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

Ed Krisiunas, WNWN International Inc.
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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

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

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

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US Cancer Death Rate

Risk Factors/Causes of Cancer in the US

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.

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.


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

• Mustargen – 1949
• Chlorambucil (Leukeran) – 1957
• Cyclophosphamide (Cytoxan) – 1959
• Melphalan (Alkeran) – 1964
• Ifosfamide (Ifex) – 1988
• Treanda – 2008


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).

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.

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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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.

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.

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.

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.

Table 1. IARC Group 1 and Group 2A Carcinogens

<table>
<thead>
<tr>
<th>Group 1 Human Carcinogen</th>
<th>Group 2A: Probable Human Carcinogen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arsenic Trioxide</td>
<td>Asbestos</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>(CA)</td>
</tr>
<tr>
<td>Bleomycin</td>
<td>(CA)</td>
</tr>
<tr>
<td>Busulfan</td>
<td>Nitrobenzene 1-5</td>
</tr>
<tr>
<td>Carboplatin</td>
<td>Methotrexate 1-5</td>
</tr>
<tr>
<td>Cytoxan</td>
<td>Mitomycin 1-5</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>Mitoxantrone 1-5</td>
</tr>
<tr>
<td>Etoposide</td>
<td>N-Acetyl-2-Methoxyimidazole</td>
</tr>
<tr>
<td>Ifosfamide</td>
<td>Mitoxantrone 2-3</td>
</tr>
<tr>
<td>Lomustine</td>
<td>Nitrogen mustard 1-3</td>
</tr>
<tr>
<td>Methotrexone</td>
<td>Nitrogen mustard 2-3</td>
</tr>
<tr>
<td>Thiotepa</td>
<td>Nitrogen mustard 3-4</td>
</tr>
<tr>
<td>Teixfedacin</td>
<td>Nitrogen mustard 4-5</td>
</tr>
</tbody>
</table>

Source: Adapted from the International Agency for Research on Cancer; http://monographs.iarc.fr/ENG/Carcinogenicity Monographs.pdf

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

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What We Found
- Many contractor employees were not comfortable taking time off work when ill.
- Some employees were concerned about repetitive tasks and prolonged standing.
- Contractor employees reported nose, eye, nose, throat, and skin irritation and weight loss associated with work time company employees.
- No employees reported any changes in their health consistent with exposure to hazardous drugs.
- Employees released particles into the air during certain job tasks.
- An employee who cleaned and repaired cleanroom meters was exposed to airborne dust that exceeded the exposure limit. A few employees were exposed to multiple active pharmaceutical ingredients.
- We found a hazardous drug manufacturer to air levels below the manufacturer's exposure limit. We also found it on a work surface.
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What We Found
- One employee was exposed to benzidine 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.

Table 1. Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings

<table>
<thead>
<tr>
<th>Activity</th>
<th>Eye protection</th>
<th>Hand protection</th>
<th>Respiratory protection</th>
<th>Engineering controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling</td>
<td>Full face reusable mask (FFR)</td>
<td>Nitrile gloves</td>
<td>Powered air-purifying respirator (PAPR)</td>
<td>Integrated compliance (IC)</td>
</tr>
<tr>
<td>Compounding</td>
<td>Latex gloves</td>
<td>Powered air-purifying respirator (PAPR)</td>
<td>Negative pressure</td>
<td>Absorbent floor and wall coverings</td>
</tr>
</tbody>
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Table 2. Personal protective equipment and engineering controls for working with hazardous drugs in healthcare settings

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Herceptin s.c.
Injection device “MyDose”
- Ein Batterie-getriebener Motor stellt die gleichmäßige s.c.-Injektion von Herceptin über ca. 5 min sicher.
- Eine LED-Leuchte zeigt den Status der Injektion an.
- Das transparente Fenster ermöglicht eine visuelle Überwachung der Injektion.

http://www.nature.com/nrc/journal/v5/n1/fig_tab/nrc1529_I1.html
http://images.slideplayer.de/2/864499/slides/slide_17.jpg

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Preference for subcutaneous or intravenous administration of trastuzumab
in patients with HER2-positive early breast cancer (ProHer): an open-label
randomised study
Prof Evarist Pauci 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/fanon/article/PIIS1470-2045(13)70383-8/abstract


Waste streams........

Solid Waste
Regulated Medical Waste
Hazardous Waste
Chemotherapy Waste
Liquid Waste
Radiological Waste
Recycling
Organic Waste
G&O Waste
Pharmaceutical Waste
Sharps
Donations

Pharmaceutical Waste and Disposal

Recommended Pharmaceutical Waste Streams

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Guidelines for the safe handling of excreta contaminated by cytotoxic agents

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JCAHO 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.

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/jcahohub/signonlineform.aspx

http://www.cytotoxicity.org/

What Happens to the Drugs Post Treatment?

A few Bad Actors are Excreted from Patients in Active Form

Chemotherapeutic drugs remain active 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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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.

References:
- http://www.cdc.gov/niosh/topics/anineplastic/nishpubs.html
- lang=en

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/UJN/TableofContents/Volume92004/No3Sept04/HazardousDrugs.aspx#Stolar83

Thank-you!

December 8
TELECLASS EDUCATION 2015 SCHEDULE RELEASE
http://www.webbertraining.com/schedule1.php

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

http://www.webbertraining.com/schedule1.php

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