New perspectives on an old nemesis: Chemotherapy - Health, safety, and waste management issues
Ed Krisiunas, WNWN International Inc.
A Webber Training Teleclass

New perspectives on an old nemesis:
Chemotherapy - Health, safety, and waste management issues

Ed Krisiunas
WNWN International Inc.

Hosted by Paul Webber
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December 4, 2014

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Objectives:

At the completion of the presentation, participants will have:

1. Knowledge of the historical perspective of health and safety standards for chemotherapy (i.e., OSHA Instruction 1986 STD 01-23-001)

2. Knowledge of the current guidance - NIOSH Alerts/WHO Guidance/JCAHO

3. Knowledge of trending issues - management of chemo waste: drugs/PPE/Sharps/patient excretions

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Disclaimer:

The mention or photos of any products is strictly for education purposes. While I do consult to a wide range of companies in the areas of waste management, Infection Prevention, and Occupational Health and Safety, I am not employed by any of the vendors of products shown in this PPT

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TERMS….

Cancer - The disease caused by an uncontrolled division of abnormal cells in a part of the body…a malignant growth or tumor resulting from the division of abnormal cells.

Chemotherapy *(Attributed to German biochemist Paul Erhlich [1854-1915]*

The treatment of cancer using specific chemical agents or drugs that are selectively destructive to malignant cells and tissues.

The treatment of disease using chemical agents or drugs that are selectively toxic to the causative agent of the disease, such as a virus or other microorganism.

Cytotoxic - Of, relating to, or producing a toxic effect on cells.

Cytostatic - Inhibiting or suppressing cellular growth and multiplication.

poptosis - (**biology**) the programmed death of some of an organism's cells as part of its natural growth and development……*Also called* **programmed cell death**

Reference: http://dictionary.reference.com/

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We are all likely to have been touched by cancer….

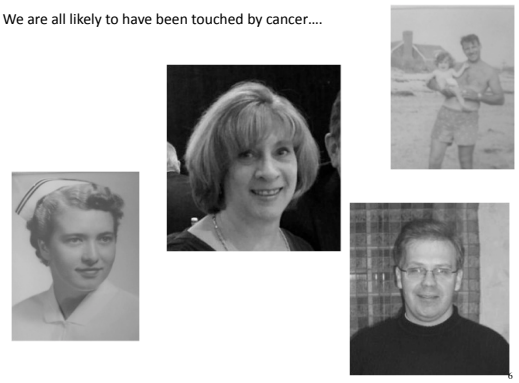

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Table C. Deaths and percentage of total deaths for the 10 leading causes of death: United States, 2009–2010

[An asterisk (*) preceding a cause-of-death code indicates that the code is not included in the *International Classification of Diseases, Tenth Revision* (ICD–10), Second Edition; see Technical Notes]

Cause of death (based on ICD–10, 2004)	Rank[1]	2010 Deaths	2010 Percent of total deaths	2009 Deaths	2009 Percent of total deaths
All causes	…	2,468,435	100.0	2,437,163	100.0
Diseases of heart (I00–I09,I11,I13,I20–I51)	1	597,689	24.2	599,413	24.6
Malignant neoplasms (C00–C97)	2	574,743	23.3	567,628	23.3
Chronic lower respiratory diseases (J40–J47)	3	138,080	5.6	137,353	5.6
Cerebrovascular diseases (I60–I69)	4	129,476	5.2	128,842	5.3
Accidents (unintentional injuries) (V01–X59,Y85–Y86)	5	120,859	4.9	118,021	4.8
Alzheimer's disease (G30)	6	83,494	3.4	79,003	3.2
Diabetes mellitus (E10–E14)	7	69,071	2.8	68,705	2.8
Nephritis, nephrotic syndrome and nephrosis (N00–N07,N17–N19,N25–N27)	8	50,476	2.0	48,935	2.0
Influenza and pneumonia (J09–J18)	9	50,097	2.0	53,692	2.2
Intentional self-harm (suicide) (*U03,X60–X84,Y87.0)	10	38,364	1.6	36,909	1.5

… Category not applicable.
[1]Based on number of deaths.

http://www.cdc.gov/nchs/data/nvsr/nvsr62/nvsr62_06.pdf

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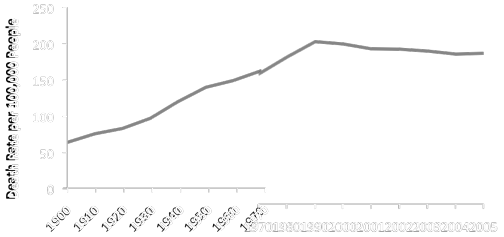
US Cancer Death Rate



Mark Clanton, MD, MPH,
Chief Medical Officer,
American Cancer Society, High Plains Division

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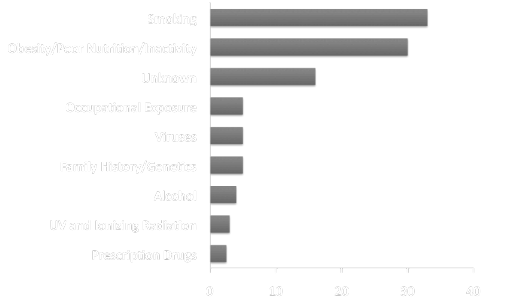
Source: 1900-1970, U.S. Public Health Service; 1971-2001, U.S. National Center for Health Statistics

Risk Factors/Causes of Cancer in the US



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"Gassed"
1919

Mustard gas

John Singer Sargent.

http://en.wikipedia.org/wiki/Gassed_%28painting%29

10

An Accidental Discovery:

From Warfare to Mainstay: Mustard Derivatives Play Evolving Role in Cancer Therapy – November 2011

The discovery of nitrogen mustard's potential in cancer therapy could easily have taken place in 1919. Edward Bell Krumbhaar, MD, PhD, who would go on to become a leading pathologist and cardiac physician in Philadelphia, Pennsylvania, was a medical officer with the American forces in France when he studied the effects of mustard gas on soldiers and noted its tendency to kill bone marrow and suppress white blood cell production.

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The breakthrough realization about the potential for using nitrogen mustard in cancer treatment, however, did not come until World War II, when the US government asked researchers at Yale School of Medicine in New Haven, Connecticut, to study potential antidotes to mustard gas as a weapon. They realized the agent's promise as a treatment for lymphoid malignancies and began developing a mouse model for testing.

