

Safe Handling of Oral Chemotherapy

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Conflict of Interest Declaration

I have developed and delivered educational programs sponsored by **BD Canada**.

Learning Objectives

- **Background review and the NIOSH definition for hazardous drugs**
- **A Review the standards and guidelines for safe handling**
- **To provide practical approaches to improve safe handling of hazardous drugs**

Poll the Audience!

Are you aware of the NIOSH hazardous medication list?

A. Yes

B. No

Weather

Today: Foggy, then sun.
High 64. Low 45.
Wednesday: Breezy, late
rain. High 59. Low 32.
Details, Page B10

138TH YEAR No. 72 M2 MD

The Washington Post

TUESDAY, FEBRUARY 15, 2005

MARYLAND
FINAL

35¢

Please pay only in areas where authorized.
Washington (See Box on Page A1)

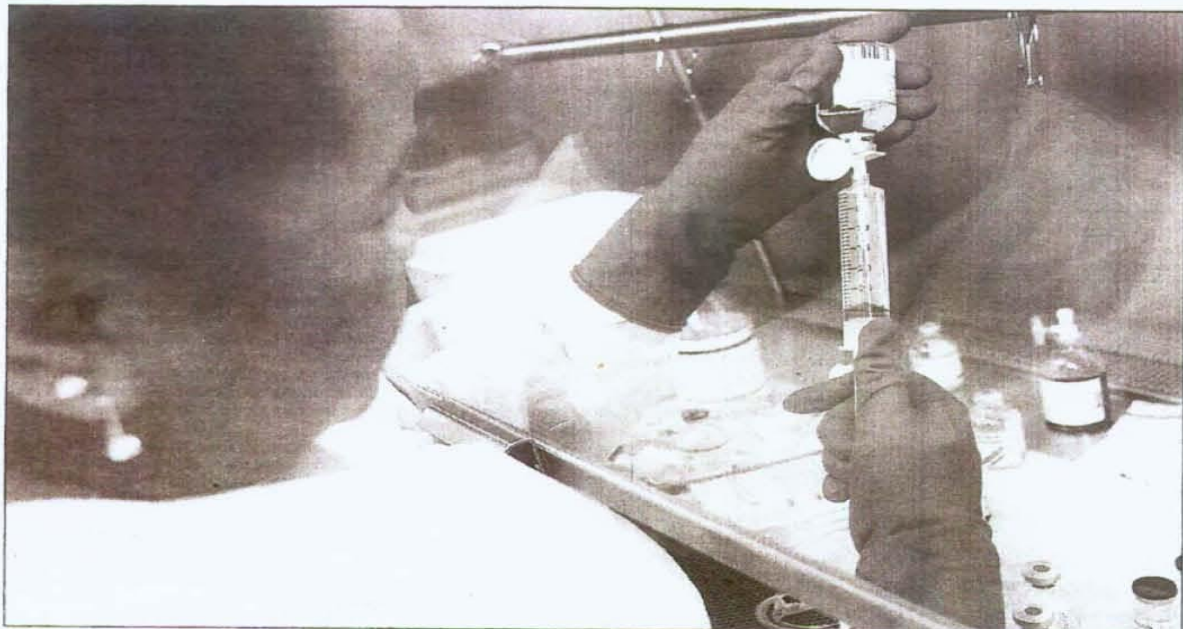
The Washington Post

HEALTH

F

TUESDAY, FEBRUARY 15, 2005

DM VA



BY CHRIS HONDROS/GETTY IMAGES

Wearing heavy gloves and working behind a protective screen, a worker prepares chemotherapy drugs at Cape Fear Valley Medical Center in Fayetteville, N.C. The toxic drugs, some of which can become airborne, pose a workplace hazard, but exposure levels have not been widely studied.

What if the Cure is Also a Cause?

*The Same Chemo
Drugs That Save
Some Cancer Patients'
Lives Put Health
Workers at Risk*

By JIM MORRIS
Special to The Washington Post

Last March, the federal government issued an unusually detailed alert to the nation's 5.5 million health care workers: The powerful drugs used in chemotherapy can themselves cause cancer and pose a risk to nurses, pharmacists and others who handle them.

Four years in the making, the alert was issued by the National Institute for Occupational Safety and Health (NIOSH). Officials with the institute—part of the Centers for

Disease Control and Prevention (CDC)—and members of a hazardous-drug advisory panel saw the document as a long-overdue first step toward addressing what could be a serious workplace health problem.

