

Safe Handling of Oral Anti-Cancer Therapy- Don't Ask Don't Touch

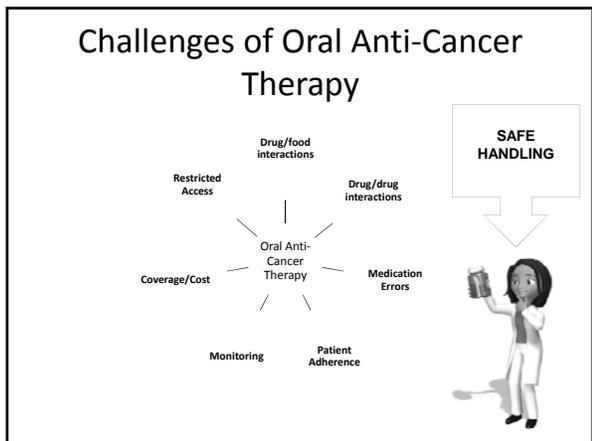
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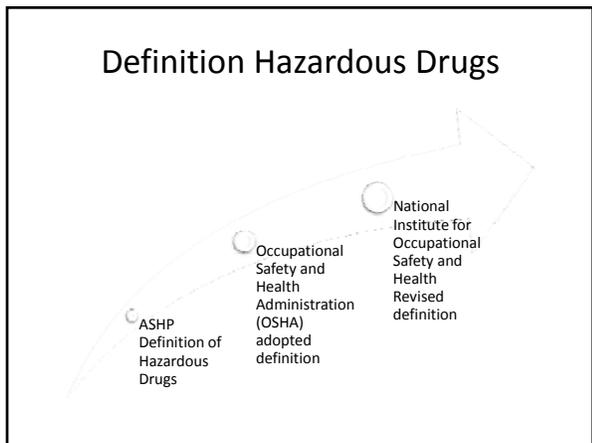
Disclosure

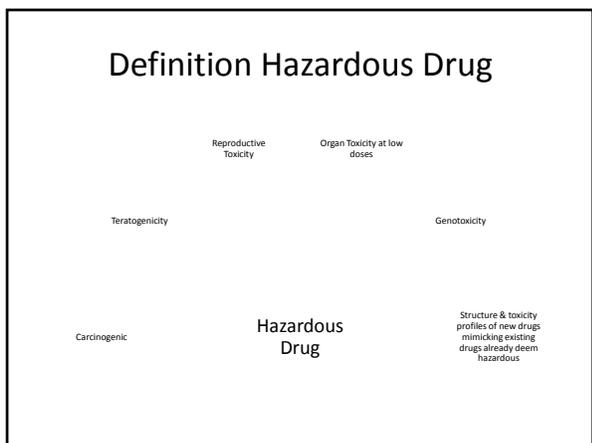
- *Speaker's Bureau/Governing Board: Celgene, Merck*
- *Any conflict was resolved through peer review.*

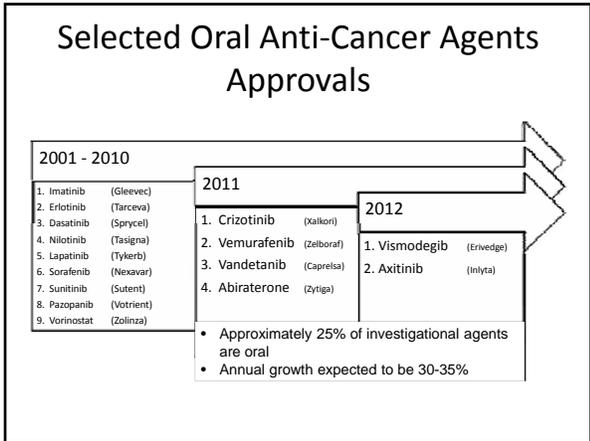
Objectives

- Discuss the elements of safe handling of oral anti-cancer therapy
- Describe the impact of safe handling on nurse and patient/caregivers