Reference : http://www.onclive.com/print.php?url=/publications/Oncology-live/2011/november-2011/From-Warfare-to-Mainstay-Mustard-Derivatives-Play-Evolving-Role-in-Cancer-Therapy

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Mustard derivatives (also known as alkylating agents) include the following:

•Mustragen – 1949

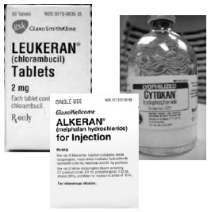
•Chlorambucil (Leukeran) – 1957

•Cyclophosphamide (Cytoxan) – 1959

•Melphalan (Alkeran) – 1964

•Ifosfamide (Ifex) – 1988

•Treanda – 2008



Reference : http://www.onclive.com/print.php?url=/publications/Oncology-live/2011/november-2011/From-Warfare-to-Mainstay-Mustard-Derivatives-Play-Evolving-Role-in-Cancer-Therapy

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Surgery and radiation therapy were the primary treatments for cancer in the 1950s. The National Chemotherapy Program, a federal program funded in 1955, supported the development of new chemotherapy agents. Due to advances in science, chemotherapy is now commonly administered for the treatment of cancer in patients with both solid tumors and hematologic malignancies. The United States Food and Drug Administration (FDA) approved 85 drugs used in the treatment of cancer between the years of 1949 and 1992, 85 drugs in the next eight years (1993-2000), and 34 drugs during the three-year period from 2001 to 2004 (FDA, 2004).

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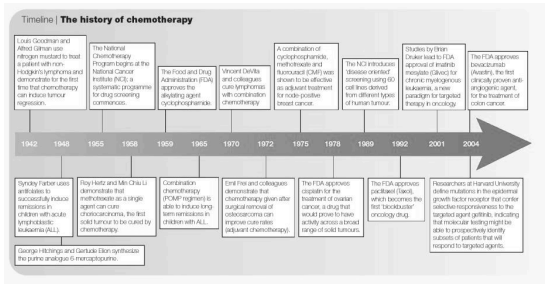

http://www.nature.com/nrc/journal/v5/n1/fig_tab/nrc1529_I1.html

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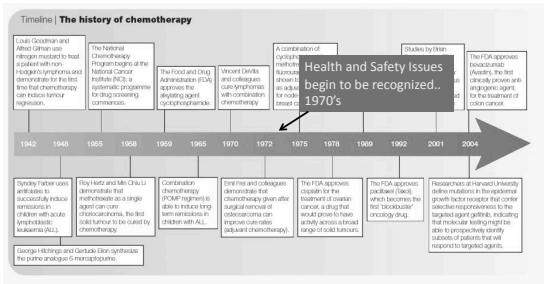

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In the 1970s, several chemotherapy agents were linked to secondary leukemia and other cancers in treated patients. This information was accompanied by the notion that health risks might extend to persons occupationally exposed to the drugs (Donner, 1978; Ng, 1970). Lancet published the first convincing evidence in a letter to the editor by Falck, et al in 1979.

In a small, but controlled study, mutagenic activity (as measured by the Ames test) was found in the urine of patients who received chemotherapy as well as nurses who administered chemotherapy. The Ames test measures genetic mutations in bacteria after exposure to compounds. Ninety percent of known carcinogens test positive on this test. The test is reliable during drug excretion in the urine, which is usually within 48 hours of exposure. It has neither high sensitivity nor specificity (Polovich 2003). Several other studies followed that demonstrated risks from occupational exposure to chemotherapy.

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In the 1970s and 1980s it was common practice for nurses to perform drug preparation activities in medication rooms on nursing units (Stolar 1988).The main route of exposure to hazardous drugs was thought to be inhalation of drug aerosols generated during preparation. To reduce this risk, OSHA guidelines state that cytotoxic drug preparation must be performed in a biological safety cabinet (BSC) in a designated area, usually a pharmacy. A BSC has vertical airflow that moves away from the worker, as opposed to horizontal airflow that moves away from the product toward the worker. Vertical airflow protects the worker, while horizontal airflow is designed to protect the sterile product from contamination. Air leaving a BSC is filtered through a HEPA (high efficiency particulate air) filter.

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[CANCER RESEARCH 42, 4792–4796, November 1982]
0008-5472/82/0042-0000$02.00

Exposure of Pharmacy Personnel to Mutagenic Antineoplastic Drugs[1]

Tot V. Nguyen, Jeffrey C. Theiss,[2] and Thomas S. Matney

School of Public Health [T. V. N., J. C. T.] and Graduate School of Biomedical Sciences [T. S. M.], University of Texas Health Science Center at Houston, Houston, Texas 77025

As a result of this study, a closed-face, vertical laminar-flow hood was purchased and installed in the outpatient pharmacy where the heaviest load of cancer chemotherapeutic agents are prepared. Additional vertical laminar-flow hoods have been ordered so that all cancer chemotherapeutic agents will be prepared for i.v. administration in an environment which minimizes the chance of occupational exposure to the pharmacy personnel of the University of Texas M. D. Anderson Hospital and Tumor Institute in Houston.

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- **Record Type:** Instruction
- **Directive Number:** STD 01-23-001
- **Old Directive Number:** PUB 8-1.1
- **Title:** Guidelines for Cytotoxic (Antineoplastic) Drugs
- **Information Date:** 01/29/1986
- **Status:** Archived

OSHA ARCHIVE

NOTICE: This is an OSHA Archive Document, and may no longer represent OSHA Policy. It is presented here as historical content, for research and review purposes only.

OSHA Instruction PUB 8-1.1 JAN 29, 1986 Office of Occupational Medicine

Subject: Guidelines for Cytotoxic (Antineoplastic) Drugs

A. Purpose. This instruction provides a description of the hazard during the use of antineoplastic drugs in the health care delivery system and recommends controls and work practice techniques to reduce the risks of that hazard.

B. Scope. This instruction applies OSHA-wide.

C. References.

1. OSHA Instruction CPL 2.45A, April 18, 1983.

2. OSHA Instruction CPL 2.59A, August 16, 1985.

D. Action. As another step in OSHA's Outreach program, Regional Administrators and Area Directors shall ensure that copies of Appendix A are mailed to all major health care facilities in SIC codes 8062 and 8069 in their respective areas. Appendix B is a letter that could be used as a vehicle to convey this document to these facilities. In conjunction with Area Offices being Full Service Resource Centers, copies of Appendix A shall be made available from the Area Office to members of health care facilities upon request.

