Oncology Medication Safety

NYSCHP Annual Assembly
Turning Stone Resort, Verona, NY
May 4, 2013

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Disclosures

➢ Speakers’ bureaus for Merck and Pfizer
Pharmacist Objectives

- Pharmacist Learning Objectives:
- Define a medication error
- Identify potential sources of medication errors in oncology pharmacy practice
- Describe an approach to prevent medication errors in oncology pharmacy settings
- Describe an approach to manage medication errors in oncology pharmacy practice

Pharmacy Technician Objectives

- Differentiate between what is and what is not a medication error
- Describe an approach to prevent medication errors during chemotherapy admixture
- Identify resources that are useful to assist in chemotherapy medication error prevention
“2 Tragedies”: Death of a little girl, and criminalization of medication errors

- The Emily Jerry Story

- [http://www.youtube.com/watch?v=Ujc1iIDn6mk](http://www.youtube.com/watch?v=Ujc1iIDn6mk)
  - Chris Jerry, Emily’s father: 27:40 – 28:45
  - Eric Cropp, PharmD: 35:49 – 40:40

Lessons learned from Emily Jerry

- Technician training/certification
- The perfect storm (a typical day?)
  - Broken printer
  - Chemo is “high alert” and checked – but the solution is in the background
  - Phone calls
  - “stat” chemo
  - Short-staffed
  - Technician planning her wedding
- “just culture”
Heme/Onc Med Errors in the News……

The New York Times

VICTIM OF SPINAL INJECTION DIES
AP
Published: May 25, 1985
A 21-year-old woman, paralyzed and comatose after a doctor mistakenly injected an anticancer drug into her spinal column, died today, officials at a hospital here said. Elmer Streeter, a spokesman for Albany Medical Center Hospital, said the woman, Lillian Cedeno of Schenectady, had died at 6:14 P.M. On Feb. 27 Miss Cedeno, who was then five and a half months pregnant, was given a spinal injection of vincristine, a medication intended for intravenous use.
In March 1989, Michael Sosnoskie of Middletown, Dauphin County, a 3-year-old Down syndrome child with leukemia and heart problems, died at Hershey Medical Center after a mix-up of two cancer-fighting drugs. One drug, vincristine sulfate, is administered by intravenous injection. The other, methotrexate, is injected directly into the spinal fluid. The two similar syringes were on the operating room tray and the doctor mistakenly injected the vincristine into Michael's spine.

In 1991, a mix-up killed Brandon Quintero, 5, when he was given vincristine intravenously, but at the higher vinblastine dose. Quintero was being treated at Duke University in Chapel Hill, N.C., for a tumor on his arm.
Big Doses of Chemotherapy Drug Killed Patient, Hurt 2d
By LAWRENCE K. ALTMAN
Published: March 24, 1995

- The patient who died, Betsy A. Lehman, was an award-winning health columnist for The Boston Globe. The other patient was a 52-year-old woman who is seriously and chronically debilitated from irreversible heart damage, Dana-Farber.
- The overdoses occurred two days apart.
- For Ms. Lehman, the correct dosage of cyclophosphamide would have been 1,630 milligrams each day for four consecutive days. Instead she received 6,520 milligrams a day for four days, four times the intended dose. The other woman received a similarly miscalculated dosage.

What is an “error”?
NCCMERP: Definition of Med Error

“Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care provider, patient, or consumer.”

NCCMERP: National Coordinating Council on Medication Error reporting and Prevention

NCCMERP examples

Such events may be related to professional practice, health care products, procedures, and systems, including:

- Prescribing
- Order communication
- Product labeling, packaging, and nomenclature
- Compounding
- Dispensing
- Distribution
- Administration
- Education
- Monitoring
- use
How common are heme/onc med errors?

Preventable ADEs by Drug Class

Drug Classes Associated with All Reported Medication Errors

Preventable ADE’s Requiring Admission


### Rates of Errors

<table>
<thead>
<tr>
<th>Errors</th>
<th>Adults</th>
<th>Pediatrics</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total #</td>
<td>90</td>
<td>22</td>
<td>112</td>
</tr>
<tr>
<td>Per 100 visits (95% CI)</td>
<td>7.1</td>
<td>18.8</td>
<td>8.1</td>
</tr>
<tr>
<td></td>
<td>(5.7-8.6)</td>
<td>(12.5-26.9)</td>
<td>(6.8-9.7)</td>
</tr>
<tr>
<td>Per 1000 med orders (95% CI)</td>
<td>8.2</td>
<td>24.1</td>
<td>9.4</td>
</tr>
<tr>
<td></td>
<td>(6.5-9.9)</td>
<td>(14.2-34.1)</td>
<td>(7.7-11.1)</td>
</tr>
</tbody>
</table>


