



TRAINING AND AUDIT

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LEARNING OBJECTIVES

- After attending the presentation, the participant will be able to
 - understand the importance of staff training in handling hazardous drugs
 - develop in-house training program
 - identify relevant references and tools that can be incorporated in your practice

Pharmacy School Education

- American Society of Health System Pharmacist (ASHP) conference on quality assurance for pharmacy – prepared sterile products reported
 - many pharmacists lack education and training on the compounding of sterile preparations
 - many pharmacists receive little or no formal education and training in pharmacy schools on the compounding of sterile preparations
 - Few pharmacy school faculty members have the knowledge and skill to teach others about this subject area
 - Instructional materials are not readily available

ASHP invitational conference on quality assurance for pharmacy prepared sterile products. Am J Hosp Pharm 1991;48:2391-7

Employee Training and Evaluation

- Pharmacists often not well trained in compounding sterile preparations, a new employee must receive proper orientation before given this responsibility
- This includes:
 - providing the employee with information
 - measuring baseline performance



Compounding Sterile Preparations 2nd edition, 2005 Pharmacist Education Phillip J. Schneider

Student Perceptions

A study of graduating pharmacy students evaluated knowledge of aseptic technique to determine if specific factors influenced this knowledge base

- Limited exposure to compounding sterile preparations as part of their academic programs
- 19% of the experiential training was in this area
- 2% of students had no exposure to sterile preparations
- 27% had no exposure in their internships
- 81% did not take any elective courses in compounding sterile preparations

Brown RE et al. Assessing factors affecting graduating pharmacy students scores on a standardized aseptic technique test. Columbus, OH: Ohio State University, College of Pharmacy 1993

Why training is important?

- Training competencies are intended to set out knowledge and skills healthcare workers need in order to minimize occupational exposures to cytotoxic drugs and related waste.



Handling Cytotoxic Drugs in Healthcare Establishments
<http://www.workcover.nsw.gov.au>

Safe Handling Of Cytotoxic Drugs

Section 4 – Education and training

- **4.2 Training in the manipulation and safe handling of cytotoxic drugs**
 - Before being permitted to work in the cytotoxic preparation facility, all staff must be trained
 - The training may be provided for pharmacists, pre-reg pharmacy graduates and pharmacy technicians
 - Other support personnel also need to be trained in dealing with cytotoxic spills, transporting cytotoxics and correct storage of agents
 - Training may be offered in-house or by an external training provider.

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Content of Training Courses

- A training program in cytotoxic reconstitution should be developed and implemented.
- This program should be structured and contains important elements.



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Content of training courses



A checklist with space for the trainee's signature and validation by the responsible supervisor should be placed in the trainee personnel record



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Risk of Exposure
Safety Cabinets/Isolator
Working In a Cleanroom
Aseptic Technique
PPE
Containment Devices
Handling of Cytotoxic Waste
Dealing with Spills
Labelling and Packaging
Transport of Cytotoxics
Environmental Monitoring
Cleaning Procedures
Health Monitoring
Documentation



Training Requirements

- Training should be tailored to the specific needs of the individual
- Should be ongoing with regular updates for any new procedures or products *eg. New hazardous drug introduced at workplace*
- Include periodic tests of staff competencies

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Trainers

- Training of staff in the manipulation of parenteral cytotoxic drugs should be undertaken by an experienced operator.
- Attend accredited training course. E.g BCOP, ASHP
- SOP for training should be developed and maintained
- Each procedure to be detailed



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Levels of Personnel

- Pharmacists
- Pre-registration Pharmacy graduates
- Pharmacy Technicians

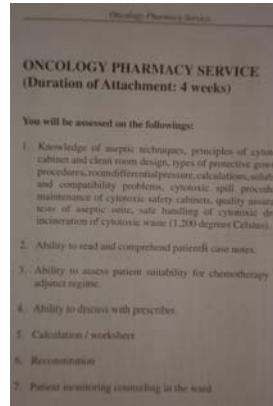


Pharmacy Undergraduates

- Receive consistent number of lecture hours(40 hours) for cancer chemotherapy module during final semester/3rd year
- This includes, practical sessions involving simulation labs (reconstitution techniques)
- Case workshops
- Hospital attachment to identify role of doctor, nurse and pharmacist in oncology care

Pre-registered Pharmacy Graduate

- Oncology Pharmacy is part of the one year Internship program
- Standard training program by Ministry Of Health Malaysia for all hospitals with CDR services
- Assessment conducted by trained and experienced pharmacists



