**Setting-up:**
**Focus on medication safety**

**Sharon Ngim, Pharmacist**

National Cancer Centre Singapore
SingHealth



## Objectives

- Review reported chemotherapy errors and their causes
- Describe strategies to prevent chemotherapy errors
- Discuss the practitioner's role in managing care of oncology patients

## Medication Errors

- Multidisciplinary and multifactorial
- Result of failure of complex interacting clinical systems
- Occur from lack of knowledge, mental lapses, or failures in systems
- Lessons lie in analysis of how systems failed, where there was no overlap, and future prevention

## Causes of Medication Errors

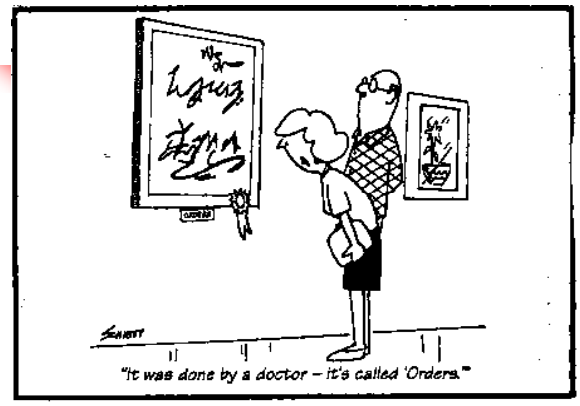
- Order writing/communication issues
- Dose miscalculations
- Drug and drug device related issues
- Incorrect drug administration
- Lack of patient education
- Poor drug distribution
  - Adapted from Cohen, Michael "Medication Errors"

## Daily Work

- Highly complex processes
- Work force issues
- Unpredictable workload and acuity
- Teams not tightly aligned
- Competing priorities

## Chemotherapy Agents

- Well studied and highly beneficial
- Narrow therapeutic window
- Adverse reactions such as myelosuppression expected
- Regimens are complex using multiple drugs in varied doses and schedules




## Potential Causes of Chemotherapy Errors

- Ordering/Prescribing
  - Use of abbreviations and acronyms
  - Name similarities
  - Total course dose confused with daily dose
  - Verbal orders
  - Trailing zero; no leading zero
  - Access to laboratory values and patient demographics

## Name Similarities

- Adriamycin
- Carboplatin (CBDCA)
- Cyclophosphamide (CTX)
- Interleukin (IL2)
- Taxol
- Vinblastine
- Nilotinib
- Aredia
- Cisplatin (Platinum)
- Ifosphamide
- Interferon
- Taxotere
- Vincristine
- Erlotinib

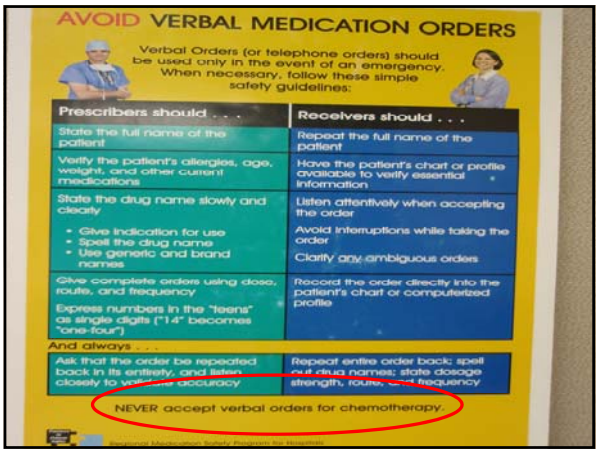
## Dose Confusion

- Daily doses often confused with course doses
- Cyclophosphamide course dose given daily
- fluorouracil over 4 hours that was intended to be administered over 4 days

August 22nd, 2006,
43 year old woman had multi-organ failure and died after a medication incident.
The cause of death as determined by the coroner was "sequelae of fluorouracil toxicity
She had inadvertently received an infusion of fluorouracil over 4 hours that was intended to be administered over 4 days for advanced nasopharyngeal carcinoma, according to a standard protocol that included high-dose fluorouracil and cisplatin in the ambulatory setting.

