

## When good drugs go bad: Patient safety in a chemotherapeutic world

Michael LeBlanc  
Clinical Pharmacy Specialist, Oncology  
Horizon Health Network  
The Moncton Hospital  
Moncton, NB



### Learning Objectives

- Describe the epidemiology of medications errors and chemotherapy errors
- To identify potential causes of chemotherapy errors
- Discuss the strategies that can be implemented in oncology centers to reduce medication errors

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## Importance of Safe Medication Use Systems

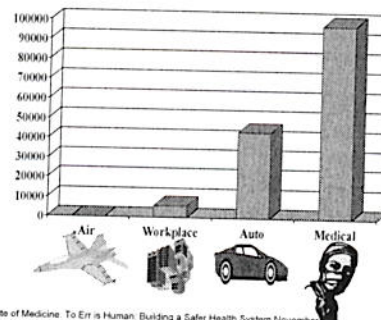
Patient safety is the freedom from accidental injury in health care.

*To err is human. Institute of Medicine; 1999. USA*

- 2.9%-3.7% hospital admissions result in adverse events
- 44-98,000 deaths/year
- \$17-29 billion costs
- 7000 deaths from medication errors



### Annual Accidental Deaths



Institute of Medicine. To Err is Human: Building a Safer Health System. November 1999. Available at <http://www.iom.edu/includes/CEFile.asp?td=4117>

## Patient safety in Canada

- Canadian Adverse Events Study
  - Reviewed charts from 20 hospitals in 5 provinces
- 7.5 adverse events per 100 admissions
- 70,000 preventable adverse events (est.)
- 9,000 - 24,000 preventable AE deaths
  - Comparable to similar health systems

Baker, G.R, Norton, P. G. et al. CMAJ, 170 (11) 2004

## Patient safety in Canada

- “Drug error kills 2 Alberta hospital patients” cbc.ca; March 19, 2004
- “Hospital errors kill thousands in Canada, study estimates” The Globe and Mail; May 24, 2004
- “Alberta officials apologize for fatal chemo overdose” The Globe and Mail; September 1, 2006
- “Wake up call for pharmacists” Montreal Gazette, September 19, 2009
- “Chemo mistakes in N.L. average 20 a year: Eastern Health” cbc.ca; October 18, 2009



## Epidemiology

- Difficult to accurately assess
- Estimated error rates
  - Inpatient medical-surgery 5%<sup>1</sup>
  - Primary care 8%<sup>2</sup>
  - Ambulatory Oncology Clinic 3%<sup>3</sup>
    - Chemotherapy only 4%<sup>0</sup>

1. Bates DW, et al. *J Gen Intern Med*. 1995;10:199-205.  
 2. Gandhi TK, et al. *J Gen Intern Med*. 2005;20:837-841.  
 3. Gandhi TK, et al. *Cancer* 2005; 104 (11): 2477-2483.

## Chemotherapy - A Perfect Storm

- Complexity of:
  - Patient
  - Disease
  - Treatment
- Narrow therapeutic index
  - Toxic at therapeutic dose
- Acuity of illness and toxicities
- Wide range of doses (e.g. methotrexate can be 10 mg or 10 g)
- Dosing based on BSA or AUC



## Chemotherapy Errors

**Table 1: Oncology Drug Product Errors by Type and Percentage<sup>a</sup>**

Type of Error	# Records	Percent (%)
Incorrect dosing/quantity	654	25
Prescribing error	721	29.4
Wrong time	666	28.5
Unsterilized drug	284	12.5
Wrong drug preparation	201	7.5
Extra dose	166	5.5
Wrong administration technique	163	4.8
Wrong patient	160	4.8
Wrong route	70	1.9
Wrong dosage form	41	1.2
Expired product	7	0.2
Dated/expired product	5	0.14

<sup>a</sup> Based on 3,594 records that exhibited at least one type of error.  
 Source: CANSULET Electronic Newsletter, April 2004 issue. USPC, Inc. Participation granted.