Documentation- Pre-registered Pharmacy Graduate

ONCOLOGY PHARMACY SERVICE

No.	Activity	Grade of Performance	Performance	Comments	Prescriber's Name & Signature
1	Assessment of Knowledge				
2	Ability to assess patient suitability for chemotherapy and adjunct regime		> 80%		
3	Calculation / Worksheet		80		
4	Reconstitution		> 80%		
5	Patient Monitoring / Counseling				

Pre-registered Pharmacist Training Log Book

Performance should be >80%

ONCOLOGY PHARMACY SERVICE

Training Period: _____
Name of Prescriber: _____

No.	Date	Title	Marking
1		Knowledge of aseptic techniques and clean room design	
2		Types of protective gowns/procedures	
3		Room differential pressure	
4		Solubility and compatibility problems	
5		Cytotoxic spill procedures	
6		Maintenance of cytotoxic safety cabinets	
7		Quality assurance tests of aseptic units	
8		Safe handling of cytotoxic drugs	
9		Incineration of cytotoxic waste	
10		Ability to read and comprehend patients' case notes	
11		Ability to assess patient suitability for chemotherapy and adjunct regime	
12		Calculation / Worksheet	
13		Reconstitution	
14		Patient Monitoring / Counseling	

IDENTIFYING STANDARD OPERATING PROCEDURES

SECTION 1: ABILITY TO ASSESS PATIENT SUITABILITY FOR CHEMOTHERAPY AND ADJUNCT REGIME (MIN 20 CASES)

SECTION 1: ABILITY TO ASSESS PATIENT SUITABILITY FOR CHEMOTHERAPY AND ADJUNCT REGIME (MIN 20 CASES)

- Screening of chemotherapy request
- Communication with the prescriber

WEEK 2

Date	Patient RN	No of Intervention	Type of Intervention	Communication with Prescriber	Status of FRP (O.A.S.P)	Name & Signature of Prescriber

Screening of Chemotherapy RX

- Checking orders before preparing worksheets
- Calculations
- Preparing Labels

Communication with Prescriber

- Intervention required based on Rx
- Confirmation of RX

Feedback to Pharmacist in-charge

- Reporting
- Evaluation

Structured Education Program involving lectures and product demonstration



Hands on Training by Experienced Operators



Pharmacy Technicians

- Our partners at work
- Very dependent, higher ratio of PT compared to Pharmacists
- Work under direct supervision of a licensed pharmacist and performs many related functions
 - Filling of RX
 - Manufacturing, Compounding, Reconstitution
 - Drug Distribution and others

Recruiting Pharmacy Technicians

- Completed formal technician training programs from university or college
- Curriculum differ from duration, medium of instruction, hospital training
- Job Orientation upon appointment
- Committed and enthusiastic to continue learning
- On the job training varies with institutions

Why is it Important to Train Our PTs?

- Pharmacist work force shortage
- Momentum for pharmaceutical care
- Momentum for safe medication use

Changes in roles of pharmacists will require changes in the roles and capabilities of pharmacy technicians

Rouse Michael J, et al. White paper on pharmacy technician 2002: Needed changes can no longer wait Am J Health-Syst Pharm 2003;60:37-51

Training Vs Education

Applying both are vital to the learning and preparation of the technicians to become competent practitioners

Training

- involves learning through instructions, repetition and hands on practice until proficiency is achieved

Education

- involves deeper understanding of subject, building on explanation and reasoning, through systematic instruction and teaching

Rouse Michael J, et al. White paper on pharmacy technician 2002: Needed changes can no longer wait Am J Health-Syst Pharm 2003;60:37-51

Also includes.....

- Site-specific training which focuses on local policies and procedures
- Ensure teaching commensurate with their roles
- Ensure maintenance of competence



Rouse Michael J, et al. White paper on pharmacy technician 2002:Needed changes can no longer wait Am J Health-Syst Pharm 2003;60:37-51

UKM MC In-House Training Program

- On-the job Training schedule
 - Part 1 - Operational (8 weeks)
 - Part 2 - Cytotoxic Reconstitution Skills (12 weeks)
- Learning Portfolio – knowledge based
 - Aseptic Dispensing Course,
 - Oncology Pharmacy Workshops
 - In-house learning (case presentations)