The next step was to be a study of actual exposures at three hospitals, operated by the universities of Maryland, North Carolina and Texas. The plan was to take blood and urine samples from about 50 pharmacists, nurses and pharmacy technicians at the hospitals and look for signs of drugs such as cyclophosphamide (usually administered intravenously to treat lym-

phoma, leukemia or breast cancer) and ifosfamide (also an IV drug, often used on lung, cervical and ovarian cancers).

But the study, formally proposed in July 2002, is on hold. Twice the CDC submitted the proposal to the Office of Management and Budget (OMB). Twice it was withdrawn, after the OMB raised questions. It has yet to be resubmitted.

OMB spokesman Chad Kolton would say only that the CDC withdrew the paperwork "to address ongoing technical concerns re-

See CHEMOTHERAPY, Page F4

What are the effects of these drugs on me?



Effects on our DNA?

- DNA damaging effects of treatment with chemotherapy: *myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML)*
- Two principle patterns of abnormalities
 1. Loss of all or part of chromosomes 5 and 7
 2. Damage to chromosome 11
- No previous studies have surveyed workers for specific chromosomal abnormalities.

Effects on our DNA?

- 63 oncology pharmacy and nursing personnel **vs** 46 non-exposed pharmacy and nursing personnel
- Mean # of drug handling events over 6 weeks - **153 events**
- High Exposure (**> 153 events**) had **↑** frequency of chromosomal abnormality
- At 100 events, there was a 20% **↑** in chromosomal abnormalities
- At 500 events, 2.5 fold **↑** in chromosomal abnormalities

Effects on our DNA? “Conclusions”

- Improvements in compliance to standards must be promoted
- The adequacy of protection that the current safe handling guidelines offer must be scrutinized.
- The risk to caregivers must be minimized

What does this
tell us about the
hospital
environment?



Case Reports

- Hazardous drugs tested in the urine of healthcare workers
 - Primary and secondary contamination
 - 13 of 20 studies detected hazardous drugs in healthcare workers urine
- Two to five “marker” drugs are sampled and analyzed in pharmacies and patient treatment areas
 - Studies across several countries have shown that at least one of the drugs was detected (BSC, countertops, floors, equipment...)

Case Reports

- Studies from Denmark show that drug vials received from manufacturers are often contaminated on the outside of the vial
- A few vials up to the entire shipment may be contaminated



What is a
Hazardous
Drug?



What Defines a “Hazardous Drug”?

NIOSH Definition!

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Geno-toxicity
- Structure & toxicity profile for new drugs that mimics existing hazardous drugs

Why Do We Care?

The same mechanisms that these drugs employ to kill cancer cells also works to damage healthy cells

NIOSH Warning

Working with or near hazardous drugs in health care settings may cause skin rashes, infertility, miscarriage, birth defects and possibly leukemia or other cancers

OSHA

“Preparation, administration, and disposal of hazardous drugs may expose pharmacists, nurses, physicians, and other health care workers to potentially significant workplace levels of these chemicals.”

Routes of Entry

- Breathing In - inhalation
- Skin - contact &/or absorption
- Swallowing - ingestion
- Eye - contact &/or absorption
- Injection - puncture wound

If patients use these
drugs at high doses
are health care
workers really at
risk?



Exposure

Patients

HIGH Dose exposure

FEW Drugs

Over several MONTHS

Health Care Workers

LOW-Dose exposure

MANY Drugs

Over several YEARS

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Standards & Guidelines

Guidelines

- ASHP
- ONS
- ISOPP
- HOPA
- European Oncology
- NIOSH

Standards

- USP 797
- OSHA
- JCAHO

Oral chemotherapy

Increasing numbers of oral antineoplastic drugs are available for cancer treatment

- May be administered at home by the patient or caregiver
- Oral chemotherapy offers convenience but poses safe-handling challenges for patients and caregivers

Oral chemotherapy in Canada

- In 1998, capecitabine was first oral antineoplastic agent available in Canada
- 2003, Birner reported that $\frac{1}{4}$ of the 200 cancer drugs in development were oral and expected to reach 25% in next decade.

**2012 - 2014:
20/39 (51%) of drugs reviewed by pCODR
have been oral agents**

Health Canada Drug Product Database

Birner A. Safe administration of oral chemotherapy. Clin J Oncol Nurs. 2003;7:158-162

Safe handling of oral chemotherapy

Well-established guidelines exist for parenteral chemotherapy in traditional settings, but safe-handling guidelines for oral chemotherapy are not as well defined

- American and Australian guidelines for oral chemotherapy
- In Canada, no national guidelines for safe-handling of oral chemotherapy in community setting; only exist for oncology pharmacists in hospital or clinic setting
- Adequate safety and support systems have not evolved as quickly as for parenteral chemotherapy

NIOSH Alert 2004. ASCO/ONS chemotherapy administration safety standards 2009. Meier K et al. EJOP 2011;5:4-10. CUPE Health and Safety Fact sheet. Cytotoxic drugs. 2011. NCCN Task Force Report 2008.