Safe Handling Oral Anti-Cancer Therapy: Pharmacist

Potential Activities that may Increase Exposure to Hazardous Drugs
• Counting out individual, uncoated oral doses and tablets from multi dose bottles
• Unit-dosing uncoated tablets in a unit-dose machine
• Crushing tablets to formulate oral liquid doses
• Compounding powders into customized dosage capsules
• Contact with drug present on exteriors of drug containers, on counting trays, on work surfaces, and on final dispensed produce
• Cleaning drug preparation areas
• Procurement/transporting hazardous-drug containers
• Removing or disposing of personal protective equipment after handling of hazardous drugs or waste

- ### Occupational Exposure
- Adverse effects of hazardous drugs first reported 30 years ago
 - Increased incidence of genotoxicity was documented in pharmacists and nurses handling antineoplastic drugs
 - Danish cancer registry
 - Increased risk for leukemia among oncology nurses and oncologist exposed to antineoplastics
 - Other studies established association b/w exposure to chemo and increased fetal loss and infertility

Occupational Exposure

- Fransman et al
 - Study to determine potential /actual dermal exposure to cyclophosphamide during performance of oncology-related tasks in a hospital
 - Conclusion
 - Significant contamination on and around the toilet
 - Use of gloves reduced personal contamination from changing bed linens from 1 to 6 fold
 - Pharmacy technicians and cleaning personnel at increased risk for exposure, however, protection provided by gloves appears sufficient

Safe Handling Oral Anti-Cancer Therapy: Patient/Caregivers

Potential Activities that may Increase Exposure to Hazardous Drugs
• Administration of anti-cancer therapy
• Storage of anti-cancer therapy
• Disposal of any materials used while handling oral anti-cancer therapy
• Transportation of anti-cancer therapy

Guidelines and Policies for Safe Handling of Oral Chemotherapeutic Agents

Selected Guidelines and Policy Examples
• ASHP Guidelines
• US Dept of Labor Occupational Safety and health Admin technical manual
• American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards
• European Society of Oncology Pharmacy declaration
• Management and Awareness of Risks of Cytotoxic Handling (MARCH) guidelines
• Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy; a consultative report prepared by Clinical Oncological Society of Australia, November 2008
• Guidelines from the Canadian Association of Pharmacy in Oncology

Issue 1: Recommendations have not been universally accepted or incorporated into practice
 Issue 2: None of the guidelines addresses all the areas for the safe handling of oral chemotherapeutic agents

Safe Handling Perspectives Oral versus Parenteral

NCI Survey	Oncology Med Safety: A 3D Status Report 2008	Patients Perspective and Safe Handling
<ul style="list-style-type: none">• Characterize safe practices for use of oral chemotherapy• Safe handling issues identified	<ul style="list-style-type: none">• Survey• 32% of respondents did not consider oral chemo as requiring same safety concerns as parenteral chemo	<ul style="list-style-type: none">• Survey• 40% of patients believed oral anticancer therapy was safer than parenteral chemo

Quick Recap

- Increased number of oral anti-cancer drugs are being approved
- Pharmacy staff, patients/caregivers are at increased risk potential exposure of hazardous drugs
 - Perception oral is safer than parenteral
- Gaps identified in guidelines regarding handling of oral anticancer therapy

Safe Handling of Oral Chemotherapeutic Agents in Clinical Practice: Recommendations from International Pharmacy Panel

- Purpose
 - Address critical areas for safe storage, handling, administration, and disposal of oral chemotherapeutic agents for manufacturers, distributors, health care workers, and patients or their caregivers
 - Can be adapted by institutions and practices for development of standardized procedures specific to their needs regarding handling of oral chemo and oral agents utilized in treatment of cancer

Storage Recommendations

Cytotoxic agents should be stored in designated area separate from noncytotoxics

Some agents are air-, moisture-, and/or light-sensitive; storage specifications should be followed

**Handling Recommendations:
Health Care Staff**

- Personal protective clothing & equipment
- Avoid using automatic counting machines
- Disposable gloves should be used for dispensing. Hands washed before/after glove application
- Compounding, crushing, splitting should be done in biological safety cabinet & involve use of disposable personal protective equipment