E. Federal Program Change. This instruction describes a change in the Federal program for which a State response is not required. Each Regional Administrator, however, shall:

1. Ensure that this change is promptly forwarded to State designees.

2. Explain the technical content of this change as well as the Region's plans for implementing it to the State designee.

3. Encourage States to adopt similar program initiatives where such initiatives are not already in place by taking the action described in D and mailing Appendix A to the identified major health care facilities.

F. Background. In January and February of 1984, OSHA mailed to hospitals and clinics a document that described the hazards of hepatitis B infection to workers in the health care delivery system and recommended work practice techniques to reduce those risks of that hazard. As evidenced from the large number of letters thanking the Agency for producing such a document and the requests for additional copies of the document, this information was widely accepted and greatly appreciated in the

OSHA Instruction PUB 8-1.1 JAN 29, 1986 Office of Occupational Medicine

professional community. As a result, this instruction is another aid to help both employers and employees recognize the hazard of handling antineoplastic drugs and prevent any adverse health effects from exposure to these drugs.

US Dept. of Labor
OSHA
STD 01-23-001
Guidelines for cytotoxic (Antineoplastic) Drugs

January 29, 1986

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STD 01-23-001 Guidelines for cytotoxic (Antineoplastic) Drugs

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Studies in the '90s.....

Biological safety cabinets (BSCs) provide imperfect protection against hazardous drug exposure. Other types of ventilated cabinets may provide containment, but are not currently available in pharmacies.

Routine handling activities can result in contamination of the worker and work environment.

There is frequent and persistent contamination of the environment where hazardous drugs are handled.

Dermal absorption of hazardous drugs as a result of contact with contaminated surfaces is another potential route of exposure.

Failure to use personal protective equipment can result in inadvertent contamination of clothing.

Workers who are not directly involved in activities related to hazardous drug handling are at risk for exposure.

Drug exposure can result in drug absorption that can be measured.

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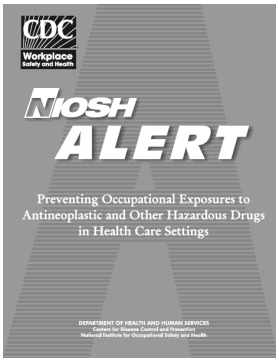

DHHS (NIOSH Publication Number 2004-165 September 2004)

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Criteria for Defining Hazardous Drugs

Drugs that meet one or more of the following criteria should be handled as hazardous:

Carcinogenicity
Teratogenicity or developmental toxicity
Reproductive toxicity
Organ toxicity at low doses
Genotoxicity
Structure or toxicity similar to drugs classified as hazardous using the above criteria

From Preventing Occupational Exposures To Antineoplastic And Other Hazardous Drugs In Healthcare Settings. (NIOSH, 2004)

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The employer responsibilities include:

Developing policies and procedures for the safe storage, transport, administration, and disposal of hazardous agents.

Identifying those hazardous drugs used in the facility and determining methods for updating the list.

Making guidance documents such as Material Safety Data Sheets (MSDS) available to health care workers who handle hazardous drugs.

Requiring that all employees who handle hazardous drugs wear personal protective equipment (PPE) designated for the purpose .

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Requiring a BSC for the preparation of hazardous drugs.

Prohibiting eating, drinking, etc. in areas where hazardous drugs are handled. Providing mandatory training for all employees based on their hazardous drug handling tasks.

Developing a hazardous-drug spill management policy and procedure.

Setting forth a plan for medical surveillance of personnel handling hazardous drugs.

Addressing in a policy workers' hazardous drug handling during pregnancy. The Oncology Nursing Society recommends that employers provide alternate duty to employees who request other assignments due to pregnancy, the desire to conceive, or breast-feeding

Monitoring compliance with safe-handling policies and procedures.

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The health care worker responsibilities include:

Participating in training before handling hazardous drugs and updating knowledge based on new information.

Referring to guidance documents as necessary for information regarding hazardous drugs.

Utilizing BSCs in drug preparation.

Consistently using recommended gloves, gowns, and face and respiratory protection.

Washing hands after drug handling activities and removal of PPE.

Disposing of materials contaminated with hazardous drugs separately from other waste in designated containers.

Cleaning up hazardous drug spills immediately according to recommended procedures.

Following institutional procedures for reporting and following up on accidental exposure to hazardous drugs.

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Investigate West

Lifesaving Drugs, Deadly Consequences

BY CAROL SMITH | OCTOBER CARES | OCT.
JULY 9, 2010

'Secondhand chemo' puts healthcare workers at risk

Healthcare worker? Take our survey here (http://www.surveymonkey.com/s/MLTFSGY)

Sue Crump braced as the chemo drugs dripped into her body. She knew treatment would be rough. She had seen its signature countless times in the ravaged bodies and hopeful faces of cancer patients in hospitals where she had spent 23 years mixing chemo as a pharmacist.

At the same time, though, she wondered whether those same drugs – experienced as a form of "secondhand chemo" – may have caused her own cancer.

Chemo is poison by design. It's descended from deadly mustard gas first used against soldiers in World War I. Now it's deployed to stop the advance of cancer.

http://www.invw.org/chemo-main

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Table 1. IARC Group 1 and Group 2A Carcinogens

Group 1: Human Carcinogens	Group 2A: Probable Human Carcinogens
Arsenic trioxide	Azacitidine
Azathioprine	BCNU
Chlorambucil	CCNU
Chlornaphazine	Chlorozotocin
Cyclophosphamide	Cisplatin
Etoposide	Doxorubicin HCl
Busulfan	N-Ethyl-N-nitrosourea
Melphalan	Mechlorethamine HCl
Semustine	N-Methyl-nitrosourea
Tamoxifen	Procarbazine HCl
Thiotepa	Teniposide
Treosulfan	
MOPP[1]	
ECB[2]	

Source: Adapted from the International Agency for Research on Cancer, http://monographs.iarc.fr/ENG/Classification/index.php.

