Standards of Practice for Oncology Pharmacy in Canada

Version 2
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Canadian Association of Pharmacy in Oncology (CAPhO)

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TABLE OF CONTENTS

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ABBREVIATIONS

ASHP	American Society of Health System Pharmacists
BCG	Bacillus Calmette-Guerin
BCOP	Board Certified Oncology Pharmacist
BSC	Biological Safety Cabinet
CAPhO	Canadian Association of Pharmacy in Oncology
CI	Confidence Interval
COG	Children's Oncology Group
COPD	Chronic Obstructive Pulmonary Disease
CTG PN	Clinical Trials Group Pharmacist Network
DEHP	[di(2 ethylhexyl) phthalate]
DUE	Drug Use Evaluation
GCP	Good Clinical Practice
HEPA	High Efficiency Particulate Air
ISOPP	International Society of Oncology Pharmacy Practitioners
IV	Intravenous
mL	milliliter
MUE	Medication Use Evaluation
NCIC	National Cancer Institute of Canada
NIOSH	National Institute for Occupational Safety and Health
NSF	National Sanitation Foundation and Regulatory Agencies
PVC	Polyvinyl chloride
QoL	Quality of Life
USP	United States Pharmacopeia

STANDARDS OF PRACTICE

Cancer is a common disease with high morbidity. An estimated 171,000 new cases of cancer (excluding 75,100 non-melanoma skin cancers) and 75,300 deaths from cancer will occur in Canada in 2009. This represents an increase of 4600 newly diagnosed cases and 1500 deaths compared to 2008. Increases in the number of new cases of cancer are primarily due to a growing and aging population. Approximately 470 Canadians will be diagnosed each day with some form of cancer (Canadian Cancer Statistics 2009).

Cancer has an enormous impact on the social fabric and economy of Canada. A large number of Canadians live with the effects of cancer, require repeated active treatment and have continuing needs for cancer care resources and support services. This increased demand and the complexity of survivors' health needs impacts the planning and development of multidisciplinary health services.

Oncology pharmacy, a patient focused practice, addresses the pharmaceutical care of both adults and children living with cancer. The provision of direct patient care by oncology pharmacists includes patient interviews, observation and contribution to the selection, modification and monitoring of patient therapy.

"As for all medications, the goal of drug administration in cancer therapy is to ensure delivery of the right drug to the right patient in the right dose and dosage form at the right time to achieve predefined outcomes improving the patient's length and/or quality of life. Achieving this goal requires a comprehensive, systematic approach by multiple providers" (Cohen 1996). A doctor, nurse, pharmacist, pharmacy technician, and other health care providers comprise a team that must work together to ensure patient safety and optimal treatment outcomes. In this role, the oncology pharmacist provides an integral service as a member of the patient care team.

"Antineoplastic drugs by virtue of their low therapeutic index come with tremendous risks. Toxicity is an expected and accepted consequence of most standard treatment regimens" (Kohler 1998). As members of cancer care and research teams, oncology pharmacists supported by oncology pharmacy technicians possess unique skills, which are founded on a specialized knowledge base. It includes knowledge of best practices, appropriate dosages, delivery techniques, formulations and routes of administration of anti-cancer drugs. Also critical are understandings of acute and long-term drug toxicities, management of cancer-related and drug-related complications, drug interactions, safe handling of hazardous drugs, ability to participate in and manage clinical trials, and the understanding and interpretation of research methodologies and outcomes.

Recently, the use of anti-cancer drugs by the oral route has been gaining prominence as a treatment modality for a variety of cancers. Oral administration of anti-cancer drugs has become part of many treatment protocols. Anti-cancer drugs used orally are hazardous and often carry the same risk as parenteral administration in terms of toxicities and potential harm due to a narrow therapeutic index. Oral therapy requires the same strict prescribing and checking of procedures used for hazardous drugs administered by other routes. Safe handling of oral hazardous drugs require the attention to detail that applies to the supply and distribution of all anti-cancer drugs

Fundamental to the development and maintenance of the role of the oncology pharmacist are Standards of Practice for Pharmacy in Oncology. Standards serve as guideposts for oncology pharmacists and as a way of communicating to peers, patients, policy makers, other professionals and the public, the roles and responsibilities of oncology pharmacists. Practice standards also provide a benchmark for evaluating the quality of services and patient care.

The application of these standards will vary depending on a combination of the nature of the practitioners involved and the nature of the practice sites. The practice spectrum ranges from the occasional cancer patient

in a small community hospital, to a cancer clinic in a large community or tertiary hospital, to a cancer centre which is part of a provincial cancer organization, to a sub-specialty oncology setting such as a blood and marrow transplant unit in a tertiary hospital.