**Handling Recommendations:
Health Care Staff**

- Separate equipment should be used for cytotoxic and noncytotoxic
- HCP who store and dispense oral chemo agents must have a written emergency plan in the event of a spill or accidental exposure
- Updated list of hazardous medications should be readily accessible to all HCP involved in handling of oral chemo agents

**Handling Recommendations:
Health Care Staff**

- Pregnant staff members
 - No consensus was reached
 - Agreed the goal minimize or eliminate any role of pregnant staff in handling chemo agents, oral or intravenous
 - Many panel members felt appropriate protection (gown, gloves) was sufficient

**Handling Recommendations:
Patient/Caregivers**

- Use gloves and wash hands before/after glove application
 - If gloves not worn, tip tablets/capsules from their container directly into medicine cup
- Wash the patient's clothes and bed linen separately from others
- Double-flush toilet after use, during use of and 4-7 days after d/c oral chemotherapy
- Return any unused, damaged, wet, or expired medication to the pharmacy

**Handling Recommendations:
Health Care Staff**

- Cleaning of nondisposable materials exposed to chemotherapy drugs
 - Counting trays, tools, and surfaces
- Limited options for cleaning surfaces
 - Limited data supporting use of cleaning agents in removal of cytotoxic agents
- Need to develop a valid, readily available, and affordable decontamination agent for safe use in health care setting and patient's home

Best Practice



- Education
 - Health care staff, patients, care givers
- Training and competencies
- Define processes for safe handling
 - Nursing, pharmacy, patients, etc
- Develop patient education tools for the “do’s and don’ts” of safe handling oral anticancer agents

Conclusion

- Oral anti-cancer agents are common and present several challenges to pharmacists in all settings
 - Retail, clinic, hospital
- Safe handling important to both health care staff and patient/care givers
 - Storage, handling, and disposal
- Recommendations from Goodin et al
 - Provide framework for implementation

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Pharmacy Practice Session:

Safe Handling of Oral Anti-Cancer Therapy – Don't Ask Don't Touch

Sandy Cuellar, Pharm.D., BCOP

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Self-assessment Questions:

1. What is the percentage of oral anticancer therapy expected to be approved annually?
 - a. 50%
 - b. 30%
 - c. 15%
 - d. 5%

2. Which of the following is a characteristic of a hazardous drug?
 - a. Carcinogenic
 - b. Organ toxicity
 - c. Reproductive toxicity
 - d. All of the above

3. Which of the following activities may cause occupational exposure to hazardous drugs?
 - a. Labeling a blister pack of thalidomide
 - b. Compounding temozolamide in to oral solution form under biologic safety cabinet
 - c. Counting uncoated tablets without gloves
 - d. None of the above

4. According to the international pharmacist panel, recommendations for pharmacist handling cytotoxic drugs includes:
 - a. Cytotoxic drugs should be in a designated area
 - b. Use of separate counting try for cytotoxic drugs
 - c. Use of gloves for dispensing cytotoxic drugs
 - d. All of the above

5. According to the international pharmacist panel, recommendations for patients/caregivers handing cytotoxic drugs include all of the following, EXCEPT:
 - a. Caregivers should wash hands after administration of oral anticancer agent
 - b. Double flush toilet during use of cytotoxic agents and 4-7 days after
 - c. Wash bed linen separately from others in household
 - d. Return any unused, wet, or expired cytotoxic agents to the pharmacy

Don't Let Oncology Drug Shortages Throw You Under the Bus

Ginger J. Ertel, Pharm.D.

The speaker has no conflict to disclose.