[1] Mustargen-oncovin-procarbazine-prednisone

[2] Etoposide-cisplatin-bleomycin

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Table 2. Antineoplastic Agents Classified by the FDA as Pregnancy Category D or X

Drug	Pregnancy Category	Drug	Pregnancy Category
Arsenic trioxide	D	Interferon alfa-2b	X
Azathioprine	D	Irinotecan HCl	D
Bleomycin	D	Leflunomide	X
Capecitabine	D	Lomustine	D
Carboplatin	D	Mechlorethamine HCl	D
Carmustine	D	Melphalan	D
Chlorambucil	D	Mercaptopurine	D
Cisplatin	D	Methotrexate	X
Cladribine	D	Mitoxantrone HCl	D
Cyclophosphamide	D	Oxaliplatin	D
Cytarabine	D	Paclitaxel	D
Dactinomycin	D	Pipobroman	D
Daunorubicin HCl	D	Procarbazine	D
Docetaxel	D	Tamoxifen	D
Doxorubicin HCl	D	Temozolomide	D
Epirubicin	D	Teniposide	D
Etoposide	D	Thalidomide	X
Floxuridine	D	Thioguanine	D
Fludarabine	D	Thiotepa	D
Fluorouracil	D	Topotecan	D
Gemcitabine	D	Tositumomab	X
Hydroxyurea	D		
Ibritumomab tiuxetan	D	Vinblastine sulfate	D
Idarubicin	D	Vincristine sulfate	D
Ifosfamide	D	Vinorelbine tartrate	D
Imatinib mesylate	D		

Source: Adapted from the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.

Note: Category D definition: There is clear evidence of risk to the human fetus, but the benefits may outweigh the risk for pregnant women who have a serious condition that cannot be treated effectively with a safer drug. Category X definition: There is clear evidence that the medication causes abnormalities in the fetus. The risks outweigh any potential benefits for women who are (or may become) pregnant.

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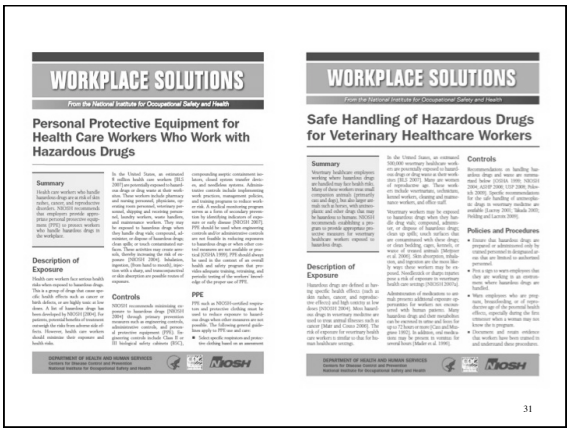