The Standards of Practice for Oncology Pharmacy in Canada (Version 2) contained in this document are intended to provide direction and set expectations for contemporary oncology pharmacy practice. Cancer care is dynamic and oncology pharmacy is and will continue to provide leadership in this important area of specialty practice. The intent is not to replace existing standards created in countries or other oncology organizations (e.g. American Society of Clinical Oncology) but rather they should be seen as complimentary and specific to Canadian oncology pharmacy practice.

The document is divided into four major sections:

Section 1 - Standards for Oncology Pharmacy Administration
Section 2 - Standards for an Oncology Pharmacy Distribution Service
Section 3 - Standards for Safe Handling of Hazardous Anti-cancer Drugs
Section 4 - Standards for a Clinical Practice in Oncology Pharmacy

Each section includes the designated Standard followed by enabling Guidelines. The word **"**should**"** indicates that the Canadian Association of Pharmacy in Oncology (CAPhO) considers the item a necessary attribute for "optimal" oncology pharmacy practice.

Practice Standards and Guidelines provide a reference base for goal setting, evaluation and review of the oncology pharmacy service. While these Standards are voluntary, they provide goals for enabling acceptable and prudent delivery of oncology pharmacy services, focused on exemplary patient care.

SECTION 1 STANDARDS FOR ONCOLOGY PHARMACY ADMINISTRATION

Preamble The Oncology Pharmacy Service

The oncology pharmacy service should be organized depending on the scope of cancer services provided by the institution (e.g. adult oncology, pediatric oncology, inpatient or outpatient, blood and marrow transplant) and may be organized differently in different provinces in Canada. When the oncology pharmacy service is part of a hospital pharmacy department, the standards may apply within the infrastructure of the pharmacy department. When the oncology pharmacy service is a separate departmental group, such as in several large cancer centres, these standards may apply directly to the department responsible for oncology pharmacy services. The standards for oncology pharmacy administration should be interpreted in context of the local organization and structure for each oncology pharmacy service.

Standard 1.1 Mission, Goals and Objectives

The oncology pharmacy service should have a published statement of its mission, goals and objectives in the areas of service, education and research. The statement should be congruent with the mission of the provincial cancer organization or institution where the oncology pharmacy service is established. When the oncology pharmacy service is provided from a hospital pharmacy department the mission, goals and objectives of the department should reflect the components of the standards unique to oncology pharmacy.

Guideline 1.1.1

The mission statement of the oncology pharmacy service should describe the department's practice philosophy and how its professional services are designed to ensure cancer patients receive optimal pharmaceutical care.

Guideline 1.1.2

Goals and objectives for the oncology pharmacy service should be consistent with the mission of the sponsoring provincial cancer organization or institution. Goals and objectives should be reviewed annually, revised when necessary and dated accordingly.

Guideline 1.1.3

Goals and objectives should include, but not be limited to, the following:

- oncology pharmacy practice consistent with the level of specialty practice, the changing needs of patients, medical, nursing and other healthcare professional staff.
- provision of oncology pharmacy services to ensure safe, appropriate and cost effective use of oncology drugs within the framework of pharmaceutical care.
- collaboration with oncology health team members in all aspects of medication use in cancer patients and education of patients receiving cancer drug therapy.
- maintenance and delivery of education and information programs for all staff involved in the provision of oncology pharmacy services, to enhance the understanding, recognition, management and prevention of drug-related problems in cancer patients, through evidence-based clinical practice and research.
- provision of an environment which encourages growth and development of individual oncology pharmacists and technical staff and fosters exemplary service.
- evidence-based practices when the evidence exists and research to determine improvements in practice when evidence to support practice is lacking or insufficient.

Standard 1.2 Systematic Planning

The oncology pharmacy service should have a plan and deploy a systematic planning process to facilitate and continuously improve achievement of its mission, goals and objectives. Plans and planning of processes should be supported by the sponsoring provincial cancer organization or institution (facility).

Guideline 1.2.1

Regular review of goals and objectives should be inclusive, involving all oncology pharmacy staff.

Guideline 1.2.2

The planning process should be strategic in that it is ongoing, broadly based, and current. It should also consider financial and other physical resources within the context of societal and professional changes occurring and contemplated.

Standard 1.3 Organization and Management

The oncology pharmacy service should be organized in a manner which facilitates the accomplishment of the overall mission, promotes the goals and objectives and effectively manages resources. The organizational and administrative structure should clearly identify lines of responsibility and accountability for the relevant components that make up the oncology pharmacy.