## Chemotherapy Errors

**Table 2: Common Chemotherapy Agents Associated in Errors**

Chemotherapy Agent	# Records	Percentage (%)
Cyclophosphamide	41	1.1
Doxorubicin	41	1.1
Etoposide	39	1.1
Fluorouracil	37	1.0
Hydrocortisone	37	1.0
Leucovorin	37	1.0
Methotrexate	37	1.0
Paclitaxel	37	1.0
Trastuzumab	37	1.0
Vincristine	37	1.0
Vinorelbine	37	1.0
Docetaxel	37	1.0
Fluorouracil	37	1.0
Methotrexate	37	1.0
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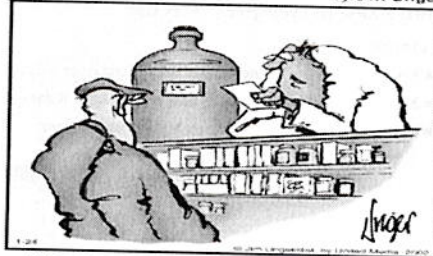
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## Causes of Chemotherapy Errors

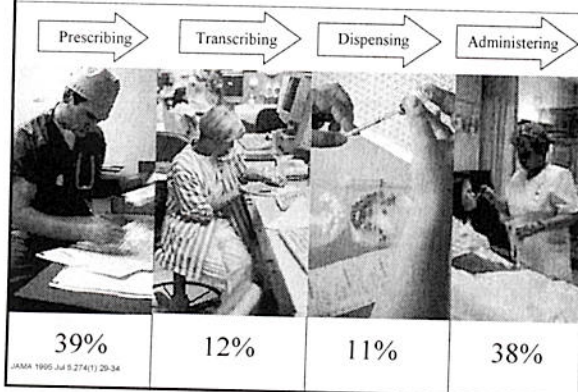
HERMAN<sup>®</sup>

by Jim Unger



"That's what it says: 'one tablespoonful, 300 times a day'."

## Failure points where medication errors occur



## Causes of Chemotherapy Errors

- Point of Prescribing
  - Poorly communicated verbal orders
  - Lack of complete pertinent patient specific healthcare information (e.g. home medications including OTC/herbal)
  - Excessive interruptions during order processing or dose preparation

## Causes of Chemotherapy Errors

- Erroneous drug doses in journal articles
  - Example
  - Journal article indicated the dose of vincristine at 1.4 mg/m<sup>2</sup> d1-8 instead of day 1 AND 8. Accidental overdose occurred.

## Causes of Chemotherapy Errors

- Failure to round doses to the nearest whole integer
- Use of trailing 0 (i.e. 1.0 mg) or lack of leading 0 (i.e. .5 mg)



## Causes of Chemotherapy Errors

- Transcription/Interpretation
  - Total course or cycle given every day
  - Example
    - Visiting physician wrote "Idarubicin 60 mg over 4 days"
    - Misinterpreted as 60 mg daily and given daily x 4 days
    - Pt died 1 month later following complications from diarrhea, vomiting, and severe neutropenia



## Causes of Chemotherapy Errors

- Order transcription
  - Similar sounding drug names within the therapeutic class
  - Example
    - 260 mg Docetaxel (Taxotere) administered instead of 260 mg paclitaxel (Taxol)
    - Patient dies 5 days later

## Causes of Chemotherapy Errors

- Drug preparation/dispensing - inpatient
  - Use of drug name abbreviations
  - Poor packaging and labeling by manufacturers
  - Lack of a proper physician order form
  - Use of trade names instead of generic names
  - Substantial distance between the pharmacy and the patient treatment area



## Causes of Chemotherapy Errors

- Drug preparation/dispensing - outpatient
  - Inconsistent safety practices
    - Handwritten
    - No BSA, diagnosis, dose/m<sup>2</sup>
    - Diagnosis
    - Independent double check
  - Frequently dispensed by community pharmacists
    - Experience
    - Confidence
    - Awareness
  - Follow up and monitoring
  - Adherence
    - capecitabine, temozolomide



## Causes of Chemotherapy Errors

- Point of preparation
  - Product prepared with aseptic technique
    - Potential for infection
  - Often prepared by pharmacy technicians who are sometimes not certified/regulated
  - Error magnified in pediatric population



