of 18% (range 0-1126%*) of the medications dispensed and not returned as pharmaceutical waste (not counting packaging) or bedside wasted.

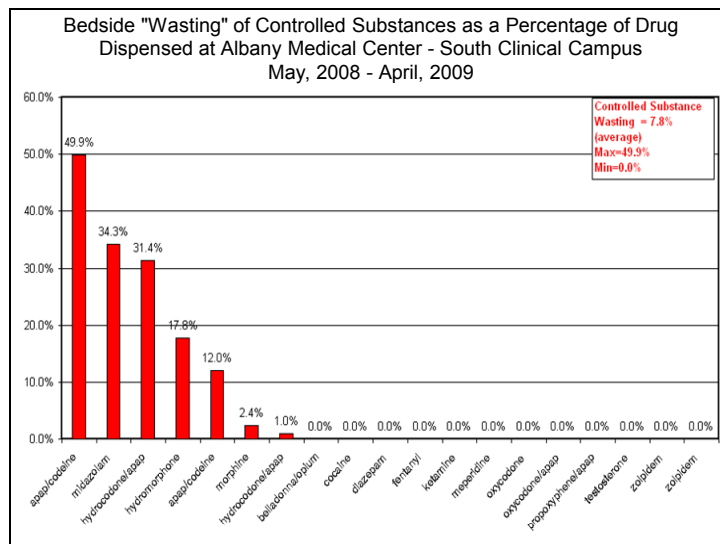
- > 91% of neostigmine dispensed is thrown out
- > 69% of bupivacaine/epinephrine dispensed is thrown out
- > 59% each of kanamycin, lidocaine/bupivacaine, lidocaine/bupivacaine/hydase, lidocaine/epinephrine/hydase, lidocaine/marcaine, and lidocaine/marcaine/hydase dispensed is thrown out
- > 49.9% of acetaminophen/codeine dispensed is thrown out
- > 40% of pilocarpine dispensed is thrown out
- > 39% of phenylephrine dispensed is thrown out
- > 36% of testosterone dispensed is thrown out
- > 30% of neomycin/polymixin/bacitracin dispensed is thrown out
- > 23% of propranolol dispensed is thrown out
- > 21% of succinylcholine dispensed is thrown out
- > 20% each of atropine and epinephrine dispensed is thrown out
- > 19% of atracurium dispensed is thrown out
- > 18% of etomidate dispensed is thrown out
- > 17% of propofol dispensed is thrown out
- > 16% of naloxone dispensed is thrown out
- > 15% of lidocaine dispensed is thrown out
- > 14% of albuterol dispensed is thrown out
- > From 1% to 10% of 35 drugs dispensed are thrown out
- > Less than 1% of 95 drugs dispensed are thrown out
- > Forty two drugs, radio-contrast agents or drug combinations were found during waste sorting but not dispensed from PYXIS® machines.

*NB: because of dilution and mixing, totals recovered may exceed amounts dispensed

Drug wasting as a percentage of drug dispensed from PYXIS® automated dispensing machines. We are collecting an average of 18% (range 0-1126%*) of the medications dispensed and not returned as pharmaceutical waste (not counting packaging) or bedside wasted.

- 91% of neostigmine dispensed is thrown out
- 69% of bupivacaine/epinephrine dispensed is thrown out
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Slide 35



Graphical representation of controlled substance wasting as a percentage of drug dispensed from PYXIS® automated dispensing machines. Wasting averaged 7.8% and was primarily due to acetaminophen/codeine liquid. This drug is normally dispensed in 12.5 mL bottles and is seldom fully dispensed. Of the controlled substances dispensed from the AMC South Clinical Campus Formulary, only 7 drugs had any significant wasting. These were almost exclusively liquid formulations, few solid dosage forms (tablet, capsule) were found as waste or recorded as wasted in the PYXIS® records. Please refer to the following slide for more detailed description of controlled substance wasting.

Bedside Wasting vs Discarding of Controlled Substances AMC-SCC data

An average of 7.8% (range 0 to 50%) of controlled substances dispensed from automated dispensing machines (PYXIS®) are bedside wasted.

- Acetaminophen and codeine dispensed as a liquid is most frequently bedside wasted (50%).
- 34% of midazolam dispensed is bedside wasted.
- 31% of hydrocodone/acetaminophen tablets dispensed are bedside wasted.
- 18% of hydromorphone liquid dispensed is bedside wasted.
- 12% of acetaminophen and codeine tablets are bedside wasted.
- 2% of morphine is bedside wasted.
- 1% of hydrocodone/acetaminophen liquid dispensed is bedside wasted.
- 12 controlled substances dispensed are not reported as bedside wasted.

An average of 7.8% (range 0 to 50%) of controlled substances dispensed from automated dispensing machines (PYXIS®) are bedside wasted.

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34% of midazolam dispensed is bedside wasted.

31% of hydrocodone/acetaminophen tablets dispensed are bedside wasted.

18% of hydromorphone liquid dispensed is bedside wasted.

12% of acetaminophen and codeine tablets are bedside wasted.

2% of morphine is bedside wasted.

1% of hydrocodone/acetaminophen liquid dispensed is bedside wasted.

12 controlled substances dispensed are not reported as bedside wasted.

Process Improvement – Propofol (Diprivan®)

Propofol is an injectable anesthetic agent used for outpatient or inpatient surgical procedures or to provide conscious sedation. It is a suspension in liquid supplied in 20, 50 or 100 mL vials. It is considered a 9 of 9 for persistence, bioaccumulation and toxicity (Environmentally classified pharmaceuticals, <http://www.janusinfo.se>). During waste segregation, propofol was found to comprise 41% of the total waste generated from the operating rooms as each case required a new vial of propofol to be opened and all propofol from the preceding case to be discarded.

Solution: 50 and 100 mL vials of propofol were removed from AMC Pharmacy inventory. Propofol would only be available in the smallest size manufactured to reduce wastage.

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Slide 38

Opportunity for Improvement

These data on wasting and disposed drugs as a proportion of pharmaceuticals dispensed at a small surgical hospital are in line with publications from the literature.