No	Item	Topic	Supervised by	Comments
1	Prescription Processing	<ul style="list-style-type: none"> • Writing of Chemotherapy Prescription • Reviewing & Interpretation of Chemotherapy Prescriptions & Protocol • Dosage Calculations for Chemotherapy • Route Of Administration of Chemotherapy • Stability & Compatibility Of Chemotherapy Solutions (Tables Available) 	Pharmacist	Also included rules sheets and used in the weeks of available time
2	On-line process of Chemotherapy prescription	<ul style="list-style-type: none"> • On-line dispensing of CDR • Worksheet preparation • Packaging & Label Writing 	Medicine	
3	General laboratory procedures	<ul style="list-style-type: none"> • Aseptic Technique in CDR • Handling, Labeling & Covering • Labeling in Chemotherapy • Disposal of Waste & procedures • Preparation of CDR in the laboratory 	Medicine/Pharmacy	
4	CDR consultation	<ul style="list-style-type: none"> • CDR usage • CDR ordering procedure • Patient records & mortality statistics • Quality problems & Equipment • Control • Preparation of CDR in the laboratory 	Pharmacist & Medicine	
5		Validation	Pharmacist	

UKMMC CDR Training Module 2007

How to Prepare Your Own Program

- A starting point – visit www.rxptec.org
- The Pharmacy Technician Educators Council (PTEC), an association representing pharmacy technician educators
- Program also includes Compounding
 - Aseptic Technique
 - Non-Sterile Compounding



ASHP Model Curriculum for Pharmacy Technician Training

- Goals divided into 2 main areas
 - major areas of job responsibility
 - foundation knowledge, skills and attitude (maintain pharmacy equipment and facilities)



American Society of Health-System Pharmacists
www.ashp.org

CONTINUOUS MEDICAL EDUCATION

- Web based information on oncology pharmacy education
- Resource information from the asian region
- On updated guidelines, protocols and training centres



www.asia4safehandling.org

Audit Tools



- Can be developed and tested in cancer centres (with cytotoxic drug preparation service)
- Can be used to assess current procedures complies to established standards
- Areas to look into:
 - microbiological testing of facility (air sampling every month)
 - checking procedures (drug and dosage errors)
 - facility maintenance (cabinets and cleanrooms every 6 months)
 - **staff validation**
 - safety measures among staff (nurses, pharmacists)

Validation of Processes



- To demonstrate the processes used during the aseptic preparation and the staff undertaking aseptic manipulation are capable of maintaining the sterility of the product.
- The *media fill test (or Broth test)* is intended to simulate routine aseptic operations, but uses microbiological media to produce units that can be tested for contamination.

Validation of Processes

- Must be performed using the same devices and same transfer methods as routine procedure.
- The test must be performed at least 3 times and filled units should be incubated at designated temp for 14 days.
- Expected results are not one positive unit is found.
- The cause of the failure must be investigated in the case of positive culture and revalidate.

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PROTOCOLS

- **Singapore ADP guidelines**
 - General aseptic technique validation form(handwashing/donning)
 - TPN validation form
 - Aseptic checklist
- **PeterMac (Aust)**
 - General aseptic technique broth transfers (initial/continuation)
- **UK National CIVAS Group**
 - Universal Operator Broth Transfer
 - Initial & Requalification
 - www.civas.co.uk



HOSPITAL UNIVERSITI KEBANGSAAN MALAYSIA PHARMACY DEPARTMENT CYTOTOXIC DRUG RECONSTITUTION UNIT GENERAL ASEPTIC TECHNIQUE VALIDATION FORM

Process for validation in aseptic practice (testing for preparation of chemotherapy drugs)

Step	Operator	Supervisor	Signatures
1. Check the aseptic technique (ATC) form			
2. Wash hands			
3. Don gown			
4. Don cap			
5. Don mask			
6. Check the aseptic technique (ATC) form			
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Validation of the Operator

- To demonstrate the aseptic technique of the operator undertaking the aseptic manipulation is capable of maintaining the sterility.
- To ensure the operator can carry these aseptic manipulations without contaminating her/himself or the environment.

•Withdrawing solution from a vial
•Addition of a solution to an infusion bag

•Use of a fluorescein dye detected with ultraviolet light is most commonly employed

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Validation of Training

- To confirm all staff have a satisfactory level of knowledge and competency for the duties they undertake.
- Training program should be validated and includes critical steps such as contamination risks.
- Re-validation should occur on a regular basis and dependent on staff turnover, duration of rosters in the area.
- Minimum, validation test carried out annually.

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Conclusion

- The pharmacy should have written policies and procedures which is
 - available to all personnel involved in cytotoxic drug preparation
 - important for personnel to understand before being allowed to prepare cytotoxic preparations
 - allows personnel competency to be assessed periodically
- *ISOPP Standard of Practice for Safe Handling of Cytotoxic Agents* is a powerful instrument because of its global acceptance and distribution.
- The audit tool completes the standards and helps the operator to evaluate and progress.

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- Thank you!