Guideline 1.3.1

The designated Pharmacist responsible for the oncology pharmacy service should demonstrate professional leadership and effectively unite and inspire oncology pharmacy staff toward achievement of best practices. In collaboration with the provincial cancer organization or institution, the designated Pharmacist responsible for the oncology pharmacy service should ensure that the following issues are addressed:

- development, articulation and implementation of the mission statement
- recruitment, retention and development of a competent staff
- development, implementation, evaluation and enhancement of the oncology pharmacy service, education programs and research initiatives
- establishment and implementation of standards for staff performance and progression
- resource acquisition to meet the relevant goals and objectives
- maintenance of the visibility of the oncology pharmacy service within the institution (hospital, clinic), organization and the community it serves through opportunities such as active participation in standing committees

Guideline 1.3.2

The designated Pharmacist responsible for the oncology pharmacy service should provide leadership and vision in the area of cancer care and understand the requirements needed for pharmaceutical care of the cancer patient including, but not be limited to:

- accountability for medication safety, evidence-based practice and appropriate fiscal management of resources

- effective delivery of pharmaceutical care services
- managing operations and budgets
- establishing criteria for workload measurement of the oncology pharmacy services and using captured workload data to effectively plan staffing and service requirements
- mentoring and developing oncology pharmacy staff and performance assessment
- a commitment to sharing knowledge and expertise in the community
- an obligation to teaching and research
- a scholarly concern for oncology pharmacy and the pharmacy profession, through liaison with other stakeholders e.g. University, Pharmaceutical Industry, Pharmacy Organizations.

Guideline 1.3.3

Criteria should be established and a mechanism should be in place for the development and periodic, broad-based review of the administrative leadership of the oncology pharmacy service.

Standard 1.4 Oncology Pharmacy Staff

The oncology pharmacy service should be staffed by sufficient numbers of professional, technical and other support personnel to facilitate the mission, goals and objectives of the program.

Guideline 1.4.1

There should be written job descriptions for all oncology pharmacy personnel clearly delineating professional and technical functions. Job descriptions should be updated as necessary to meet the needs of contemporary specialty practice.

Guideline 1.4.2

Technical and support personnel should be assigned to minimize the direct involvement of oncology pharmacists in technical and clerical activities.

Guideline 1.4.3

As available, professional and technical staff should be provided oncology pharmacy-specific training and/or certification to enhance and ensure their competence. Training and/or re-certification programs may be required on a regular basis as part of the quality assurance for an oncology pharmacy service. When provided, staff should be responsible for attendance and participation in these programs.

Guideline 1.4.4

Professional and technical staff should be provided with scholarly and educational opportunities to facilitate and enhance knowledge and to maintain professional or technical competence. When possible, at least one continuing education program should be made available to professional and technical staff on an annual basis. When provided, staff should be responsible for ensuring participation in continuing education programs that present appropriate oncology data in a balanced format.

Guideline 1.4.5

Staffing patterns should focus on patient needs and safety, demands for service, provision of best practices and the cost effective, evidence-based use of oncology drugs.

Guideline 1.4.6

Hours of the oncology pharmacy service should meet the scope and demands of the program and provide timely services in meeting needs of cancer patients. A policy should be developed for provision of after hour services in emergency situations.

Guideline 1.4.7

All oncology pharmacists should:

- be able to apply a broad, integrated knowledge of the core functional information associated with oncology pharmacy while solving problems and making decisions during completion of their professional responsibilities
- consistently accept responsibility and be accountable for the actions and decisions in providing oncology pharmacy services
- effectively use the communication skills required to consistently demonstrate professional competence and integrity
- maintain an adequate level of competency as required to provide the oncology pharmacy service, including provision of pharmaceutical care, drug information; patient education and supervisory management of drug distribution to ensure the safety, accuracy and quality of cancer drug therapy, with application of management principles as they pertain to the site of oncology pharmacy practice.

Guideline 1.4.8

All oncology pharmacy technicians should:

- work as a team with the oncology pharmacist in applying technical knowledge to oncology pharmacy services
- effectively use the communication skills required to enhance desirable service outcomes
- be accountable for their actions in providing oncology pharmacy services
- demonstrate competence, accuracy and integrity
- demonstrate competent aseptic technique and handling of hazardous drugs in the preparation of oncology drugs
- maintain competence related to technical knowledge and its application to oncology pharmacy services

Standard 1.5 Policies and Procedures

Appropriate policies and procedures for oncology pharmacy services should be established at any location where patients receive cancer treatment.