- In 2001, it was estimated that over \$13.00 of medications were wasted from each surgery, thus for a facility that does 8,000 cases/yr it would represent \$104,000 in costs due to wasted drugs based on 2001 drug costs.
- We have already seen a marked decrease in propofol wastage caused by our removal of the larger (50 and 100 cc) propofol vials.
- Processes to reduce lidocaine, succinylcholine and bupivacaine wastage will be designed and implemented.

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In 2001, it was estimated that over \$13.00 of medications were wasted from each surgery, thus for a facility that does 8,000 cases/yr it would represent \$104,000 in costs due to wasted drugs based on 2001 drug costs.

We have already seen a marked decrease in propofol wastage caused by our removal of the larger (50 and 100 cc) propofol vials.

Processes to reduce lidocaine, succinylcholine and bupivacaine wastage will be designed and implemented.

Tours and Dissemination of Knowledge Gained

- Seven, two-hour tours announced by HANYS.
- Fifty-one participants registered.
- Twenty-nine hospital, government, waste management and consulting organizations from Puerto Rico to Canada.
- Survey forms collected from each tour group.

Seven, two-hour tours of SCC pharmaceutical waste operations announced by HANYS.

Fifty-one participants registered: 26% safety or environmental services; 20% compliance; 19% administration; 13% clinician; 11% RPh; 4% scientist; and 7% other.

Twenty-nine hospital, government, waste management and consulting Organizations from Puerto Rico to Canada: 62% hospitals; 21% government; 6% pharmacy and 12% other (waste management, services, journalism).

Survey forms collected from each tour group.

Survey Results

- Program highly rated - eighty-five percent
- Would recommend to peers - eighty-five percent
- Presentations were of a lot or a great deal of help - eighty-three percent
- Educational materials useful - seventy-two percent
- Tour an impetus for change at their institution - sixty-one percent
- Tours a lot or a great deal of assistance to understanding the program - sixty percent
- Only 9% felt the tours were of some or no help in understanding the program.

Eighty-five percent of respondents rated the program highly overall..

Eighty-five percent of respondents would recommend the program to their peers.
Eighty-three percent of respondents felt the presentations were of a lot or a great deal of help.
Seventy-two percent of respondents felt the educational materials were very useful.
Sixty-one percent of the respondents felt the tour was an impetus for change at their institution.
Sixty percent of respondents felt the tours were of a lot or a great deal of assistance to understanding the program.
Only 9% felt the tours were of some or no help in understanding the program

Slide 41

Model Education Plan

- **Purpose:** Find optimal education plan to support pharmaceutical waste management program
- **Goal:** Staff compliance with JCAHO and State and Federal pollution prevention standards
- **Plan:**
 1. Audience: Nursing, PA's, The Anesthesia Group, PC
 2. Staff Meeting Presentations one month prior to Stage 2.
 3. Poster development for medication rooms
 4. Flyer development for mailbox distribution
 5. Manager follow up to determine staff knowledge
 6. Trainee feedback to refine training
 7. Develop & Test training DVD

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Model Education Plan (cont'd)

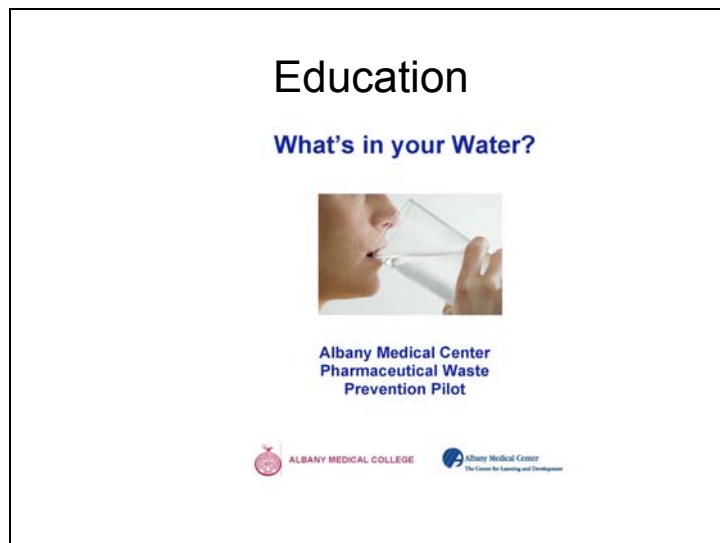
- **Outcome:** Managers and Directors hold staff accountable for incorporating change into practice.
- **Metrics:**
 1. Post test – 80% minimum passing. Completion rates for each job title, 99% target rate. New hires must receive training at hire.
 2. Random trainee follow-ups. Correct response rates below 80% trigger retraining.

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Random trainee follow-ups. Correct response rates below 80% trigger retraining.



Model education flyer developed by AMC Department of Nursing Education and Development for use in “Train the Trainer” sessions held before pilot project roll out.

Clinical Staff Handout (Cont'd)

What is pharmaceutical waste?

Many medications and personal care products contain toxic chemicals which are being found in wells, lakes, and rivers. The Federal Environmental Protection Agency (EPA) has developed standards for the safe disposal of medications to keep toxic chemicals out of our water supply.

AMC is piloting a system at the South Clinical Campus for the safe disposal of pharmaceuticals as part of an EPA grant.

- This program will reduce pollution while saving energy and water.
- This pilot will contribute to the development of strategies for the region in pharmaceutical pollution prevention.

Who does this apply to?

Registered Nurses, Physicians, Nurse Anesthetists, Licensed Practical Nurses, Respiratory Therapists, and Pharmacists are responsible for the safe disposal of medications.

What are examples of pharmaceutical waste?

Some examples of medications that are toxic in the environment are:

- Warfarin
- Nitroglycerine
- Chloral Hydrate
- Reserpine

An example of a personal care product that is toxic in the environment is medicated shampoo which contains selenium (Seisen Blue®).

What do I need to know?

All medications (tablets, capsules, liquids, and topicals) not returned to the pharmacy or Pyxis machine must be discarded in specified containers located throughout the clinical areas, and in dirty utility rooms.