- Point of administration

### Teenager dies after drug error



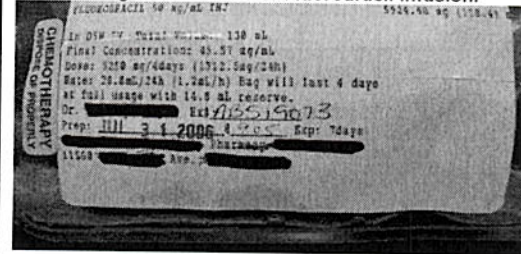
## Causes of Chemotherapy Errors - 31 Incidence of Intrathecal Vincristine

Year	Patient details	Country	Year	Patient details	Country
2003	Child - 2 year old	USA	1991	Female - 16 year old	England
2003	Male - 0 year old	USA	1990	Male - 16 year old	England
2002	Female - 12 year old	Spain	1989	Adult	USA
2001	Female - 3 year old	Germany	1989	Male	Israel
2001	Male - 57 year old	Germany	1988	Female - 9 year old	England
2001	Male - 18 year old	England	1988	Male - 36 year old	England
1999	Male - 12 year old	England	1987	Female - 17 year old	Australia
1999	Male - adult	England	1987	Female - 10 year old	England
1999	Female - 7 year old	Saudi Arabia	1984	Female - 2 year old	Ireland
1999	Male - 3 year old	South Korea	1983	Male - 16 year old	USA
1998	Female - 7 year old	Canada	1983	Female - 23 months old	USA
1998	Child	USA	1982	Female - 8 1/2 year old	Israel
1992	Child	Saudi Arabia	1980	Female - 29 year old	USA
1991	Male - 23 year old	USA	1978	Female - 5 1/2 year old	USA
1990	Female - 56 year old	England	1968	Female - 2 1/2 years	USA

## Causes of Chemotherapy Errors

### Point of Administration

Figure 1. Label for Fluorouracil infusion.



## Event Summary

- Denise Melanson of Rainbow Lake, Alberta
  - Teacher's assistant and mother of two teenage sons
  - Cross Cancer Institute in Edmonton
  - Advanced but treatable cancer of the nasal passage (nasopharyngeal carcinoma).
- On July 3, 2006,
  - received an infusion of fluorouracil over 4 hours rather than over 4 days.
  - admitted to hospital 4 days later with profound mucositis and pancytopenia
  - hemodynamic collapse and multi-organ failure before her death.



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## Strategies to prevent chemotherapy errors



## Prevention Strategies - Prescribing

- Initial chemotherapy must be written by a qualified physician
- Don't allow verbal orders for chemotherapy
- Use pre-printed order templates (forms)
- Use computerized prescriber order entry
- Cite a literature reference for all chemotherapy protocols when ordered
  - can be built into pre-printed forms or CPOE

### Prevention Strategies - Prescribing

- Use TALLman lettering for drug names that look alike or sound alike
- No abbreviations are allowed
- ISMP rules for decimals and zeros (10mg vs. 10.0 mg, and 0.10mg vs. 0.1 mg)
- Use generic names for all drugs, vs. brand name or abbreviations
- If investigational drug, verify that an informed consent was signed

### Prevention Strategies – Dose description

- Require chemotherapy doses written as mg/kg or mg/M2 or AUC (e.g. 400 mg/M2)
- Require a final calculated total dose to be written by the prescriber (example for a 1.67M2 patient: 30 mg/M2 (50mg total dose))
- Prohibit writing total patient chemotherapy dose for entire course (e.g., 1600 mg/M2 over 4 days)
- Require the number of days or doses to be specified (e.g., 4 days)
- Require the interval between doses (e.g., Q 24 h)
- Require the infusion rate to be defined (e.g., infuse over 4 h)
- Round chemotherapy doses to closest whole number (e.g., 30.2mg rounded to 30 mg)

### Prevention Strategies - Dosing

- Require patient dosing weight to be indicated (e.g., actual, lean, calculated)
- Independent calculation of all chemotherapy doses, by two practitioners
- Validate BSA calculation
- Verify ordered dose is within normal limits for the protocol in which it is used
- Screen for height and weight changes since last course of therapy
- Verify previous dose adjustments are still appropriate for the patient
- Track and monitor total lifetime dose for anthracycline drugs
- Screen for current lab results before each dose of chemotherapy
- Screen to verify correct course (or cycle) of therapy
- Screen for appropriate time interval between courses of therapy