Don't forget to mention the CAPCA guidelines?



Who is at risk?

Those who handle or are exposed to oral antineoplastic agents, including:

- HCPs, e.g., physicians, pharmacists and nurses
- Patients/caregivers ??????
- Family members (including children and pets)
- Caregivers at home health care agencies and assisted-living facilities

Goodin S et al. *JOP* 2011;7:7-12. CCS. Safety precautions during chemotherapy, 2011. NIOSH Alert 2004. ASCO/ONS chemotherapy administration safety standards 2009.

Routine pharmacy tasks may result in hazardous drug exposure

- Counting out individual, uncoated tablets from multi-dose bottles
- Dosing uncoated tablets in a unit-dose machine
- Crushing tablets to formulate liquid oral doses
- Compounding powders into customized dosage capsules
- Contacting drug residue on drug containers, counting trays, work surfaces, floors

NIOSH Alert 2004.

Routine handling tasks may result in hazardous drug exposure, cont'd.

- Handling either unused hazardous drugs or contaminated waste generated at any stage of drug preparation
- Cleaning drug-preparation areas
- Transporting hazardous-waste containers
- Removing or disposing of personal protective equipment after handling hazardous drugs or waste

Patient and caregiver issues

- Patient/caregiver may have misconceptions about the ease of administration and side-effect profile of oral chemotherapy
- Lack of checks and balances
- Patient awareness of biohazards of oral chemotherapy not well investigated

Safeguards for oral chemotherapy: playing catch-up

- Few safeguards in routine use for parenteral chemotherapy have been adopted for oral chemotherapy
- Only Canadian Association of Pharmacists in Oncology (CAPHO) has standards of practice for patient education about safe handling of oral chemotherapy
 - Specifically for oncology pharmacists in hospital and clinic settings
 - **No guidelines for HCPs, community pharmacists, patients/caregivers**

NCCN Task Force Report 2008; CAPHO standards of practice for oncology pharmacy in Canada, Nov 2009, v2; CUPE Health and Safety Fact sheet. Cytotoxic drugs, 2011.

International guidelines for safe handling of oral chemotherapy*

Developed by an international panel of experts to address critical gaps, including:

- Lack of acceptance and adoption of current guidelines in clinical practice
- Lack of safe-handling guidelines for all stakeholders, i.e., industry, HCPs, patients/caregivers
- Lack of standardized procedures for all settings, i.e., industrial, healthcare, community, home
- Gaps in procedures specific to oral chemotherapy, e.g., adherence, medical errors, monitoring of side effects

*No formal process was used to reach a consensus; therefore, these guidelines are not truly evidence-based.