If there is any visible medication or personal care product remaining in any syringe, bottle, or tube, it must be discarded in the specified container.

Chemotherapy waste handling is **unchanged**.

Sharps disposal is **unchanged**.

Empty medication containers or personal care product bottles are to be discarded into the normal trash.

Electrolyte solutions (ex. IV fluids) may be discarded into the sewer system.

Medications are **NEVER** discarded into normal trash, "red bag" trash, or the sewer system.

What can I do to keep our water free from toxins?

Discard all medications into pharmaceutical waste containers.

When do we start?

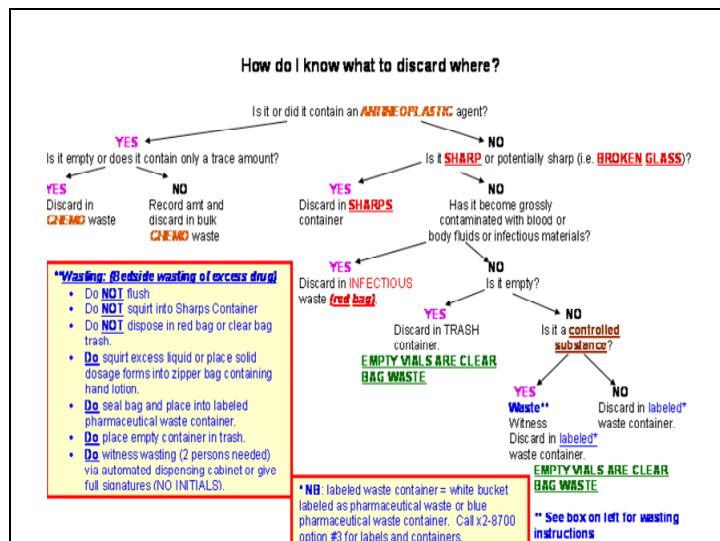
Feb 1, 2008

What happens next?

This pilot project will be evaluated and will provide the basis for the implementation of pharmaceutical pollution prevention not only at the AMC main campus but throughout northeastern New York.

What's in your water.....is up to you!

Opportune timing due to widespread news reports of drinking water contamination by pharmaceuticals appearing in local news outlets. Flyer was distributed to all nursing and patient care staff on the South Clinical Campus prior to roll out of the pilot project. A laminated 11" x 14" color poster of the flyer was produced and placed near each pharmaceutical waste container and copies given to each nurse manager.



Flow chart laminated and placed near each blue pharmaceutical waste container. Other copies distributed to nursing staff and placed at PYXIS® machines.

Education Activities:

- April 2, 2008: AMC Nursing education rounds for nursing units and radiology for SCC. 55 Staff trained. 20 posters and 65 handouts distributed.
- April 24 & 25, 2008: Presentations by AMC & Stericycle staff to Environmental Service & Clinical Staff . 4 presentations, 24 attendees.
- June 11, 2008. Announcement and summary of program by HANYS and availability of tours sent to all CEO's and Compliance Officers of HANYS Member Hospitals.
- July 14, 2008. Stericycle resends the HANYS announcement to all Stericycle Healthcare customers.
- July 25, 2008 Resent HANYS announcement to pharmwaste listserv at pharmwaste@lists.dep.state.fl.us
- July 25, August 1, August 22, September 26 and October 24. Tours of the South Clinical Campus and education sessions on pharmaceutical waste collections scheduled. July 25 – 8 (maximum) attendees.
- Dr R. Mankes - NEWMOA presentation. USEPA Region 2 Headquarters, NY,NY May 7,2008.
- Dr R. Mankes – Roundtable participant, Commissioners' Roundtable on Pharmaceutical Waste, NY DEC & NY DoH, NY DEC Headquarters, Albany, NY May 15, 2008.

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Slide 47

**Education assessment tours -
Pharmaceutical waste pilot program - SCC**

- **Methods:** Clinical staff were interviewed relative to knowledge of the program, location & type of container, call numbers for container change out and needs of the clinical staff. Comments were solicited as to education effectiveness and suggestions for improvement. Presence of educational posters was verified and additional information was made available for distribution.
- **Results:** 19 of 19 staff surveyed correctly responded (100%). 14 of 14 (100%) clinical areas had pharmaceutical waste containers in use with posters & education materials. Staff questions involved controlled substance disposal and barium contrast agent.

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Slide 48

Waste Accumulation

- **Containers?**
 - √ Size ?
 - √ Number ?
 - √ Location ?
 - √ Type ?
 - √ Liners ?
 - √ Liquids ?
 - √ Labeling & closures ?
 - √ Mounting?



4 gallon compatible
Waste container



2 gallon incompatible
Waste container

Examples of pharmaceutical waste containers. Blue 4 gallon container with flap closed top such that container is closed unless material is being added to container. Smaller 2 gallon incompatible container (one only located in Pharmacy for such waste as silver nitrate applicators). Issues to be determined: Size ?

- Number ?
- Location ?
- Type ?
- Liners ?
- Liquids ?
- Labeling & closures ?
- Mounting ?

Slide 49

PHARMACEUTICAL WASTE PROGRAM LOCATIONS

LOCATION	ROOM #	CONTAINER COLOR
RADIOLOGY (CT SCAN)	(SCC 125Q)	BLUE
M. R. I.	(SCC 148B)	BLUE
O. R. ROOM # 1	(SCC 295)	BLUE
O. R. ROOM # 2	(SCC 293)	BLUE
O. R. ROOM # 3	(SCC 292)	BLUE
O. R. ROOM # 4	(SCC 289)	BLUE
O. R. ROOM # 5	(SCC 287)	BLUE
O. R. ROOM # 6	(SCC 286)	BLUE
O. R. ROOM # 7	(SCC 285)	BLUE
O. R. ROOM # 8	(SCC 283)	BLUE
PACU / RECOVERY	(SCC 290)	BLUE
PRE OP	(SCC 294)	BLUE
POST OP	(SCC 242)	BLUE
PHARMACY DISPENSING ROOM	(SCC 243)	BLACK**
ECMU (WEST HALL) MED ROOM	(SCC 273)	BLUE

** Only location for disposal of non-compatible RCRA pharmaceuticals (6 NDC's of 2,700 NDC's in formulary)

Location of pharmaceutical waste containers. Note AMC South Clinical Campus has no Emergency Room so no containers placed for ER.