Poll Question #1

- Is your institution faced with oncology drug shortages?
1. Yes
 2. No



Poll Question #2

- Does your institution and community have a standardized process for chemotherapy services from diagnosis to treatment?
1. Yes
 2. No

Objectives

- Describe a process for chemotherapy standardization across health care organizations in a community
- Describe the value of a standardized process for chemotherapy ordering, handling, and administration

Background

- Five healthcare organizations
 - Two hospitals
 - Three clinic practices
- Facility specific chemotherapy order form
- Drug shortages

Issues

- Patients unsatisfied
- Physicians unsatisfied
- Drug shortages
- Hand written orders
- Scheduling – feast or famine
- At risk for errors

Methods

- Multidisciplinary team
 - Representative from each organization, nursing, pharmacy, administration, scheduling, physicians, patients
- Defined the GOAL
- Mapped the process
 - Current state
 - Identified breakdowns
- Developed new process

Overview New Process

- Standardized order sheet **criteria**
- Patient education
- Scheduling - **blocks**
- Insurance verification
- Pharmacy **procurement** specialist
- Confirm appointment

Physician and Patient

- Standardized order sheet **criteria** – community wide
 - Electronic orders
 - Electronic transmission
- Patient education
 - Before therapy begins
 - Set expectations
 - What to expect
 - When to expect

Registration and Scheduling

- Scheduling
 - Developed block scheduling
 - Electronic routing of orders to pharmacy and nursing
- Insurance verification
 - Inform patient of their responsibility

Pharmacy Procurement Specialist

- Review reimbursement and patient assistance
- Facilitate product procurement
 - Maintain minimum quantities (weekly inventory)
 - Relationships
 - Industry representative
 - Local hospitals and clinics
 - Monitor availability
 - Secure product
 - Communication with care givers

Communicate

- Confirm appointment
 - Patient
 - Physician office
- Weekly distribution - oncology medication shortages to physicians

Lessons Learned

- Manage expectations
- Scheduling
- Handling of physician orders
- Physician awareness of drug shortages
- Marketing / buy-in of the new process
- Evaluation of inventory management processes

Value

- Valuable steps were occurring in departments but they were not communicating with each other
- The process built rapport between departments
- Improved patient safety
- Increase patient satisfaction
- Respectful of patient's time
- Shortages-
 - Rescheduling or changing therapy before the patient arrives for scheduled visit

Self-Assessment

- Which of the following processes was implemented for chemotherapy standardization across health care organizations in a community
 - a) Standard order form criteria, patient education, block scheduling, product review, appointment confirmation
 - b) Standard order forms, open scheduling, product review, appointment confirmation
 - c) Physician preference order forms, patient education, block scheduling, product review, appointment confirmation
 - d) Electronic order forms, open scheduling, open formulary, appointment confirmation

Self-assessment

- Which of the following is not a reason to standardize chemotherapy processes in a community with shared physicians?
 - a) To improve patient safety
 - b) To improve patient satisfaction
 - c) To increase drug cost
 - d) To improve physician satisfaction

Self-assessment

- A pharmacy procurement specialist was developed to:
 - a) Review the pharmacy stock portfolio
 - b) Review reimbursement and patient assistance programs
 - c) To develop the hospital budget
 - d) To assist the chief financial officer

Questions



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Self-assessment Questions:

- 1) Which of the following processes was implemented for chemotherapy standardization across health care organizations in a community
 - a) Standard order form criteria, patient education, block scheduling, product review, appointment confirmation
 - b) Standard order forms, open scheduling, product review, appointment confirmation
 - c) Physician preference order forms, patient education, block scheduling, product review, appointment confirmation
 - d) Electronic order forms, open scheduling, open formulary, appointment confirmation

- 2) Which of the following is not a reason to standardize chemotherapy processes in a community with shared physicians?
 - a) To improve patient safety
 - b) To improve patient satisfaction
 - c) To increase drug cost
 - d) To improve physician satisfaction

- 3) A pharmacy financial analyst was developed to:
 - a) Review the pharmacy stock portfolio
 - b) Review reimbursement and patient assistance programs
 - c) To develop the hospital budget
 - d) To assist the chief financial officer

Finding Chemo: The Search for Oncology Guidelines

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SIUE School of Pharmacy

Disclosure Statement

- Author of this presentation has nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation

Objectives

- Describe at least two internet sites to find current guidelines concerning oncology treatments.
- Identify other sources to go to when current guidelines are not available.

How much of your daily practice involves oncology?