### Errors and Harm

<table>
<thead>
<tr>
<th>Errors</th>
<th>Adults</th>
<th>Pediatrics</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>POTENTIAL Harm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total #</td>
<td>55</td>
<td>9</td>
<td>64</td>
</tr>
<tr>
<td>Per 100 visits</td>
<td>4.4</td>
<td>7.7</td>
<td>4.7</td>
</tr>
<tr>
<td>Per 1000 orders</td>
<td>5.0</td>
<td>9.9</td>
<td>5.4</td>
</tr>
<tr>
<td>ACTUAL Harm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total #</td>
<td>11</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>Per 100 visits</td>
<td>0.9</td>
<td>3.4</td>
<td>1.1</td>
</tr>
<tr>
<td>Per 1000 orders</td>
<td>1.0</td>
<td>4.3</td>
<td>1.3</td>
</tr>
</tbody>
</table>

## Errors and Harm

<table>
<thead>
<tr>
<th></th>
<th>Adults</th>
<th>Pamidronate, 5FU, cyclophosphamide most commonly associated with medication errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orders Reviewed</td>
<td>8008</td>
<td></td>
</tr>
<tr>
<td># Chemo orders</td>
<td>2454 (31%)</td>
<td></td>
</tr>
<tr>
<td># Med Errors (total)</td>
<td>249 (3%)</td>
<td></td>
</tr>
<tr>
<td># Med Errors (Chemo only)</td>
<td>92 (4% of chemo)</td>
<td></td>
</tr>
<tr>
<td>Potential ADEs with chemo</td>
<td>80 (3%)</td>
<td></td>
</tr>
</tbody>
</table>


## Oral Chemotherapy

Weingart SN et al. Cancer 2010; 116:2455-1464
Which class of drugs are most commonly associated with medication errors?

1. Chemotherapy
2. Cardiovascular agents
3. Pain medications
4. Antidiabetic agents

Why do heme/onc med errors occur?
The New York Times

VICTIM OF SPINAL INJECTION DIES
AP
Published: May 25, 1985

➢ The first inquiry criticized the hospital for poor supervision and ineffective control of toxic or dangerous drugs.

➢ The second inquiry determined that the doctors involved would not be charged with medical misconduct.

May 21, 1997
Hazard Warning
The latest edition of the widely used text, Cancer: Principles and Practice of Oncology, lists a chemotherapy regimen in a manner that could lead to a fatal overdose. In the EPOCH regimen in table 44.6-12 on page 2272, doses are listed as:

- etoposide 200mg/m² IV infusion days 1 to 4
- vincristine 1.6mg/m² IV infusion days 1 to 4
- doxorubicin 40mg/m² IV infusion days 1 to 4

Cyclophosphamide and prednisone are also included in the regimen.

This method of dose expression is ambiguous. The doses for etoposide, vincristine, and doxorubicin are course doses which are supposed to be given as a continuous IV infusion over a four-day period. Similarly expressed doses have led to errors in which the entire course dose was administered daily for 4 days. This type of error has happened many times, including the well known incident in Boston 1995.

Instead, the regimen for etoposide, vincristine and doxorubicin should state:

- etoposide 50mg/m²/day IV infusion days 1 to 4
- vincristine 0.4mg/m²/day IV infusion days 1 to 4
- doxorubicin 10mg/m²/day IV infusion days 1 to 4

ISMP. Accessed from http://www.ismp.org/Newsletters/acute-care/articles/19970521_2.asp on 2/16/09
MIME AND MINE:
SAFETY PROBLEMSPOSED BY INVESTIGATIONAL DRUG NAME ABBREVIATIONS AND ACRONYMS

From the December 3, 1997 issue

PROBLEM: Abbreviations and acronyms are commonly used to describe chemotherapy regimens and specific investigational drugs, but this practice often leads to confusion. Because of similar names of drugs used in various regimens, acronyms are often nearly identical and, therefore, easily confused. In addition, some abbreviations used for investigational drugs are similar to those used for established drugs, which also causes confusion.