Slide 50

Waste Segregation

- **No Sharps!**
- **No RMW !**
- **No Controlled Substances!**
- **Chemo in separate chemo containers!**
- **No free liquids (Zip Lock baggies)!**

Quality Assurance:
 Routine Waste Audit to be conducted at least Monthly.
 Bi-monthly routine drug containers to include OR's & Patient Care Areas (Radiology, Oncology).
 Review of "Check" containers for appropriate disposal.

Waste segregation flow chart for use by pharmacy / environmental health and safety staff members to separate RCRA from Non-RCRA wastes. For this pilot project we had 3 separate waste profiles: 2 were RCRA (antineoplastics – U, P and D wastes; pharmaceuticals – D, U and P listed wastes) and 1 was non-RCRA pharmaceuticals. These were separated by HAZWOPER trained staff and packaged for pick up. Because New York State retained epinephrine salts as a P listed waste until late 2009, Hazardous waste pickups for the South Clinical Campus were scheduled every 90 days so that we did not accumulate 2.0 pounds of P listed waste at any time. This allowed us to retain our Conditionally Exempt Small Quantity Generator (CESQG) status.

Slide 51

Waste Segregation

- Time consuming & Labor intensive – 2 staff members x 15 minutes / container.
- High level of training required to identify drugs.
- High level of security & regulatory approval for staff by New York State required as controlled substances are commonly found in the pharmaceutical waste bins (despite the label no controlled substances).
- Sharps maldisposals into pharmaceutical waste make waste sorting hazardous and PPE is required

Issues revealed during pilot study:

For waste segregation it was time consuming and labor intensive requiring 2 highly trained staff members at 15 minutes for each container. A high level of training was required to identify drugs. Dr R. Mankes, a pharmacologist and toxicologist with over 30 years of experience supervised or performed each sort. Dr Mankes was assisted by 2 bachelor level technicians with special training in pharmacy and chemical hazards. A high level of security and regulatory approval for staff by New York State was required as controlled substances are commonly found in the pharmaceutical waste bins (despite the label no controlled substances). This included swipe and PIN access to the waste storage area, unique locks for each pharmaceutical container, and prior regulatory approval (by the New York State Bureau of Narcotic Enforcement) of personnel involved in handling of drugs. Sharps maldisposals into pharmaceutical waste make waste sorting hazardous and PPE is required.

Pharmaceutical Waste Compliance Service Overview

- Objective: develop and implement a hospital-wide, regulatory-compliant, pharmaceutical waste management program in order to minimize environmental impact from improper handling and disposal of pharmaceutical waste.
- Components:
 - RX formulary waste characterization analysis
 - RX formulary DOT waste stream analysis
 - Hospital pharmaceutical waste accumulation tracking
 - Source and volume analysis of hospital pharmaceutical waste generation
 - Waste sort on code functionality.
 - Logistics modeling
 - On-site RX waste segregation
 - Pharmacy returns.
 - Manifested waste pick-up, transport and disposal of hazardous and non-hazardous pharmaceutical waste

In our proposal we had designated that an outside contractor would provide pharmaceutical waste compliance services. These would include containers, supplemental training, waste pick up and disposal and formulary characterization. Facilities wishing to use an outside contractor should develop a “needs” list to use to determine the services required. A model plan used in the pilot project is presented above and includes:

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RX formulary DOT waste stream analysis

Hospital pharmaceutical waste accumulation tracking

Source and volume analysis of hospital pharmaceutical waste generation

Waste sort on code functionality.

Logistics modeling

On-site RX waste segregation

Pharmacy returns.

Manifested waste pick-up, transport and disposal of hazardous and non-hazardous pharmaceutical waste

Problem Areas

- Security
- Waste pick ups from rooms
- Diagnostic Radiology – Barium Waste
- Mixed Wastes
- Controlled substance disposal, e.g., Chloral Hydrate & Paraldehyde RCRA & DEA Regulated, “wasting” of narcotics into toilet, sink.

During the pilot we identified some problem areas

Security – as mentioned earlier, a secure, limited access storage area was deemed essential, particularly when maldisposed controlled substances were segregated from the pharmaceutical waste containers. In our case, a swipe and PIN access controlled by AMC Security was added to the Hazardous Waste Storage Building on the South Clinical Campus (Refer to video of tours and sorting). Waste pickups from rooms were conducted on an as needed basis by the patient care staff calling a central number when the bins became $\frac{3}{4}$ full. This however was supplemented by Biosystems staff who, during their rounds to change out reusable sharps containers, also changed out full pharmaceutical waste bins. Diagnostic Radiology – Barium Waste was initially thought to be a problem do to potential volumes of liquid waste generated. However, it was found that barium waste was not significantly generated at AMC’s South Clinical Campus due to the unit dosing of barium which is used in very limited cases at SCC (as compared to AMC’s main hospital). Mixed Wastes Controlled substance disposal, e.g., Chloral Hydrate & Paraldehyde RCRA & DEA Regulated, “wasting” of narcotics into toilet, sink.

Problem Areas (cont'd)

- State RCRA
- Nitroglycerin
- Epinephrine
- Alcohol swabs
- Container closure, Labeling and tracking?
- When do pharmaceutical waste containers have to be labeled hazardous waste? 90% of waste is non-regulated?