1. No oncology
2. Very little oncology
3. Some oncology
4. Mostly oncology
5. All oncology

The Case of EK

- EK is a 61 year old female recently diagnosed with stage II epithelial ovarian cancer. She underwent cytoreductive surgery including TAH/BSO and placement of intraperitoneal port. The patient was determined to be optimally debulked. The patient is to start chemotherapy. Orders are received to start intraperitoneal therapy.

You are the pharmacist who receives the order. You are familiar with IP chemotherapy for stage III disease, but not stage II. Where can you look for guidelines to help?

1. American Society of Clinical Oncology (ASCO)
2. Gynecology Oncology Group (GOG)
3. National Comprehensive Cancer Network (NCCN)
4. Oncology Nursing Society (ONS)

Reason for Seeking Guidelines

- Assist with treatment selection
- Justification for 3rd-party payers

Where Not To Find Guidelines

- Primary literature
- Cancer research cooperative groups
- Textbooks
- Wikipedia

Types of Guidelines

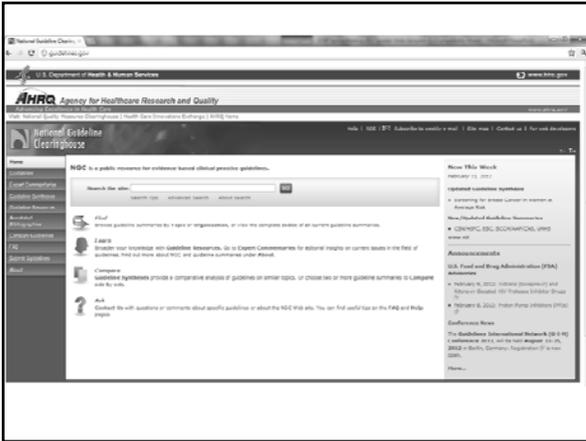
- Evidence-based
- Consensus-based

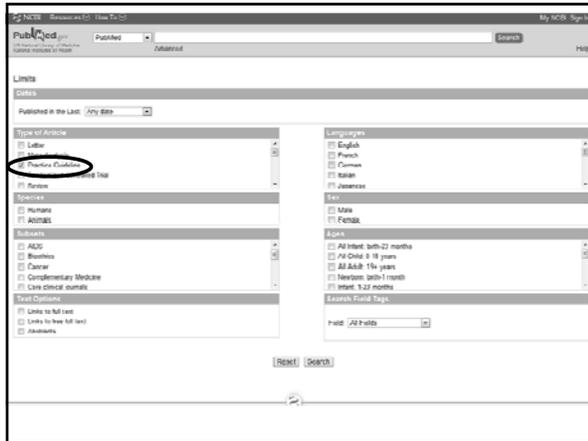
Finding Guidelines

- Know where to look, or...
- National Guidelines Clearinghouse¹
 - guidelines.gov
- PubMed²

guidelines.gov

- Agency for Healthcare Research and Quality
- Allows for comparison of guidelines





Cancer Treatment Guidelines

- Few organizations produce guidelines
- Rapid evolution of evidence in treating cancer makes guideline publication difficult
- Sources:
 - National Comprehensive Cancer Network³
 - European Society for Medical Oncology⁴

National Comprehensive Cancer Network

- www.nccn.org
- Alliance of 21 cancer centers
- 44 panels, 900 people
- Guidelines are both evidence and consensus-based
- Regularly updated
- Requires registration to access

NCCN Categories of Evidence and Consensus

Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate

Category 2a: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate

Category 2b: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate

Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

NCCN Guidelines

Cancers			Screening	Supportive Care
AML	Hepatobiliary	Occult primary	Breast	Pain
Anal	Hodgkin's	Ovarian	Cervical	Antiemetics
Bladder	Kidney	Pancreatic	Colorectal	Anemia
Bone	Melanoma	Prostate	Lung	Fatigue
Breast	Mesothelioma	Small cell lung	Prostate	Distress Mgmt
Cervical	Multiple Myeloma	Soft tissue sarcoma		CSFs
CML	MDS	Testicular		Palliative care
Colorectal	Neuroendocrine	Thymoma		Infections
Esophageal	NHL	Thyroid		VTE
Gastric	Non-melanoma skin	Uterine		
Head/Neck	Non small cell lung			

NCCN Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer Guideline Chart

Due to copyright, we may not post chart on website. Please go to NCCN.org for copy of chart.