Available from www.ismp.org accessed 2/16/09

Where the Errors Occur

Where the Errors Occur: Oral Chemo

Weingart SN et al. Cancer 2010; 116:2455-1464

Look Alike/Sound Alike
ISMP Alert! Acute Care Edition

<table>
<thead>
<tr>
<th>Drug 1</th>
<th>Drug 2</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alerkan</td>
<td>Leukeran</td>
<td>vol 5(1); 1/12/00</td>
</tr>
<tr>
<td>Carboplatin</td>
<td>Cisplatin</td>
<td>Vol 1 (22); 11/6/96</td>
</tr>
<tr>
<td>Daunorubicin</td>
<td>Idarubicin</td>
<td>Vol 6 (22); 10/31/01</td>
</tr>
<tr>
<td>Daunorubicin</td>
<td>Liposomal</td>
<td>Special alert</td>
</tr>
<tr>
<td></td>
<td>daunorubicin</td>
<td>8/18/98</td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>Liposomal</td>
<td>Vol 9 (14); 7/15/04</td>
</tr>
<tr>
<td></td>
<td>doxorubicin</td>
<td></td>
</tr>
<tr>
<td>Folinic acid</td>
<td>Folic acid</td>
<td>Vol 8 (20); 10/2/03</td>
</tr>
</tbody>
</table>

### Look Alike/Sound Alike

ISMP Alert! Acute Care Edition

<table>
<thead>
<tr>
<th>Drug 1</th>
<th>Drug 2</th>
<th>Volume</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infliximab</td>
<td>Rituximab</td>
<td>Vol 9</td>
<td>2/12/04</td>
</tr>
<tr>
<td>Leucovorin</td>
<td>Leukeran</td>
<td>Vol 8</td>
<td>10/2/03</td>
</tr>
<tr>
<td>Leukeran</td>
<td>Myleran</td>
<td>Vol 5</td>
<td>1/12/00</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>Nab-paclitaxel</td>
<td>Vol 10</td>
<td>3/10/05</td>
</tr>
<tr>
<td>Platinol</td>
<td>Patanol</td>
<td>Vol 2</td>
<td>1/15/97</td>
</tr>
<tr>
<td>Propylthiouracil</td>
<td>Purinethol</td>
<td>Vol 8</td>
<td>8/21/03</td>
</tr>
</tbody>
</table>


### Look Alike/Sound Alike

ISMP Alert! Acute Care Edition

<table>
<thead>
<tr>
<th>Drug 1</th>
<th>Drug 2</th>
<th>Volume</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taxol</td>
<td>Taxotere</td>
<td>Vol 6</td>
<td>2/7/01</td>
</tr>
<tr>
<td>Taxol</td>
<td>Paxil</td>
<td>Vol 2</td>
<td>1/15/97</td>
</tr>
<tr>
<td>Vinblastine</td>
<td>Vincristine</td>
<td>Vol 5</td>
<td>5/17/00</td>
</tr>
<tr>
<td>Xeloda</td>
<td>Xenical</td>
<td>Vol 4</td>
<td>9/8/99</td>
</tr>
</tbody>
</table>

Which of the following is a reason why medication errors occur with chemotherapy?

1. “Unjust” culture
2. Lack of PGY2 oncology residency
3. Abbreviations / acronyms
4. USP-797 restrictions

What can we do to prevent heme/onc med errors?
The public outcry after the death of Lillian Cedeno and her child in 1985 helped push New York lawmakers to adopt a stringent mandatory reporting law for hospital patient mishaps.

By contrast, following the death of Michael Sosnoskie in 1989, Pennsylvania officials limited their inquiry to the doctor's actions. No negligence was found and she returned to practice. And that's where it ended.

Under Pennsylvania law, hospitals must report to the state only in cases of an "interruption in service," such as a fire or labor strike.

http://www.meyersmedmal.com/article-hospital-mistakes.html accessed 2/16/09

In North Carolina, Quintero's death in 1991 and three earlier deaths prompted the North Carolina Board of Pharmacy to adopt mandatory reporting for fatal medication errors caused by pharmacists.

http://www.meyersmedmal.com/article-hospital-mistakes.html accessed 2/16/09
Recommendations from Gandhi et al.

<table>
<thead>
<tr>
<th>Intervention</th>
<th># ADE’s averted (n=203)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPOE</td>
<td>158 (78%)</td>
</tr>
<tr>
<td>Standardized templates</td>
<td>54 (27%)</td>
</tr>
<tr>
<td>Drug dose check</td>
<td>25 (12%)</td>
</tr>
<tr>
<td>Guided dose algorithms</td>
<td>29 (14%)</td>
</tr>
<tr>
<td>Remove free text fields in order entry</td>
<td>21 (10%)</td>
</tr>
<tr>
<td>Drug-drug interaction check</td>
<td>11 (5%)</td>
</tr>
<tr>
<td>Drug-patient characteristic check</td>
<td>8 (4%)</td>
</tr>
<tr>
<td>Non-computer methods</td>
<td>41 (20%)</td>
</tr>
</tbody>
</table>


Recommendations from Walsh, et al.