RCRA laws often vary by state and may significantly differ from US EPA regulations making compliance for healthcare difficult. Drugs which are regulated in one state may be unregulated by either the US EPA or another state. For example, up to July 15, epinephrine salts were RCRA Regulated in New York State but not RCRA regulated by the US EPA, leading to the unique dichotomy that epinephrine discarded by patient care staff at the Albany Veterans Administration Hospital (a federal facility located directly across the street from the Albany Medical Center) was not an acutely toxic P listed RCRA regulated waste. The same epinephrine, discarded by a staff member at Albany Medical Center would be treated as an acutely toxic P-listed RCRA regulated waste. Nitroglycerin is specifically listed as a RCRA waste but few healthcare workers are aware that unless the nitroglycerin is in a form which is reactive (D003) it is exempted from regulation. Alcohol swabs are considered ignitable (D001) wastes if they contain over 20% alcohol. How does a healthcare worker decide that a used alcohol skin swab contains 20% alcohol? Containers used for pharmaceutical wastes present additional issues. If they are not self closing, it is likely the container will remain open even when materials are not being added to it in violation of RCRA regulations. Many pharmaceutical containers are single use and disposed with the waste. This adds weight and expense to the program as well as increasing plastic burning in the incinerators from the packaging. Obviously, a reusable container system with an inner plastic bag liner is preferable to the single use container system. If a facility uses a single container system, each container should be considered a satellite accumulation area and be labeled and managed accordingly. If a multiple container system is used wherein the patient care staff are charged with an initial waste sorting, only the container designated for RCRA pharmaceuticals need be considered a satellite accumulation area and be labeled and managed accordingly.

**Pharmaceutical Waste
Compliance Program – Graduated
Roll Out to Main Hospital In-
Patient Nursing Units**

June, 2009 Controlled Substances

August – September, 2009 non-
controlled drug waste

Main Campus Pilot Program.

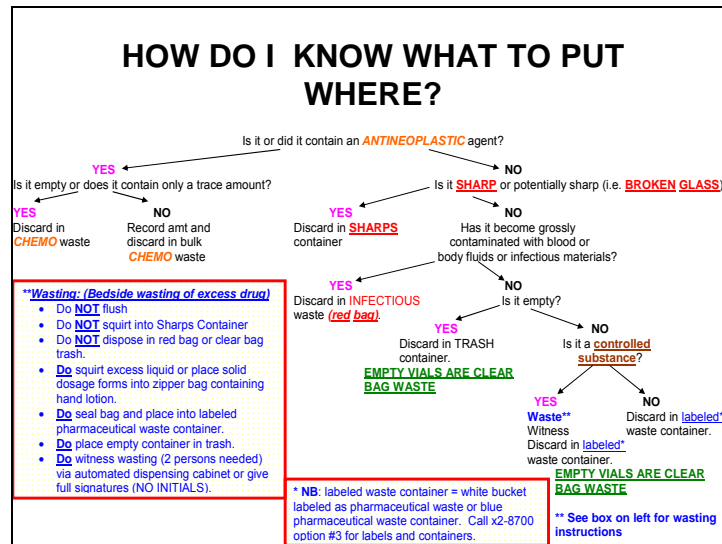
- Initiated June, 2009.
- Goal to develop a process for drug disposal that would prevent drugs from being introduced into the water system or disposed of in sharps containers on the main Albany Medical Center Hospital Campus.
- Four patient care areas involved: general medical-surgical (D2N); pediatrics (C7); orthopedics (C6) and apheresis (M3)
- Bedside wasting of liquid formulations common.
- Over ½ of drugs such as levofloxacin (antibiotic) or acetaminophen with codeine elixir (narcotic) are wasted into toilets and sinks.
- Pilot implemented on 4 units, wasting of controlled substances into 3 gallon step cans with absorbent. Good compliance.
- Eighty four percent of drugs dispensed at AMC (main campus) have a 0% wasting and are predominantly solid dosage forms dispensed as unit doses.

Main campus pilot program.

Initiated June, 2009. Goal to develop a process for drug disposal that would prevent drugs from being introduced into the water system or disposed of in sharps containers. Four patient care areas involved: general medical-surgical (D2N); pediatrics (C7); orthopedics (C6) and apheresis (M3). The pilot started in June and was limited to bedside wasting of controlled substances. Each unit was provided with a 3 gallon step-on waste can and absorbent. The healthcare staff was instructed to waste controlled substances into the can, where the material would be absorbed and rendered non-recoverable. The staff was trained by pharmacy and nursing staff. Over ½ of drugs such as levofloxacin (antibiotic) or acetaminophen with codeine elixir (narcotic) are wasted into toilets and

sinks. Pilot implemented on 4 units, wasting into 3 gallon step cans with absorbent. Non-controlled Substance Disposal The units were provided with receptacles for disposal of drug waste in late August to early September. The staff was trained by pharmacy and nursing staff. The units are using the containers and are contacting the appropriate staff when pickups are needed. Eighty four percent of drugs dispensed at AMC (main campus) have a 0% wasting and are predominantly solid dosage forms dispensed as unit doses. Liquids squirted into drug containers making “Drug soup” Need for reeducation.

Slide 57



Slightly modified flow chart for the Main AMC campus

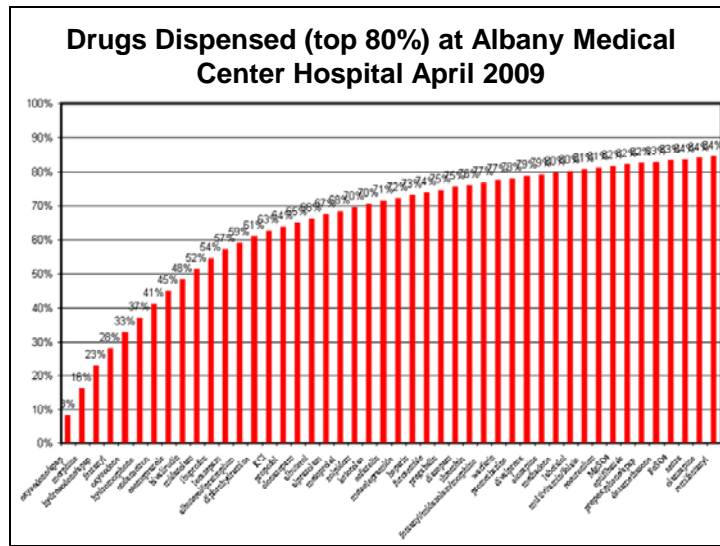
Slide 58

Satellite Accumulation

- Colored Rx waste containers will be placed in the Patient-care areas
- Clinicians (nurses, physicians) will put pharmaceutical waste in the colored containers
- Clinicians will call the CALL Center (x2-4444) when a container is 3/4 full

Satellite Accumulation areas on the main campus
 Colored Rx waste containers will be placed in the Patient-care areas
 Clinicians (nurses, physicians) will put pharmaceutical waste in the colored containers
 Clinicians will call the Call Center (x2-4444) when a container is 3/4 full

Slide 59



Graphical representation of the most dispensed drugs from PYXIS® automated dispensing machines on the AMC Main campus during April,2009. Compare this graph to the analogous data from South Clinical Campus (slide 30).