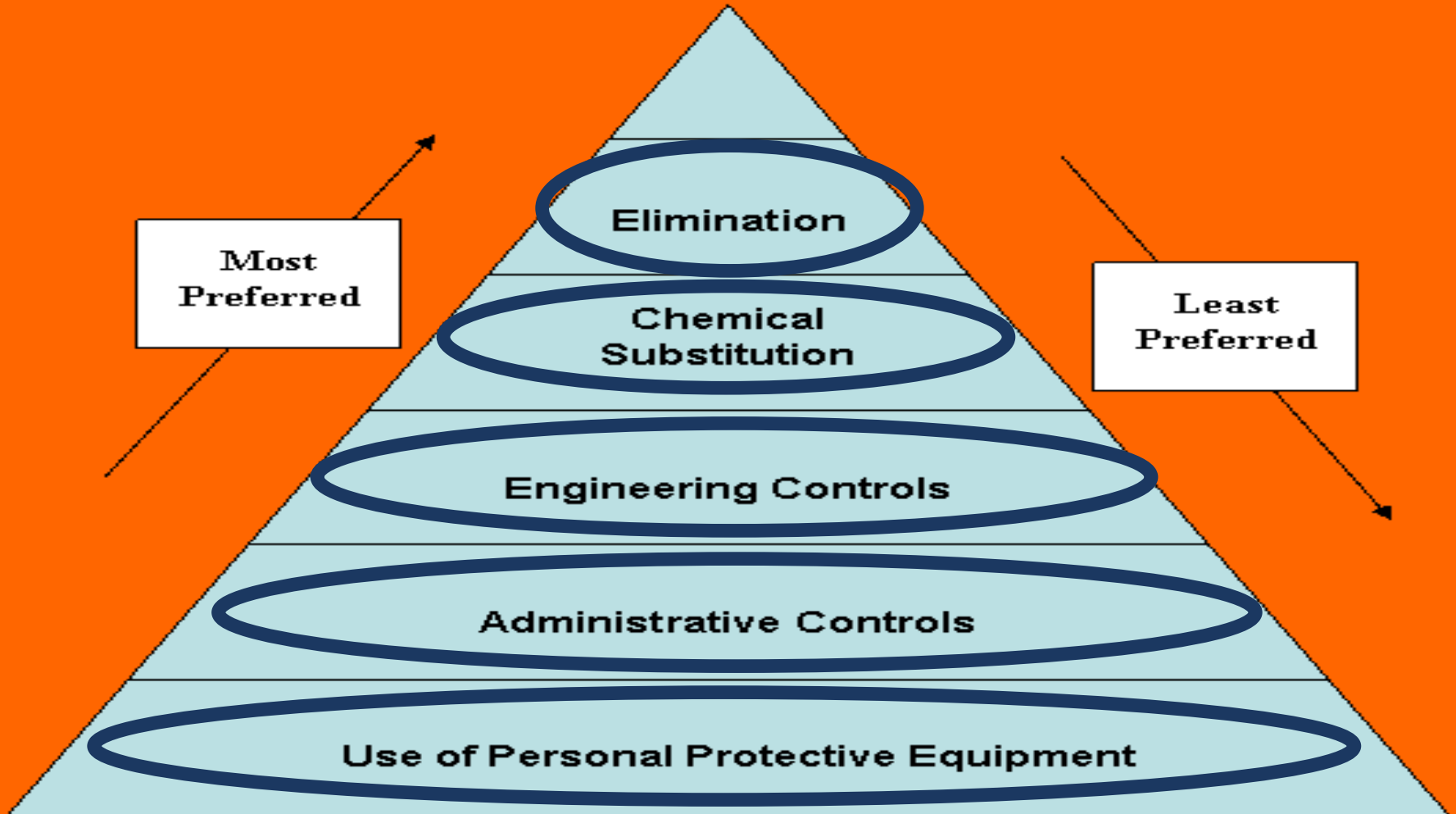
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**What controls can
we use to protect
the environment?**



Hierarchic Order of Protection

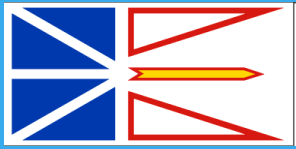


Poll the Audience!

Do you or your staff wear Personal Protective Equipment when you are dispensing Oral Anti-cancer agents?

a) Yes

b) No



National Survey Community Pharmacy



Awareness of Oral Anticancer Drugs by Canadian Pharmacists 2010

Adequate knowledge of Oral Anticancer Drugs (OAD)?	67% answered NO
#1 Reason for Knowledge Gaps	Lack of oncology CE events in my area.
Use of Personal Protective Equipment	Gloves 7% YES Mask 1% YES Clothing / Gown..30% YES
Use of Hazardous Medication Labels	16% - YES
Use of a Separate Counting Tray for OAD?	27% - YES
Counselling on the safe handling of OAD	21% - YES

1. Abbott, R., Edwards, S., et al. Canadian Pharmacy Journal, 2011;144:220-226
2. Abbott, R., Edwards, S., et al. National Oncology Pharmacy Symposium. 2011 poster

International safe-handling guidelines for pharmaceutical industry

- Use effective procedures for packaging and segregation
- Minimize drug handling and provide user-friendly information on how to compound liquid formulations
 - provide appropriate numbers of tablets or capsules per cycle
 - consider unit packaging
 - consider new dosage strengths
- Provide up-to-date safe-handling educational materials to all stakeholders

International safe-handling guidelines for HCPs

- Institute correct use of personal protective clothing and equipment to minimize health risks
- Do not use automatic counting machines for oral chemotherapy
- Use disposable gloves; wash hands before and after glove use
- Use separate equipment for cytotoxic and non-cytotoxic agents

International safe-handling guidelines for HCPs, cont'd

- Use a biological safe cabinet and disposable protective gear for pill manipulation
- Have a written emergency plan for accidental spills or exposure
- Keep an updated list of oral anti-neoplastic agents handy

Summary

- Exposure to hazardous medications poses a real health risk
- Utilize the hierarchy of controls for safe handling
- Continuing research and focus on the issue of safe handling

**We need to be Proactive
NOT Reactive!**

Things to Think About

- Is the medication hazardous?
- Is it a high risk or a low risk agent?
- What is the activity?
 - Dispensing? Or Compounding?
- Determine what PPE should be worn based on the risk
 - Drug Risk, Activity performed, etc...
- **Hierarchy of Control?**

Questions/Comments/Experiences

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Thank you!
Thank you!