ASHP Guidelines

- Education, competency, and credentialing
- Communication and access to information
- Schedule coordination
- Standardize medication ordering
- Computerized prescriber order entry (CPOE)
- No oral orders except to d/c
- No stat orders for chemo
- Standardize dose calculations
- Standardize medication orders
- Establish dosage limits and acceptable routes of administration
- Investigational drug service support
- Multidisciplinary medication order verification


Education

- Names of cancer drugs
- FDA-approved indications vs. investigational protocol
- Routes of administration
- Administration schedules
- Appropriate dosages and max dose limits
- Appropriate handling
- Potential adverse effects
- Potential drug interactions

Technician Ratios & Volume

<table>
<thead>
<tr>
<th>State</th>
<th># Of Retail Rx Filled</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>393,885,063</td>
<td>1:1 or 2:1</td>
</tr>
<tr>
<td>New York</td>
<td>253,796,344</td>
<td>2:1</td>
</tr>
<tr>
<td>Florida</td>
<td>235,306,094</td>
<td>3:1</td>
</tr>
<tr>
<td>Texas</td>
<td>234,485,214</td>
<td>2:1</td>
</tr>
<tr>
<td>Indiana</td>
<td>72,975,200</td>
<td>6:1</td>
</tr>
<tr>
<td>Idaho</td>
<td>19,437,116</td>
<td>6:1</td>
</tr>
</tbody>
</table>

Communication: Elements of medication profiles

- Patient name and unique identifier
- Brief medical hx with cancer dx
- Known drug allergies/intolerances
- Vital stats (ht, wt, BSA, BMI, sex, labs)
- Details of drug regimen and how compounded, lots/exp dates
- Diluents
- Primary reference for treatment regimen
- Treatment cycle and course # w/ dates of administration, how tolerated, cumulative amount of drug if applicable (e.g., doxorubicin)
Checkpoints in the System

- Prescribing
- Preparation
- Dispensing
- Administration


Checkpoints at Prescribing

- Prescriber should write entire order:
  - Chemo, pre-meds, supportive care
- For counter-signed orders (ie PA’s), authorized prescriber should carefully review order

Checkpoints in Preparation

- Compare written order to published standards
  - Original study when possible
  - Investigational drug protocol
- Product verification
  - Calculations, diluents, etc.
  - Independent double-check by someone who did not prepare original worksheet
- Verify product with preparation worksheets against original order
  - Independent double-check by someone who did not prepare original worksheet


Checkpoints in Dispensing

- Verify patient identity if given to an outpatient
- Patients who self-administer drugs should also do a double-check!!
Checkpoints in Administration

- 2 independent verifications of prepared product (label) against prescriber order
- Examine appearance
- Patients who self-administer should check product identity and verify labeled instructions
- Encourage patients to ask questions about their treatment


Which of the following strategies are you most likely to implement to improve chemo med safety?

1. Educate the team about medication safety
2. Implement double-checks
3. Minimize distractions
4. Utilize standard order sets
What are your processes?

- What training do you offer to pharmacists and pharmacy technicians who work in chemotherapy areas?
- Who is credentialed to mix chemotherapy?
- Do you have annual competency evaluations? What do they entail?
- Do you have chemotherapy order templates?
- WHEN will your CPOE go live?

Some Additional Assistance

- Hematology/Oncology Pharmacists Association (HOPA)
  - www.hoparx.org
  - Active list-serve
  - Excellent annual meeting
  - Other educational tools in development
  - HOPAU
- National Comprehensive Cancer Network (NCCN)
  - www.nccn.org
  - Clinical practice guidelines – with regimens!
  - Chemotherapy order templates
Additional Assistance

  
  • Checklists for chemotherapy admixture
  • List of recommended competencies for the multidisciplinary team
  • List of essential elements for order
  • Description of system of double-triple checks for chemotherapy orders
  • Task list which describes Role of the Pharmacist

Additional Assistance

➢ ISMP Guidelines for Standard Order Sets:

➢ ISMP Webinars (each ~$200)
  • Safe Strategies with Oral Chemotherapy - 4/23/2013:
    [https://www.registrationheadquarters.com/events/?80ad4d8a58bd4962a53215431a846843a](https://www.registrationheadquarters.com/events/?80ad4d8a58bd4962a53215431a846843a)
  • Challenges in Oncology Medication Safety – 2/15/2012:
Questions?