Slide 60

Cumulative 80% Pharmaceuticals Dispensed at Albany Medical Center Hospital April, 2009						
Drug	Cum_pct (%)	Pct (%)	Out	Ret	Wst	Net
AMCH MAIN	100%	100%	22,155	1,072	877	20,203
oxycodone/apap	8.3%	8.3%	1,842	42	3	1,797
morphine	16.2%	7.9%	1,748	48	119	1,575
hydrocodone/apap	23.1%	6.8%	1,517	43	8	1,468
fentanyl	28.1%	5.0%	1,116	111	255	753
oxycodone	32.9%	4.8%	1,061	79	6	1,036
hydromorphone	37.1%	4.3%	942	18	158	767
ondansetron	41.2%	4.1%	905	58	4	844
esomeprazole	44.9%	3.7%	809	9	1	799
bivalirudin	48.4%	3.5%	778	301	0	477
midazolam	51.5%	3.1%	692	107	106	481
ibuprofen	54.4%	2.9%	652	19	1	632
lorazepam	57.1%	2.6%	584	8	69	506
albuterol/ipratropium	59.1%	2.0%	440	16	2	422
diphenhydramine	60.9%	1.8%	405	9	3	393
PCI	62.6%	1.7%	383	7	0	376
propofol	63.9%	1.3%	282	10	5	267
clonazepam	65.1%	1.2%	271	3	12	257
albuterol	66.3%	1.2%	259	6	0	253
gabapentin	67.4%	1.1%	252	7	3	244
metoprolol	68.5%	1.1%	236	2	1	233
zolpidem	69.5%	1.0%	231	9	1	221
ketorolac	70.5%	1.0%	211	7	4	200
cefazolin	71.4%	0.9%	205	3	0	202
metoclopramide	72.3%	0.9%	202	7	1	194
heparin	73.1%	0.8%	179	15	1	163
tocosamide	73.9%	0.8%	178	4	0	174
prezabalin	74.7%	0.8%	173	1	0	172
diazepam	75.5%	0.8%	171	8	12	151
thrombin	76.2%	0.7%	147	21	0	126
fentanyl/midazolam/morphin	76.8%	0.6%	141	1	0	140
warfarin	77.4%	0.6%	141	1	0	140
promethazine	78.1%	0.6%	139	0	43	97
divalproex	78.6%	0.6%	128	0	0	128
clonazepam	79.2%	0.5%	118	0	3	115
methadone	79.7%	0.5%	116	0	4	112
labetalol	80.2%	0.5%	113	6	1	106

The top 80% of drugs dispensed from PYXIS® automated dispensing machines on the main AMC campus. Compare to slide 31 from the South Clinical Campus. The main 630 bed AMC campus dispenses far more controlled substances and pain relievers than the Acute Care (23 hour stay) 20 bed South Clinical Campus. The top 6 drugs dispensed on AMC's main campus (accounting for 37% of drugs dispensed) are controlled substances as compared to one controlled substance (midazolam) in the top 6 at the South Clinical Campus. Propofol, the most commonly dispensed (and wasted) drug at the South Clinical campus, contributes but 1.3% of all drugs dispensed on the main campus.

Satellite Accumulation Containers

**Compatible Rx Waste
(Blue container with a blue label)**

**Non-compatible Rx Waste
(Black container with a black label)
Not found on nursing units. May use in pharmacy.**

Containers
Reusable: 2 types
Compatible Rx Waste
(Blue container with a blue label)
Non-compatible Rx Waste
(Black container with a black label)
Not found on nursing units. May use in pharmacy.

Rx Waste Container & Label



COMPATIBLE PHARMACEUTICAL WASTE
(Hazardous Waste – Satellite Accumulation Container)

KEEP LID CLOSED

DO NOT REMOVE OR DISPENSE ITEMS FROM THIS CONTAINER

NO SHARPS
(Use appropriate sharps container)

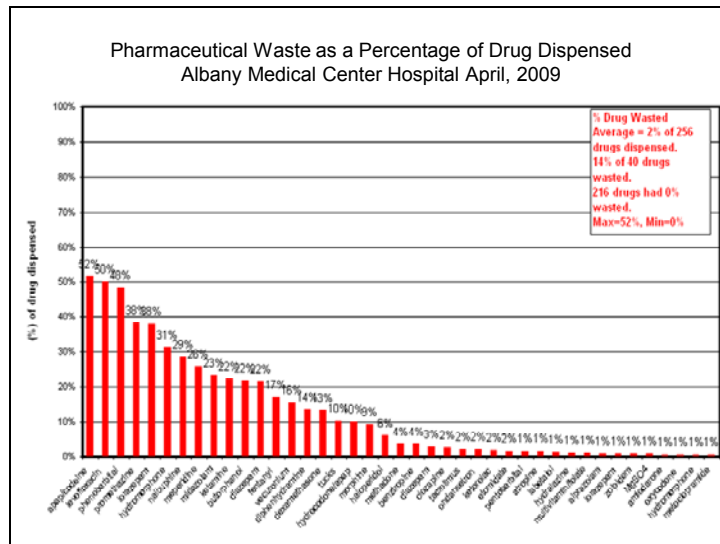
NO INFECTIOUS / BIOHAZARDOUS
(No blood or body fluids)

NO CONTROLLED SUBSTANCES
(Witness waste per policy)

NO FREE LIQUIDS
(Use zip lock bag to contain liquid before placing in container)

Photo of reusable compatible waste container (4 gallon) and label.
Note label states “Hazardous Waste”, “Satellite Accumulation Container”
Detailed warnings on label no sharps, no dispensing, no biohazards, no controlled substances, no free liquids

Slide 63



Graphical representation of pharmaceutical wasting as a percent of drug dispensed from PYXIS® automated dispensing machines on the AMC main campus in April, 2009, compare to slide 32.