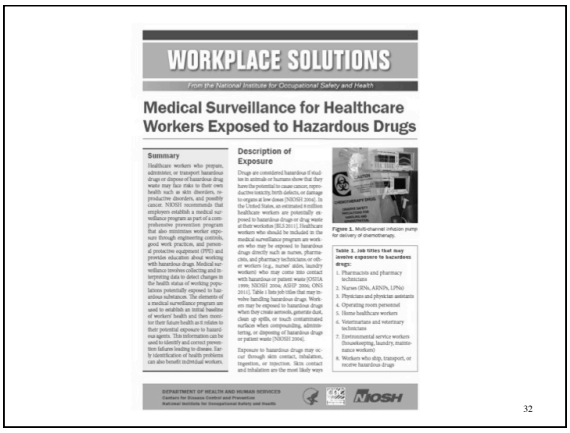

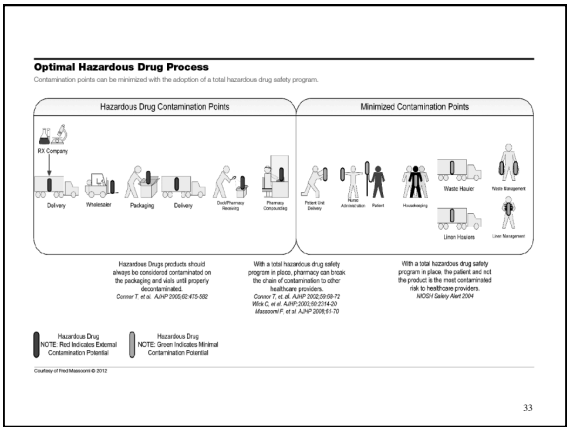

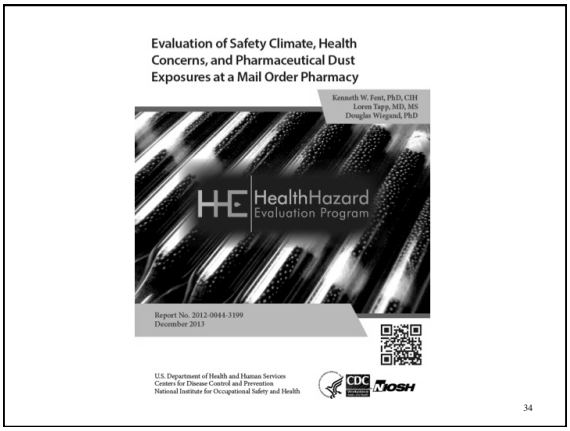

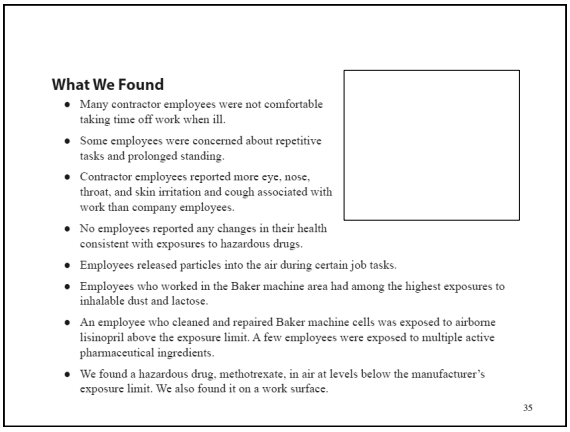

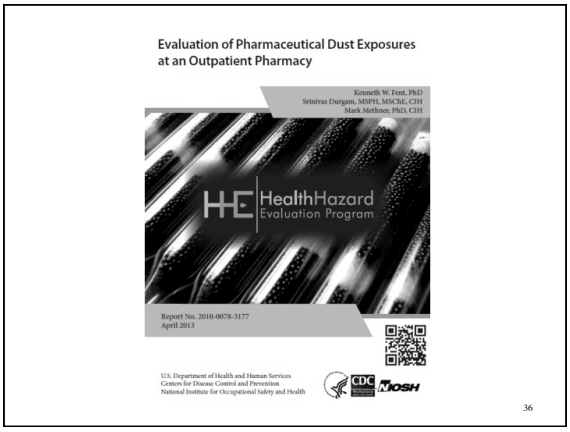

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What We Found

- One employee was exposed to lisinopril on two workdays at levels near or above the manufacturer's exposure limit.
- Dust was released into the air when automatic dispensing machine canisters were cleaned with compressed air. Filling canisters with tablets produced lower levels of dust in the air.
- After employees used compressed air to clean canisters, more than an hour passed before the small particles produced were no longer in the air.
- We found lactose and active pharmaceutical ingredients in the dust in the air. Lactose was found on surfaces throughout the pharmacy. This suggests that some dust in air and on surfaces was from pharmaceuticals.
- Some employees wore nitrile gloves when handling pharmaceuticals. Employees did not wear protective clothing or safety glasses.

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NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014

NDHHS (NIOSH)
Publication Number 2014-138 (Supersedes 2012-150)
September 2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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Table 5. Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings[a]

Formulation	Activity	Double gloves	Protective gown	Eye protection	Respiratory protection	Ventilated engineering controls
Intact tablet or capsule	Administration from unit-dose package	no (single glove should be used)	no	no	no	N/A
Tablets or capsules	Cutting, crushing or otherwise manipulating tablets or capsules	yes	yes	no	yes, if not done in a control device	yes[c]
	Administration	yes	yes	no[c]	yes, if powder generated	N/A
Oral liquid drug	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes[c]
	Administration	yes	yes	no[c]	no[c]	N/A
Topical drug	Compounding	yes	yes	yes	yes, if not done in a control device	yes[c]
	Administration	yes	yes	yes, if liquid that could splash[b]	yes, if inhalation potential	N/A
Ampoule	Opening	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI

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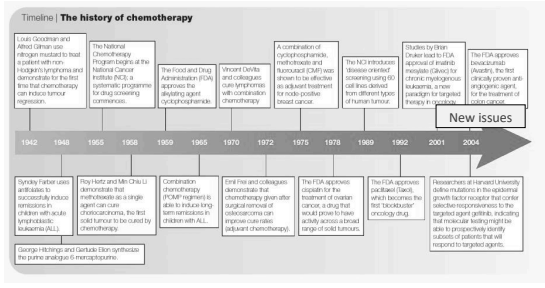
Table 5 (Continued). Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings[a]

Formulation	Activity	Double gloves	Protective gown	Eye protection	Respiratory protection	Ventilated engineering controls
Subcutaneous, intramuscular injection	Preparation (withdrawing from vial or ampoule)	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Administration from prepared syringe	yes	yes	yes, if liquid that could splash[b]	yes, if inhalation potential[c]	N/A
Intravenous solution	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI; recommend use of CSTD
	Administration of prepared solution[e]	yes	yes	yes, if liquid that could splash[b]	yes, if inhalation potential[c]	N/A; recommend use of CSTD
Solution for irrigation	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI; recommend use of CSTD
	Administration (bladder, HIPEC, limb perfusion, etc.)	yes	yes	yes	yes	N/A
Powder/ solution for inhalation	Inhalation	yes	yes	yes	yes	yes, when applicable

40



http://www.nature.com/nrc/journal/v5/n1/fig_tab/nrc1529_I1.html

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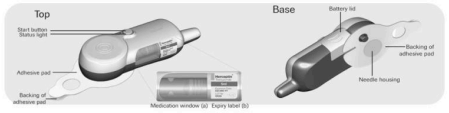
Herceptin s.c.
Injektionsdevice "MyDose"



- Ein Batterie-getriebener Motor stellt die gleichmäßige s.c.-Injektion von Herceptin über ca. 5 min sicher.
- Die Nadel wird erst bei Start der Injektion ausgefahren und nach dem Ende ins Gehäuse zurückgezogen.
- Eine LED-Leuchte zeigt den Status der Injektion an.
- Das transparente Fenster ermöglicht eine Erfolgkontrolle der Injektion.

http://images.slideplayer.de/2/864499/slides/slide_17.jpg

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New perspectives on an old nemesis: Chemotherapy - Health, safety, and waste management issues

Ed Krisiunas, WNWN International Inc.

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Preference for subcutaneous or intravenous administration of trastuzumab in patients with HER2-positive early breast cancer (PrefHer): an open-label randomised study
Prof Xavier Pivot MD et al

The Lancet Oncology, Volume 14, Issue 10, Pages 962 - 970, September 2013

Nine out of 10 (91.5 per cent) HER2-positive breast cancer patients preferred the subcutaneous (SC) injection of Herceptin (trastuzumab) – an injection in the skin – to the current practice of intravenous drip delivery. Patients reported less pain and discomfort and spent up to 80 per cent less time in the hospital chair, as a SC injection around five minutes per visit, compared with 30-90 minutes for IV treatment.

http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2813%2970383-8/abstract

http://www.bsms.ac.uk/about/news/herceptin-by-injection-is-quicker-and-preferred-say-breast-cance/

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C. Caring for Patients Receiving CDs.

1. Personal Protective Equipment. Personnel dealing with blood, vomitus, or excreta from patients who have received CDs in the last 48 hours should wear surgical latex gloves and disposable gowns, to be discarded after each use as detailed under Waste Disposal. (No protective equipment is necessary for ordinary patient contact for employees not dealing with drug administration or bodily secretions.) Hands should be washed after removal of gloves or after contact with the above substances.

2. Linen. Linen contaminated with CDs, blood, vomitus, or excreta from a patient who has received CDs up to 48 hours before should be placed in a specially marked laundry bag and the laundry bag placed in a labeled impervious bag. This laundry bag and its contents should be prewashed, and then the linen should be added to other laundry for an additional wash. Laundry personnel should wear surgical latex gloves and gowns while handling this material. (No additional gain is made by autoclaving items contaminated with CDs, unless they are also contaminated with infectious waste.)

D. Waste Disposal.

1. Equipment. Cytotoxic waste disposal sealable plastic or wire tie bags of 4-mil thick polyethylene or 2-mil polypropylene, labeled with a cytotoxic hazard label and colored differently from other hospital trash bags, should be used for the routine accumulation and collection of used containers, syringes, discarded gloves, gowns, goggles and any other disposable material. All CD-related wastes should be put into these bags, and nothing else.