## Verbal Orders

- Verbal orders should not be allowed for chemotherapy




## Drug Ordering/Prescribing

- Leading zero; no trailing zero
- No verbal orders
- Attending co-signature requirement
- Disease, stage, prior chemotherapy, concomitant drug history, treatment history, lab values and patient demographics should be easily accessible

## Literature References in Error

- Article read: vincristine 1.4mg/m2 days 1-5
  - Should have read: vincristine 1.4mg/m2 day 1 only
- Abstract read: cisplatin 75mg/m$^2$ & 5FU 1000 mg/m$^2$/day on day 1 to 4
  - Article read: cisplatin day 1 and 5FU 96 hours
- If unfamiliar with a regimen, review more than one citation and confirm doses make sense

## Chemotherapy Errors

- Preparation
  - Packaging and labeling
  - Formulation confusion
  - Inadequate patient information
  - Excessive interruptions
- Drug Storage

## Drug Packaging and Labeling

- Many products are incredibly similar
- Brand name often larger than generic name
- Several deaths attributed to product mix ups or overdoses because wrong vial size used
- Concentration thought to be vial size

## Label Confusion

- Navelbine 5 mL vials labeled as 10 mg/mL
- Vials assumed to contain only 10 mg not 50 mg
- Patients received fivefold overdoses due to label misreading

## Prevention of Packaging/Labeling Mix-ups

- Stock limited doses of same drug
- Separate sound-a-like drugs physically
- Standardize label format – generic name only
- Pharmacy double checks

## Chemotherapy Preparation

- Overfill in drug and diluent vials
  - Taxotere 20 mg vial contains 23.6 mg and 80 mg vial contains 94.4 mg
- Follow exact reconstitution instructions
- Standard reconstitution guidelines, preparation checking process, document amount added to IV bag or syringe, track staff involved in preparation

## Formulation Confusion

- Doxorubicin doses of 60 to 75 mg/m$^2$ every 21 days
- Liposomal doxorubicin 20 mg/m$^2$
- Hospital prepared liposomal product not conventional product

## Inadequate Patient Information

- Lack of height, weight, BSA on order
- Lack of information regarding tumor type being treated
- AUC dosing
- Protocol information

## Drug Storage

- Do not arrange alphabetical by generic name for look- and sound-alike
- Use of bins for product segregation
- Use high-alert/caution stickers indicating chemotherapy
- Designated chemotherapy storage area
- Proper lighting

## Chemotherapy Errors

- Administration
  - Inadequate multidisciplinary communication
  - Incorrect route of administration
  - Patient misidentification
  - Limited education of healthcare professionals and patients

## Incorrect Route of Administration

- Intravenous doses of vincristine or doxorubicin administered intrathecally
- Changes in packaging have been made but errors continue to occur
- Unique processes for intrathecal product preparation, dispensing, administering, labeling and delivery
- Computer system with route restrictions
- Stability data supporting dilution of vincristine in 25 mL to 50 mL

## Patient Education

- Patients should be educated about drug names, doses, routes of administration, schedule, color of medication
- Caregivers should verify patient identity
- Encourage patient questions

## Oral Chemotherapy

## Background

**Although oncologists prescribe oral chemotherapy for an increasing number of indications, little is known about safeguards and common practices for using these medications.**

## Overview

- Oral chemotherapy use increasing
  - Estimated 25 million doses dispensed in 2006
  - More than 25% of 400 anti-neoplastic agents in FDA pipeline are oral agents
- Increased convenience, control, tolerability (in some cases)
- But potential safety risks?
  - C4QI leaders, NCCN task force

## Oral Chemotherapy Risks

- Patients on multiple medications
- Patients self-administration
- Perception that a pill is less harmful than IV
- Prescriptions written by provider (various methods) and not reviewed by oncology pharmacist or nurse

## Oral Chemotherapy Risks

- Patient may not return to clinic/office for follow-up monitoring for several weeks
- Prescriptions filled at local pharmacies that do not have chemotherapy expertise or complete patient information
- Oncology and non-oncology uses of these agents
- Safe handling issues in the home

## Oral Chemotherapy Risks

- Monitoring of patients
  - May not be done directly
  - Based on caregiver/patient assessment
- Communication for dose changes
  - Via phone vs. in person based on patients reports
  - Recording of current dose to pharmacy, in medical record

## Oral Chemotherapy Risks

- Shifting sites of care
  - Inpatient admission to oncology unit or non oncology unit
  - Is oral chemotherapy continued?
  - What provider is responsible for order writing and dosing?
  - Where does the medication come from?