Slide 64

**Medications Recorded as Wasted from PYXIS®
Records Albany Medical Center Hospital April, 2009**

Only an average of 2% of 256 drugs dispensed at the Albany Medical Center Hospital were recorded as wasted in the PYXIS® dispensing system records. Forty of the medications dispensed averaged 14% wasting with a range from 52% to 1%. Liquid medications were by far the most frequently wasted and were predominantly controlled substances, antibiotics, and antihistaminics / anti-inflammatory drugs.

Of the non-controlled drugs:

- 50% of levofloxacin liquid dispensed was wasted.
- 38% of promethazine liquid dispensed was wasted
- 29% of nalbuphine liquid dispensed was wasted
- 16% of vecuronium liquid dispensed was wasted.
- 14% of diphenhydramine liquid dispensed was wasted.
- 13% of dexamethasone liquid dispensed was wasted.
- 6% of haloperidol liquid dispensed was wasted.
- 4% of benztropine dispensed was wasted.
- Five drugs (3 solid and 2 liquids) were 2% wasted.
- Thirteen drugs (6 solid and 7 liquid) were 1% wasted.
- **Of 22,061.8 mL of propofol dispensed, only 98.2 mL were recorded as wasted.**
- Two hundred sixteen (84%) medications dispensed had 0% wasted.

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Of 22,061.8 mL of propofol dispensed, only 98.2 mL were recorded as wasted.
Two hundred sixteen (84%) medications dispensed had 0% wasted.

Slide 65

Controlled Substances

According to NYS Section 80.51 of the Rules and Regulations of Controlled Substances:

To discard a controlled substance means to “render it totally unrecoverable and beyond reclamation.”

Traditionally, this has been to flush it or pour it down the sink.

Today, in the interest of preserving the environment this is no longer acceptable. Alternative methods need to be utilized.

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Today, in the interest of preserving the environment this is no longer acceptable. Alternative methods need to be utilized.

Waste vs. Destruction

'Wasting' - for single-unit doses or partial doses remaining after the administration or attempted administration of a portion of liquid or solid unit dose of a controlled substance.

- done immediately after the administration or attempted administration;
- destroyed on premise of an institutional dispenser by a pharmacist or nurse;
- destruction witnessed by a second pharmacist, nurse or other responsible person designated by the administrator; and
- the controlled substance is rendered totally unrecoverable and beyond reclamation.

NYS Section 80.51 of the Rules and Regulations of Controlled Substances

'Wasting' - for single-unit doses or partial doses remaining after the administration or attempted administration of a portion of liquid or solid unit dose of a controlled substance.
done immediately after the administration or attempted administration;
destroyed on premise of an institutional dispenser by a pharmacist or nurse;
destruction witnessed by a second pharmacist, nurse or other responsible person designated by the administrator; and
the controlled substance is rendered totally unrecoverable and beyond reclamation.

Waste vs. Destruction

'Destruction' - for controlled substances that are undesired, deteriorated, obsolete or for any reason no longer needed.

Options for destruction include the five following mechanisms:

1. Return to the licensed manufacturer/distributor from whom controlled substance was procured;
2. Surrender to a 'Reverse Distributor' licensed by DOH;
3. Surrender to Bureau of Narcotic Enforcement (BNE);
4. Surrender to DEA; or
5. Perform on-site destruction:
 - must receive written approval from BNE first;
 - complete forms DOH 2340 and DOH 160 and submit to BNE;
 - the controlled substance is rendered totally unrecoverable and beyond reclamation.

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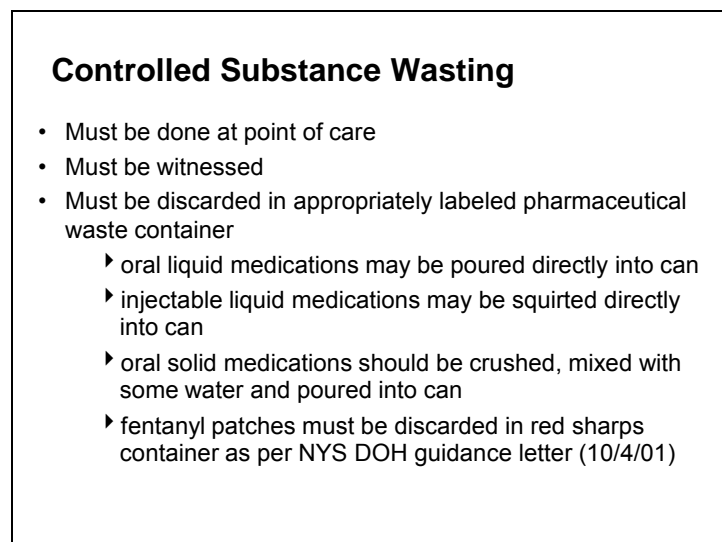
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Illustration of bedside wasting equipment to be used during AMC pilot

Slide 69



Controlled Substance Wasting

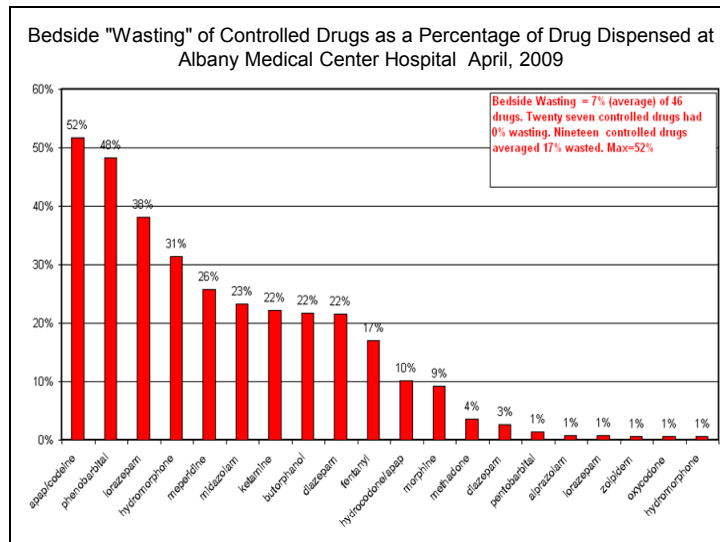
Must be done at point of care

Must be witnessed

Must be discarded in appropriately labeled pharmaceutical waste container

1. oral liquid medications may be poured directly into can
2. injectable liquid medications may be squirted directly into can
3. oral solid medications should be crushed, mixed with some water and poured into can
4. fentanyl patches must be discarded in red sharps container as per NYS DOH guidance letter (10/4/01)

Slide 70



Graphical representation of bedside wasting of controlled substances as recorded in PYXIS® automated dispensing machines from the Albany Medical Center main campus during April, 2009.