Guideline 1.5.1

A Policies and Procedures Manual should be available which reflect situations unique to oncology pharmacy practice. The Policies and Procedures Manual should identify personnel involved in each oncology pharmacy activity and should provide them with clear direction on the scope of their functions and responsibilities.

Guideline 1.5.2

Policies and procedures should be consistent with the goals and objectives of the oncology pharmacy service and identify, but not be limited to, the following:

- roles and responsibilities of oncology pharmacists and oncology pharmacy technicians
- requirements for best practices and consistency in performance
- direction for orientation of new oncology pharmacists and oncology pharmacy technicians
- requirements and methods to promote optimal communications

Guideline 1.5.3

The Policy and Procedures Manual should be updated regularly to incorporate current best practices, with a minimum requirement that all policies and procedures be reviewed biennially to ensure they accurately document current practice.

Guideline 1.5.4

Written policies and procedures for the safe handling of hazardous drugs should be established and regularly reviewed (Section 3).

A list of hazardous drugs that require special handling should be created in every facility that provides drug preparation and drug administration services.

The hazardous drug list should be posted in all work areas where hazardous drugs are received, stored, prepared and administered.

Standard 1.6 Documentation

The designated Pharmacist responsible for the oncology pharmacy service should develop policies and procedures to describe documentation of pharmacy activities.

Guideline 1.6.1

The designated Pharmacist responsible for the oncology pharmacy service should ensure there are policies and procedures to describe documentation of pharmacy patient care activities including, but not be limited to, the following:

- quality control measures taken to ensure integrity of parenteral, oral and topical prescriptions for anti-cancer drugs
- practices that promote patient safety and meet legal requirements
- prevent or manage drug-related problems
- a consistent systematic approach to develop drug monitoring plans for the identification of patient allergy status,,prior serious adverse drug reactions and potential drug interactions
- monitoring of serum drug levels when appropriate;
- documentation of any required recommendations or modifications to drug orders
- patient counseling on appropriate drug use to support optimal patient care
- provision of drug information

Guideline 1.6.2

The oncology pharmacist should document patient care activities according to departmental and institutional policies and procedures.

Guideline 1.6.3

The oncology pharmacist should consistently identify situations that require documentation in the patient's health record.

Guideline 1.6.4

The oncology pharmacist completes required documentation in a concise, complete, timely manner including only necessary information using a specific documentation format for consistency, clarity and ease of retrieval.

Standard 1.7 Oncology Drug Advisory Committee

The designated Pharmacist responsible for the oncology pharmacy service should ensure that oncology drug use within their practice or institution adheres to the approved formulary and funding guidelines for oncology drugs as determined by their provincial or institutional oncology drug advisory committee (e.g. Oncology Pharmacy and Therapeutics Committee, Oncology Systemic Therapy Committee). If oncology drug use is reviewed and approved within the scope of the practice site, the designated Pharmacist responsible for the oncology pharmacy service should be an active participant of the multidisciplinary drug advisory committee performing the oncology drug reviews both retrospectively and prospectively.

Guideline 1.7.1

Topics the oncology drug advisory committee should discuss and evaluate include, but are not limited to, the following:

- development of practice guidelines for the safe, cost-effective use of oncology drugs
- maintenance of a formulary of approved oncology drugs
- review of policies and procedures for improvement in drug use
- review of medication incidents, close calls and serious adverse drug reactions
- critical evaluation of requests for use of all new and expensive oncology drugs

Guideline 1.7.2

The oncology drug advisory committee should meet regularly and should document its activities, recommendations and decisions.

Standard 1.8 Treatment Guidelines

Oncology pharmacists should be active participants in the development of evidence-based cancer treatment guidelines, through critical appraisal of the literature and clinical trials and the appropriate application of the evidence or should be familiar with relevant provincial, national and international based guidelines for the treatment of cancer.

Guideline 1.8.1

Oncology pharmacists should participate where appropriate in establishing treatment guidelines for specific cancer disease sites in the local institutions or provincial programs.