## Potential Risks Associated with Oral Chemotherapy

- Literature review (Partridge et al)
  - Safety profiles from research studies
  - Adherence is variable
- Cancer Center Survey (Weingart et al)
  - Describes current state of how these agents are managed
- Pediatric study and other reported errors with these agents

## Oral Chemotherapy Errors

- Disconnect between infusional and oral chemotherapy
- Literature and studies have focused on inpatient or office practice settings
- One recent study of errors associated with oral chemotherapy in children with ALL

## Oral Chemotherapy Errors

- Errors typically in over or under dosing during administration
- No published consensus guidelines on how these agents should be managed

## Oral Chemotherapy Errors-Examples

- Lomustine overdose error
- 6-MP errors in pediatric population
- Cyclophosphamide dosing error
- Capecitabine dosing confusion
- Methotrexate scheduling misinterpretation

## Ways to Improve Safety of Oral Chemotherapy

## Oral Chemotherapy Practices

- Electronic order writing enhancement
- Oncology pharmacist counsels all patients receiving capcitabine; includes a calendar
- Exploring ways to identify and have oncology pharmacist review oral chemotherapy prescriptions

## Oral Chemotherapy Patient and Caregiver Education

- Patients should understand the drug, dose, frequency and indication
- Use of a calendar for complex schedules
- Agent should be stored in a safe place
- When taking the medication, transfer to a medicine cup to avoid contact
- Caregiver to wear gloves during administration
- Wash hands after taking

## Oral Chemotherapy Patient and Caregiver Education

- Unused medication should be returned to pharmacy for disposal
- If medications are dropped on the floor, gather with a paper towel for proper disposal
- Swallow each tablet
- Provide instructions for missed doses, adverse effects etc.

## Optimizing Chemotherapy Safety

- Order templates
  - Establish approval process
  - Include drug, dose, pt demographics, hydration, antiemetics, support care
- List doses as mg/m2 or mg/kg; include daily dose and number of days
- Include BSA, diagnosis, protocol name
- Use generic drug names
- Prescribe doses in mg
- Leading zero; no trailing zero
- List relevant lab values

## Optimizing Chemotherapy Safety

- No verbal orders
- Avoid use of abbreviations
- Established dose ceilings
- Availability of patient information
- Availability of references, research protocols and clinical decision aids
- Process for review of new regimens

## Optimizing Chemotherapy Safety

- Multidisciplinary dose checking
- Double check dose against reference/protocol
- Double check calculations in pharmacy and nursing
- Double check all preparations

## Optimizing Chemotherapy Safety

- Staff education & competency
- Patient education & medication safety involvement
  - Drug name, dose, route, schedule, color of medication
- Don't guess! ASK!
- Take time to understand the protocol
- Process for questioning orders

## Optimizing Chemotherapy Safety

- Distribute ISMP's Medication Safety Alert! newsletter & conduct educational programs on medication error prevention
- Realize errors are everywhere, can and will happen at your institution – creation of a safety culture
- Be supportive of staff involved in errors
- Monitor and publicize errors that are described in literature and JCO sentinel event alerts

## Standing Order Template

- Computerized templates containing protocol/regimen specific medications
- Created by pharmacy
- Verified by multidisciplinary team prior to activation
- Includes protocol name, cycle number, hydration, antiemetics, supportive care meds
- Standard format
  - Generic name, daily dose, route, frequency, administration guidelines
- Reflect any required dose alterations

## Safety Strategies

- Multidisciplinary group to analyze, discuss causes and solutions of near misses and errors
- Education of staff about actual, relevant events
- Open discussions with senior leadership support; executive walk rounds
- Educate and partner with patients and families
- Observation of key processes
- Conduct monthly safety rounds

## Interventions (Near Miss) Data

- Capture of nursing, pharmacy interventions
- Look for patterns
- Look for systems issues to fix
- Publicize actions taken
- Give staff positive feedback
- Empower end users to suggest changes

"Improvement of safety in health care and the continuous reduction of error depend on the design and re-design of our systems of work"

Don Berwick, MD
President and CEO
Institute for Healthcare Improvement

Nothing will change until you make an effort to change it

## Thank you.....