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**Controlled Substances Recorded as Wasted from
PYXIS® Records
Albany Medical Center Hospital April, 2009**

Controlled substances in liquid form were commonly recorded as wasted in the PYXIS® records of the Albany Medical Center Hospital in April of 2009, averaging 7% of 46 controlled substances dispensed. Of these, over one half (27) had 0% wasting.

- 52% of acetaminophen/codeine liquid dispensed was wasted.
- 48% of phenobarbital liquid dispensed was wasted.
- 38% of lorazepam liquid dispensed was wasted.
- 31% of hydromorphone liquid dispensed was wasted.
- 26% of meperidine liquid dispensed was wasted.
- 23% of midazolam liquid dispensed was wasted.
- 17% of fentanyl liquid dispensed was wasted.
- 9% of morphine liquid dispensed was wasted.
- 8 controlled substances dispensed in tablet or dry form ranged from 1% to 4% wasting.

Controlled Substances Recorded as Wasted from PYXIS® Records Albany Medical Center Hospital April, 2009

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Slide 72

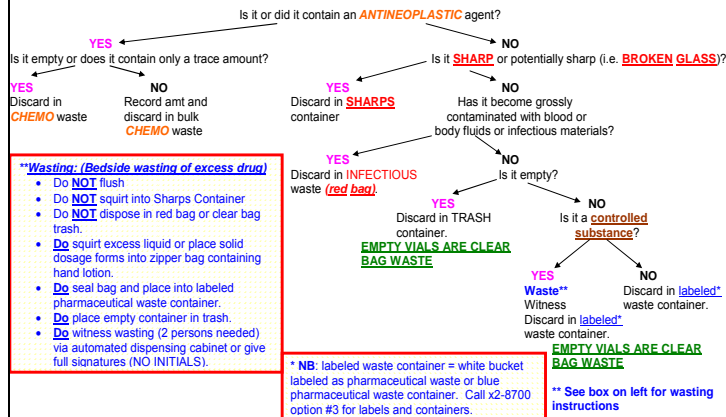
**Bullet Points – Controlled
Substances**

- Fentanyl patches must be wasted into SHARPS containers
- All controlled substance medication should be removed from its original containers and discarded in labeled controlled substance pharmaceutical waste containers
- All empty containers which previously contained controlled substances should be disposed of in regular trash.
- Wasting documentation in PYXIS® remains unchanged and should be done in conjunction with these procedures

Bullet Points

- When in doubt, refer to FLOW CHART
- All unopened, unused medications (including controlled substances) should be returned to pharmacy
- All empty tubing, syringes, etc should be disposed of in regular trash.
- All medication vials containing partial amounts of medication (except controlled substances) should be discarded in labeled pharmaceutical waste containers (currently BLUE).

HOW DO I KNOW WHAT TO PUT WHERE?



Educational Tour of Albany Medical Center's South Clinical Campus.

Pharmaceutical Waste Collection in Operating Rooms.



Tour conducted for regulators and healthcare administrators through HANYS (Healthcare Association of New York State) and NY DEC

Dr. Mankes (US EPA PI) describing pharmaceutical waste management process to tour group



Michael Murphy, RN, Director of Patient Care Services for the South Clinical Campus discussing patient care aspects of the pharmaceutical waste management system.



Question from representative of NY DEC commissioner on pharmaceutical waste management process.



Close up of secure pharmaceutical waste container with wire bracket, lock and labeling "satellite accumulation area."



Michael Murphy, RN, Director of Patient Care Services for the South Clinical Campus discussing patient care aspects of the pharmaceutical waste management system.



NB: No sinks or drains in operating rooms, thus no wasting possible

Close up of a pharmaceutical waste collection bin secured to a medication cart in the post anesthesia care unit (PACU) at the Albany Medical Center's South Clinical Campus.



Flow charts and reminders located near the pharmaceutical waste collection bin in the post operative care unit (Post-Op) at the Albany Medical Center's South Clinical Campus.



Dr. Mankes (US EPA PI) demonstrates opening of a full pharmaceutical waste collection bin in the South Clinical Campus' central hazardous waste accumulation area.



Dr. Mankes demonstrates weighing of contents from a full pharmaceutical waste collection bin.



Dr. Mankes demonstrates use of heavy puncture resistant gloves due to maldisposals of sharps into pharmaceutical waste collection bin.



Dr. Mankes demonstrates close up of syringe labeling during sorting of pharmaceutical waste.



Dr. Mankes demonstrates sorting of pharmaceutical waste using long forceps.



Sorted pharmaceutical waste – propofol syringes and vials are the predominant waste discarded from the South Clinical Campus' Operating Rooms.



Dr. Mankes demonstrates maldisposal of controlled substance into pharmaceutical waste bin to representatives of NY DEC, NY Board of Pharmacy.



Dr. Mankes demonstrates sorting of pharmaceutical waste.



Examples of waste pharmaceuticals recovered from the South Clinical Campus Operating Rooms.



Sharps containers in central hazardous waste accumulation area at the Albany Medical Center's South Clinical Campus.



Central hazardous waste accumulation area at the Albany Medical Center's South Clinical Campus.



Conference room and participants for pharmaceutical waste tour at the Albany Medical Center's South Clinical Campus.