A-14

OSHA Instruction PUB 8-1.1 JAN 29, 1986 Office of Occupational Medicine

a. Needles, syringes, and breakable items should be placed in a plastic vial or puncture proof box before they are placed into the bag; needles should not be clipped or capped nor syringes crushed. The bag should be kept inside a covered waste container clearly labeled "cytotoxic waste only."

b. At least one such receptacle should be located in every area where the drugs are prepared or administered so that the waste need not be moved from one area to another. The bag should be sealed when it is filled and the carton should be taped.

2. Handling. Housekeeping personnel must wear gowns and surgical latex gloves when handling the waste containers, and should be instructed on the necessity of handling this waste with care and on procedures governing spills and leaks.

3. Disposal. These wastes must be handled separately from other hospital trash, and must be regarded as toxic (hazardous) wastes and disposed of in accordance with applicable regulations. (See reference 57 and/or more recent publications.)

a. Disposal in a licensed sanitary landfill for toxic wastes is an acceptable alternative. If waste is to be picked up by a commercial disposal firm, the company must be licensed, and the waste must be held in a secure area in covered, labeled drums lined with 6.5-mil polyethelene liners.

b. Chemical inactivation of CDs is often ineffective and may produce by-products that are more mutagenic than the parent drug. (See reference 31.) Therefore, with the exception of nitrogen mustard, which can be safely inactivated by sodium thiosulfate, chemical inactivation should be avoided until safe chemical procedures are developed.

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Waste streams……..

Solid Waste	Regulated Medical Waste	Hazardous Waste	Chemotherapy Waste
Liquid Waste	Radiological Waste	Recycling	Organic Waste
C&D Waste	Pharmaceutical Waste	Sharps	Donations

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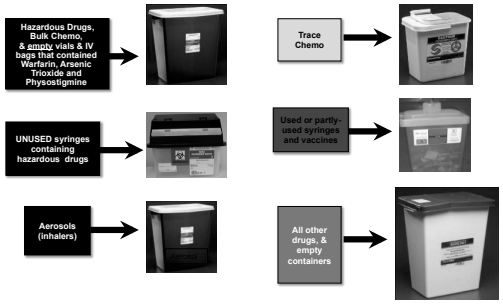
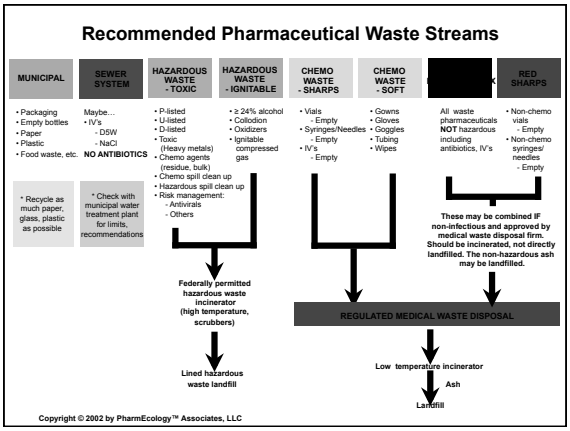
Providence Health & Services (Portland Service area) https://practicegreenhealth.org/pubs/sharing/ProvidencePharmaceuticalTrainingPowerpoint.pptx

Pharmaceutical Waste and Disposal





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New perspectives on an old nemesis: Chemotherapy - Health, safety, and waste management issues

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Bull. Environ. Contam. Toxicol. (2003) 71:170–175
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DOI: 10.1007/s00128-003-0145-7

Environmental Contamination and Toxicology

Mutagenicity of Antineoplastic Drug Residues Treated in Health Care Waste Autoclave

M. D. Bassi, J. Morotton

Hygiene Department, Faculty of Pharmacy and Biochemistry, University of Buenos Aires, Junin 956, Piso 4°, CP1113AAC Buenos Aires, Argentina

Received: 19 July 2002/Accepted: 15 March 2003

The results obtained when 5-fluorouracil, doxorubicin, cisplatin, carboplatin, methotrexate and cyclophosphamide were tested with the *Salmonella typhimurium* assay are shown in Table 1. Doxorubicin, 5-fluorouracil, cisplatin, carboplatin, did not show any variation in mutagenic activity after autoclaving.The same concentration-response curves were found before and after treatment.

Methotrexate was shown to be nonmutagenic in the Ames test and autoclaving did not generate mutagenic products. Similar results were obtained when the methotrexate was tested with *Saccharomyces cerevisiae* D7 conversion and reversion assay and *Bacillus subtillis* Rec assay (data not shown)

Surprisingly cyclophosphamide showed a variation in its mutagenic effect after autoclaving. Before treatment, its mutagenicity was only detected with TA 100 strain in the presence of the S9 fraction. After treatment the drug was still mutagenic on TA 100 strain with or without S9 activation. Its mutagenic potency was increased by a factor of 5.

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Guidelines for the safe handling of excreta contaminated by cytotoxic agents

Yaakov Cass and Catherine F. Musgrave

Am J Hosp Pharm. 1992; 49:1957-8

Examination of the pharmacokinetics of antineoplastic agents indicates that the potential danger to health-care providers does not end with drug administration. Persons handling the excreta from patients receiving antineoplastics, or equipment soiled by the excreta, may be exposed to cytotoxic contamination, because the excreta may contain residues of the antineoplastic agent administered or its active metabolites.