### Prevention Strategies - Administration

- Nurses double check patient identification
- Nurses double check infusion rate
- Nurses double check and verify correct infusion site
- Verify that premedication orders, including hydration are complete before administration of chemotherapy
- Conduct a 'Time Out' to verify the patient, drug, dose, route, and rate are correct prior to proceeding

### Prevention Strategies – Dispensing and preparation

- Label all chemotherapy with a label that identifies it as 'Chemotherapy'
- Verify that written orders, computer order entry, and printed label all match, based on the written order
- Validate that the drug volume, infusion volume, and infusion rate on label are correct
- Label all vincristine as "For IV use only – FATAL if given by other routes"

### Other Strategies

- Medication Huddles
- Independent Double Check
- Computer Provider Order Entry
- Medication Reconciliation
- Seamless Care
- Toxicity monitoring

## Independent Double Check

- Independent double checks should be done on error prone processes such as the use of high alert medications.  
[http://www.ismp.org/Pages/ismpp\\_faqs.html](http://www.ismp.org/Pages/ismpp_faqs.html)
- Independent double checks serve two purposes:
  - (i) detect a serious error before it reaches a patient
  - (ii) to bring attention to the systems that allow the introduction of human error

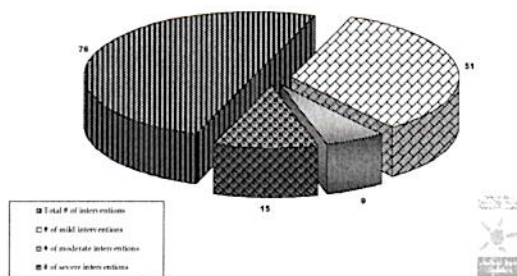
## Evidence that Independent Double Check increases safety

- Research shows that people find about 95% of all mistakes when checking the work of others
- Human factors suggest that double checks are more effective if they are performed independently
- Double checks should only be applied strategically to situations that most warrant their use – prescribing, dispensing, and administering select high alert medications.

<http://www.ismp.org/isa/articles/time.htm>

## Independent Double Check Stats from DHBMCC

Independent Double Check Interventions of Chemotherapy Letters by Clinical Pharmacist  
from Sept 2004 to Sept 2005



## Medication Huddles (Safety Briefings)

- Assembly of front line staff for a debriefing on medication safety
- Originated from Institute for Healthcare Improvement's Idealized Design of the Medication System (IDMS) team.
- The team developed Safety Briefings to increase safety awareness among frontline staff and to help develop a culture of safety.
- Used in aviation and other industries, safety briefings incorporate discussions of safety into the daily routine.

<http://www.ihc.org/NR rdonlyres/971CB2E8-4E23-448D-92BD-D680B4F62FA3/1044/SafetyBriefings.pdf>

## Critical Elements to ensure success of Medication Huddles

- Nonpunitive
- Brief
- Easy to use
- Identify in advance a list of safety concerns for discussion

<http://www.ihc.org/NR rdonlyres/971CB2E8-4E23-448D-92BD-D680B4F62FA3/1044/SafetyBriefings.pdf>

## Medication Huddles sample

Start Time \_\_\_\_\_ End Time \_\_\_\_\_

Ask the following questions and record answers:

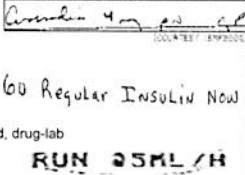
- 1) How many people encountered a safety issue related to medications today?  
\_\_\_\_\_ (based on show of hands) TIP: *Give me and discuss the issue*
- 2) How many people had an "almost" or "near miss" with a medication today?  
\_\_\_\_\_ (based on show of hands) — REINFORCE POSITIVE
- 3) How many people had patients who asked questions or made comments about medications today?  
\_\_\_\_\_ (based on show of hands)  
For those who raised a hand, how many were "near misses" that the patient's question or comment prevented?  
\_\_\_\_\_ (based on show of hands) — REINFORCE POSITIVE
- 4) What safety issues have people seen that should have prompted action? What process changes should be made to improve patient safety?  
\_\_\_\_\_