Reproduced with permission from the NCCN clinical practice guidelines in oncology (NCCN guidelines®) for ovarian cancer (v.2.2012). © 2012 national comprehensive cancer network, inc. available at: NCCN.org. accessed [month and day, year]. To view the most recent and complete version of the NCCN guidelines®, go on-line to NCCN.org.

European Society for Medical Oncology

- www.esmo.org
- European equivalent of American Cancer Society
- Produces guidelines for multiple cancer types as well as supportive care
- Annual updates planned
- Does not require registration
- Uses traditional level of evidence (I-V) and grade of recommendation (A-D)

ESMO Levels of Evidence⁵

Levels of Evidence

- I. Meta-analyses of randomized controlled trials or randomized trials with high power
- II. Randomized trials with lower power
- III. Nonrandomized trials, such as cohort or case-controlled series
- IV. Nonexperimental studies, such as descriptive and case series
- V. Case reports and clinical examples.

Grades for Recommendation

- A. There is evidence of type I or consistent findings from multiple studies of types II, III, and IV.
- B. There is evidence of types II, III, and IV, and findings are generally consistent.
- C. There is evidence of types II, III, and IV, but findings are inconsistent
- D. There is little or no systematic empirical evidence

Case of EK (continued)

- You have verified the appropriateness of the IP chemotherapy for EK and are preparing to process the orders for the IP cisplatin. The antiemetic regimen is one you are not familiar with:
 - Dexamethasone 12mg IV today, 8mg days 2-3
 - Palonosetron 0.25mg IV x 1
 - Fosaprepitant 150mg IV x 1

Where should you look for guidelines to help verify the appropriateness of the antiemetic regimen?

1. American Society of Clinical Oncology (ASCO)
2. Gynecology Oncology Group (GOG)
3. National Comprehensive Cancer Network (NCCN)
4. Oncology Nursing Society (ONS)

Supportive Care Guidelines

- Available from more sources than treatment based guidelines
- Require less frequent updates
- Sources:
 - NCCN
 - ESMO
 - ASCO
 - MASCC

American Society of Clinical Oncology⁶

- www.asco.org
- Produces multiple guidelines
- Limited in areas of treatment selection
- Narrative based description of evidence⁷
- Supportive care guidelines:
 - Antimetotics
 - ESAs
 - Chemoprotectants
 - CSFs

Multinational Association of Supportive Care in Cancer

- www.mascc.org⁸
- Only source for guidelines on management of mucositis
- Joint guidelines with ESMO for CINV

When We Can't Find Guidelines

- Meta-analyses
- Cochrane Reviews⁹
- Primary literature
- clinicaltrials.gov¹⁰

Oncology Guidelines Summary

Source	Website	Comments
NCCN	www.nccn.org	<ul style="list-style-type: none"> • Numerous guidelines in treatment of various malignancies as well as supportive care • Frequently updated
ESMO	www.esmo.org	<ul style="list-style-type: none"> • European guidelines for treatment of various malignancies as well as supportive care
ASCO	www.asco.org	<ul style="list-style-type: none"> • Some supportive care topics
MASCC	www.mascc.org	<ul style="list-style-type: none"> • Supportive care focus
ACS ¹¹	www.cancer.org	<ul style="list-style-type: none"> • Early detection/screening • Nutrition and physical activity for prevention

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Self-assessment Questions:

1. Which of the following websites provides guidelines for the treatment of newly diagnosed stage IIIa breast cancer?
 - a. www.nccn.org
 - b. www.asco.org
 - c. www.cancer.org
 - d. www.ons.org

2. Which of the following websites provides direct information (including methods and results) about ongoing and completed clinical trials?
 - a. www.nccn.org
 - b. www.clinicaltrials.gov
 - c. www.guidelines.gov
 - d. www.esmo.org