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Notes Safe handling of excreta

Table 1.
Cytotoxic Agents and Times for Protective Handling of Patient Excreta[a]

Cytotoxic Agent	Route of Administration[b]	Duration of Protective Precautions	Cytotoxic Agent	Route of Administration[b]	Duration of Protective Precautions
Bleomycin sulfate[7,10]	i.v., i.m., or s.c.	Urine: 72 hr; 50% excreted in first 24 hr	Ifosfamide[11,13]	i.v.	Urine: 48 hr
			Mechlorethamine hydrochloride[7,9]	i.v., i.p., or on the skin	Urine: 48 hr
Busulfan[7,9,11]	p.o.	Urine: 12–24 hr			
Carboplatin[11]	i.v.	Urine: 24–48 hr; 60% excreted in first 24 hr	Melphalen[7,9,11]	p.o.	Urine: 48 hr Feces: 7 days
Chlorambucil[7,9]	p.o.	Urine: 48 hr	Mercaptopurine[7,8]	p.o.	Urine: 48–72 hr; 50% excreted in first 24 hr
Cisplatin[7,12]	i.v.	Urine: 7 days			
Cyclophosphamide[7,10]	i.v., p.o., or into a body cavity	Urine: 72 hr Feces: 5 days after oral dose Bathing patient: 72 hr Oral procedures: 72 hr	Methotrexate[7,10]	p.o., i.v., i.m., i.t., or i.a.	Urine: 72 hours; major problem with urine during first 8 hr Feces: 7 days
			Mitomycin[8,10]	i.v., i.a., i.p., into a body cavity, or into the eye	Urine: 24 hr
Cytarabine hydrochloride[9,11]	i.v., i.t., s.c., or i.m.	Urine: 24 hr			
Dactinomycin[11]	i.v.	Urine: 5 days; 20% excreted in first 24 hr			
Daunorubicin hydrochloride[9,11]	i.v.	Feces: 7 days Urine: 48 hr	Mitoxantrone hydrochloride[7,8,11,14]	i.v.	Urine: 6 days Feces: 7 days
Doxorubicin[7,10]	i.v.	Feces: 7 days Urine: 6 days Feces: 7 days	Thioguanine[9,11]	p.o.	Urine: 24 hr
			Thiotepa[9,11]	i.v., i.m., into a body cavity, into a tumor, i.a., or i.t.	Urine: 24 hr Urine: 72 hr
Epirubicin hydrochloride[12]	i.v.	Urine: 7 days Feces: 5 days			
Etoposide[9,11]	i.v., p.o.	Urine: 4 days Feces: 7 days	Vinblastine sulfate[7,8,11,14]	i.v.	Urine: 4 days Feces: 7 days
Fluorouracil[7–11]	i.v., i.a., on the skin, or into the eye	Urine: 48 hr	Vincristine sulfate[7,8,10,14]	i.v.	Urine: 4 days Feces: 7 days

[a] If specific precautions are not listed for a drug, a minimum precautionary time of 48 hours is recommended. Information in the table should be reassessed periodically with regard to recently published literature.
[b] i.v. = intravenous, i.m. = intramuscular, s.c. = subcutaneous, p.o. = by mouth, i.t. = intrathecal, i.a. = intra-arterial, i.p. = intraperitoneal.

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Guidelines for Managing Cytotoxic Waste in the Community Setting

Document prepared for Home and Community Care (HACC) workers in the Northern Grampians Region

NORTHERN Grampians SHIRE COUNCIL

Version No: 2	Created Date: December 2010
Review Date: January 2012	Revision Date: January 2013

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SPILLAGE:

Process Standard	Key Points
All spillages should be dealt with immediately according to recommended OH&S worksafe guidelines	
Drug spillage should only be handled by trained personal	**Drug Spills - seldom occur in the home. In the event a spill does occur - don't touch** • Patients who are receiving parental chemotherapy at home will have been instructed on how to manage this situation • Patients will be instructed to: o Single or double bag the device and tubing with plastic bags, tie off and report back to the centre where they have received their treatment • If a spill occurs on the floor etc – leave and call the service where they have received their treatment – a spill kit will be required
Surface spills - vomit, urine or faeces	**Use PPE gloves (double glove – preferably with nitrile gloves but latex gloves acceptable) and gown** • Clean spill with disposable paper towels • Wash contaminated surfaces well with water using paper towels **Recommendation:** Double glove and gown in instances where clients have been incontinent who require assistance with their hygiene

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HANDLING CYTOTOXIC WASTE

Process Standard	Key Points
Health Care Professionals, patients and family members should understand safe handling of cytotoxic waste and be aware of the potential hazards of exposure. **Correct disposal minimises risk**	
Emptying commodes	**Use PPE Gloves (double glove preferably with nitrile gloves but latex gloves acceptable) and gown** • Empty pan contents into the toilet • Soak or wash the pan with copious amounts of water and dry with a paper towel **Recommendation:** The contents of ostomy bags can be emptied into the toilet
Cleaning the toilet	**Use PPE Gloves (double glove preferably with nitrile gloves but latex gloves acceptable)** • Flush the toilet on the long cycle with the lid down before cleaning • Toilet brush – can be rinsed at completion of cleaning for future use
Cleaning the bath or shower	**Use PPE Gloves (double glove preferably with nitrile gloves but latex gloves acceptable)** • Wash down area well with water first then clean as normal
Changing bed linen	**Use PPE Gloves (double glove preferably with nitrile gloves but latex gloves acceptable) and gown** **Soiled linen only** – faces, urine or vomit • Soak excess waste on linen with paper towels • Fold linen so as the contaminated area is innermost • Wash separately in the washing machine on the long cycle in hot or cold water. You don't need any special type of washing detergent • Dry outside on the clothes line
Disposal of contaminated rubbish	Place all contaminated rubbish (wet or dry) into a separate plastic rubbish bag, tie off and place in the patients rubbish waste bin
Main Points to Remember: 1. Wash your hands well before placing gloves on and after you have removed them 2. Precautions should be carried out for **7days following a clients treatment** 3. If in doubt about what to do contact your team leader to request assistance from the Grampians Integrated Cancer Service Monday to Friday on (03) 5320 4782 or 0434 658 518	

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JCHAHO input….

MM.06.06.01 requires safe administration of medication and that the family should be informed regarding other concerns (including proper disposal) when new medications are started.

PC.02.03.01 Requires that a learning needs assessment is completed and that patient education, then, is provided based on this assessment. This would certainly include education related to safe use, disposal, etc. of medications the patient has received during a hospital encounter, and/or medications to be continued after discharge.

MM.05.01.09 Discusses the use of cautionary labels on medications dispensed. There is a cautionary label which says "chemotherapy," and during the education process under PC as stated above, education regarding what one should do when the medication has the "chemotherapy" sticker on the container of medication. Included once again in the information provided should be a referral to this sticker and what that means in terms of proper disposal and danger to others with whom the patient may contact.

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NPSG.03.06.01 includes requirements about maintaining accurate medication information, providing patients with a list of medications to continue after their hospital encounter, and educating patients on the importance of managing medication information to the patient when he or she is discharged from the hospital or at the end of an outpatient encounter.