<http://www.ihc.org/NR rdonlyres/971CB2E8-4E23-448D-92BD-D680B4F62FA3/1044/SafetyBriefings.pdf>

### DHBMCC Medication Huddle Examples

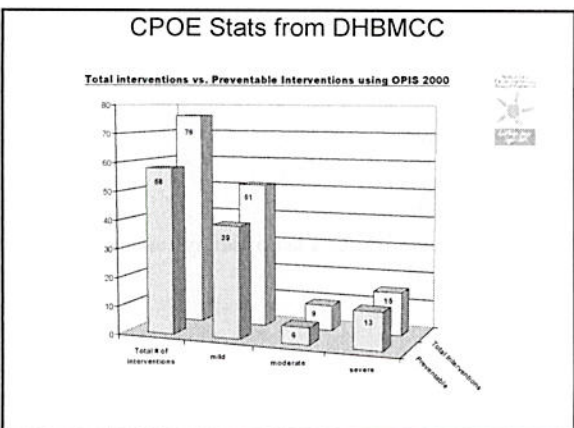
Category	Issue	Outcome
Organizational Policy	Abbreviations being used when writing chemotherapy orders. (Ex. CPT-11)	Updated chemotherapy ordering policy with chemotherapy ordering "Do's and Don'ts"
Front Line Tools	Discontinuities between physician ordering with CPOE's and nursing interpretation of these orders.	Pharmacy meeting to update physicians on how to implement chemotherapy ordering strategies to circumvent these problem.
Education of Providers	Patient received 65/mg Xeloda when the Rx was written as 165/mg.	Pharmacy department in coordination with provincial pharmacy association organizing continuing oncology education for community pharmacists and rural nurses.

- ### Computer Provider Order Entry (CPOE)
- Ordering of tests, medications, and treatments for patient care using computers
  - Institute of Medicine
    - "Technology is an essential part of the answer"

- ### Potential benefits of a CPOE
- **Quality Improvements**  
Eliminate lost orders and errors resulting from illegible handwriting
  - **Process Improvements**  
Protocol management  
Order Sets
  - **Error Reduction**  
Eliminates dosing errors  
Interactions check; drug-drug, drug-food, drug-lab  
Improved legibility
  - **Cost Reductions**  
Eliminates duplicate orders  
Decreases time to verify orders
- 

- ### Evidence that CPOE Systems increase safety
- Reduction in medication errors
    - Bates et al. (1998) - 55 percent reduction in serious medication errors
    - Preventable adverse drug events decreased 17%
    - Potential ADE's estimated to decrease 84%
- Bates DW. Effect of CPOE on Prevention of Serious Medication Errors. JAMA 1998; 280: 1311-16

- ### CPOE is not yet the panacea
- JAMA Study: Computer Order Entry Systems Can Increase Medication Errors
  - CPOE system facilitated 22 types of medication errors
  - Problem patterns emerged from two sources,
    - (i) information errors caused by the fragmentation of key clinical data and by the failure to integrate the hospital's various computer and information systems.
    - (ii) human-machine interface flaws that occurred because the CPOE system did not correspond with clinicians' usual work behaviour or work organization, according to the study
- Keppel, Mofay, et al. JAMA. 2002;287:1197-1203





## Seamless Care

- Randomized Controlled Trial
- Recruiting 200 medical oncology patients
  - Completed follow up July 2007
  - Data being analysed
- Two phases
  - Seamless Care Report
  - Toxicity Assessment and Follow-up
- Outcomes being analyzed
  - Economic
  - Humanistic
  - Clinical

## Seamless Care

- Strategies implemented following Seamless Care trial
  - Toxicity Assessments post every cycle:
    - all adjuvant breast cancer patients
    - high risk oral chemotherapy patients
  - Medication Reconciliation

## Summary

- Chemotherapy patients are at very high risk of errors and negative outcomes
- Some strategies have been proven to reduce this risk, but work still needs to be done
- Need to optimize use of technology and human resources

## Thank you



michael.leblanc@horizonmb.ca  
506-857-5342