MM.01.01.03 include requirements for safe management of high alert and hazardous medications and also references requirements at EC. 02.02.01 which addresses risks associated with disposing of hazardous medications. Lastly, organizations are required to be in compliance with law and regulation regarding proper use, handling and disposal of such medications (see LD.04.01.01).

Each of the accreditation standards referenced above are found in the Comprehensive Accreditation Manual for Hospitals. Each accredited organization's Accreditation Coordinator has a copy of this manual containing these requirements.

Post questions to: https://web.jointcommission.org/sigsubmission/sigonlineform.aspx

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http://www.cytotoxicsafety.org/

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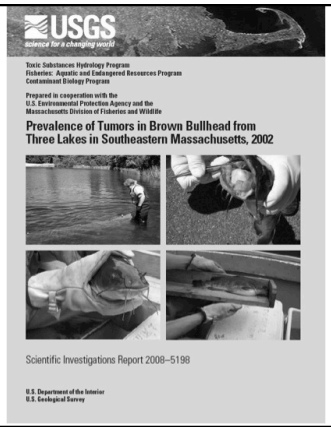

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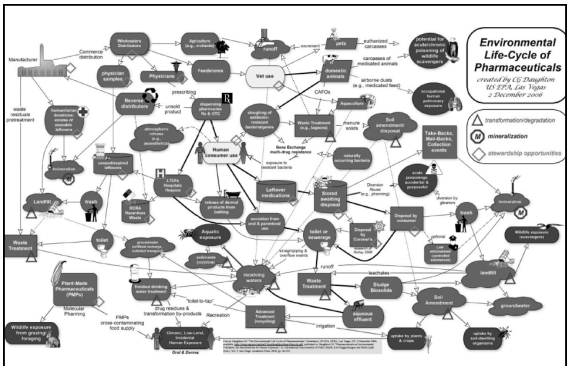

http://www.epa.gov/esd/bios/daughton/drug-lifecycle.pdf

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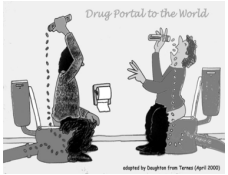
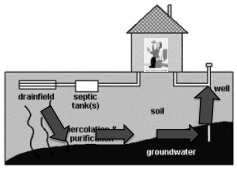
What Happens to the Drugs Post Treatment?



A few Bad Actors are Excreted from Patients in Active Form

Cytotoxic chemotherapeutic drugs remain active Post-Patient (after excretion from patient)
Waste drugs enters watershed, source of our drinking water.
85% of infusion patients are sent home with no equipment to manage toxic chemicals excreted in their urine, feces, sweat and other bodily fluids.



Septic Systems Destroyed and the well poisoned

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Study on the environmental risks of medicinal products

FINAL REPORT

Executive Agency for Health and Consumers
12 December 2013

bio Intelligence Service

Recent pharmacovigilance legislation in the EU acknowledges that the pollution of waters and soils with pharmaceutical residues is an emerging environmental issue. The European Commission was asked to deliver a report on the scale of the issue, the causes, and possible policy options to mitigate such impacts. More recently, in the framework of the adoption of the Directive regarding priority substances in the field of water policy, the Commission has been asked to develop, instead of the report, a strategic approach to pollution of water by pharmaceutical substances by the end of 2015.

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References:

http://www.cdc.gov/niosh/topics/antineoplastic/nioshpubs.html

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People.™

OCCUPATIONAL EXPOSURE TO ANTINEOPLASTIC AGENTS

NIOSH Publications

This section includes NIOSH numbered publications on occupational exposure to antineoplastic and other hazardous drugs.

Alerts

Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings (http://www.cdc.gov/niosh/docs/2004-165/)
DHHS (NIOSH) Publication No. 2004-165 (2004)

Hazardous Drug List Update

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014 (http://wwwdev.cdc.gov/niosh/docs/2014-138/default.html)
DHHS (NIOSH) Publication No. 2014-138 (September 2014)

Workplace Solutions

Preventing Worker Deaths and Injuries When Handling Micotil 300® (http://www.cdc.gov/niosh/docs/wp-solutions/2007-124/)
DHHS (NIOSH) Publication No. 2007-124 (2007)

Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs (http://www.cdc.gov/niosh/docs/wp-solutions/2009-106/)
DHHS (NIOSH) Publication No. 2009-106 (2008)

Safe Handling of Hazardous Drugs for Veterinary Healthcare Workers (http://www.cdc.gov/niosh/docs/wp-solutions/2010-150/)
DHHS (NIOSH) Publication No. 2010-150 (2010)

Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs (http://www.cdc.gov/niosh/docs/wp-solutions/2013-103/)
DHHS (NIOSH) Publication No. 2013-103 (2013) - supersedes 2007-117

http://www.cdc.gov/niosh/topics/antineoplastic/nioshpubs.html 1/9

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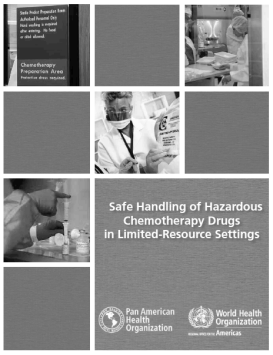

http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=24983&Itemid=&lang=en

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ON LINE Journal of Nursing Issues

Volume 9 – 2004 No 3: Sept'04
Hazardous Drugs

Safe Handling of Hazardous Drugs

Martha Polovich, MN, RN, AOCN

http://www.nursingworld.org/MainMenuCategories/ANAMarketplace/ANAPeriodicals/OJIN/TableofContents/Volume92004/No3Sept04/HazardousDrugs.aspx#Stolar83

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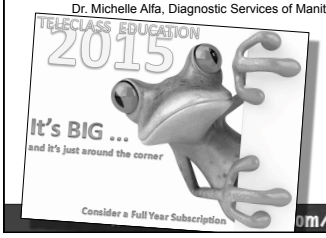
Thank-you!

Coming Soon

December 8 **TELECLASS EDUCATION 2015 SCHEDULE RELEASE**
http://www.webbertraining.com/schedulep1.php

December 11 **ENVIRONMENTAL CLEANINGIN HEALTHCARE: IS MONITORING OF CLEANING COMPLIANCE REALLY NEEDED?**
Dr. Michelle Alfa, Diagnostic Services of Manitoba



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