Guideline 1.8.2

The development of evidence-based treatment guidelines should describe treatment options which lead to optimal patient outcomes and assist with decisions related to the use of all anti-cancer drugs

Guideline 1.8.3

Evidence-based treatment guidelines should be developed using a standardized framework to:

- identify the clinical condition
- gather evidence systematically and evaluate validity by identifying bias
- review and grade the strength of the evidence (evaluate results) using validated scales of publication quality
- apply the evidence to the institutional or provincial practices and define limitations necessary for practical implementation
- create the guidelines based on validity, criteria, applicability and generalizability
- disseminate guidelines and educate users
- implement the guidelines
- evaluate the guidelines and modify them when necessary

Guideline 1.8.4

Desirable attributes for evidence-based treatment guidelines, should include, but not be limited to:

- validity, magnitude, precision, believability
- strong evidence/relevance of results, statistical significance
- estimated outcomes/clinical significance
- reproducible/sampling variation including random error, “p” value, confidence interval (CI)
- reliable, avoiding systematic error (bias)
- representative of the population
- clinically applicable
- clinically feasible
- clarity and worth (rating through framework)
- multidisciplinary process
- schedule review and update based on new evidence
- documentation (single studies, phase II, phase III and meta-analysis)

Standard 1.9 Medication Safety

All oncology pharmacists responsible for the provision of oncology pharmacy services should provide leadership in implementing practices to minimize the risk of medication errors with anti-cancer drugs and participate in medication reconciliation processes. Unlike most other drugs, anti-cancer drugs generally have a narrow therapeutic window, and the opportunity for significant adverse events is greater than in other therapeutic areas. Medication safety practices have greater significance and may need to be more stringent when anti-cancer drugs are provided.

Guideline 1.9.1

Recommendations for preventing medication incidents with anti-cancer drugs should include, but are not limited to, the following:

- standard use of oncology-specific computerized physician order entry or pre-printed physician orders for specific anti-cancer drug regimens
- a dose-verification process with as many independent checks as possible (at a minimum a check by two licensed professionals e.g. pharmacist, nurse, physician)
- a detailed check list covering prescribing, dispensing and administration of chemotherapy and supportive care
- all doses should be calculated independently by the physician, pharmacist and nurse
- dosage limits should be established per protocol and a confirmation process set up for doses that exceed limits before these drugs are administered
- limits should be entered into pharmacy computer systems, listed on pre-printed order forms, stated on the product packaging, placed in strategic locations in the institution and communicated to employees
- standardization of the prescribing vocabulary using generic terminology, standard acronyms and implementation of policies which avoid prescribing language known to be associated with increased errors (e.g. Institute for Safe Medication Practices "Do Not Use List")
- participation in the medication reconciliation process which identifies the patient's most complete medication history, including allergies and use of prescription, non-prescription and natural products (See Section 4)
- identification of potential drug interactions
- education of patients about all aspects of their anti-cancer drugs as patients represent the last line of defense against errors

Guideline 1.9.2

A multidisciplinary team should review every medication incident reported with anti-cancer drugs and specific steps should be taken to minimize risk.

Guideline 1.9.3

Corrective action should not be punitive, but focus on competency, risk reduction and preventive measures.

Standard 1.10 Medication Incident Reporting

There should be written policies and procedures on strategies to minimize the risk of medication incidents related to the use of anti-cancer drugs which impact the care of cancer patients.

Guideline 1.10.1

A written report should be prepared to describe all medication incidents occurring in prescribing, dispensing or administering cancer medication.

Guideline 1.10.2

There should be a system to review the processes that contribute to all incidents.

Guideline 1.10.3

The reports should be analyzed and necessary action taken to minimize the possibility of repeat occurrence.

Guideline 1.10.4

All medication incidents should be communicated to the oncology pharmacy team in a non-accusatory, educational format with the purpose of preventing future occurrences.

Standard 1.11 Quality Assurance Program

The oncology pharmacy service should use a Continuous Quality Improvement (CQI) process with a focus on emerging technology, new knowledge and high-risk areas to evaluate best practices for clinical service to cancer patients.

Guideline 1.11.1

Continuous quality improvement builds on quality assurance by extending activities beyond problem resolution to ongoing improvement of all key processes.

Guideline 1.11.2

Core theoretical constructs of the CQI process include:

- focus on cancer patients
- focus on processes and continual improvement
- medication incident surveillance and reporting programs
- preventive measures within the system
- impact of medication incidents on patients' quality of life
- education programs

Guideline 1.11.3

The pharmacists from the oncology pharmacy service should follow a CQI process to evaluate the service provided to cancer patients.

Documentation should include, but not be limited to, the following:

- identification of problems or areas requiring improvement
- data collection and analysis
- actions necessary to improve performance
- assessment of outcome indicators
- actions to resolve problems and improve quality of care

Standard 1.12 Adverse Drug Reaction Reporting

The oncology pharmacy service should co-ordinate, in co-operation with the oncology medical and nursing staff, an adverse drug reporting system for anti-cancer (antineoplastic) drugs. This system should concentrate on unexpected serious or life–threatening adverse drug reactions or unusual adverse drug reactions to anti-cancer drugs.

Guideline 1.12.1

An adverse drug reaction reporting system should include, but not be limited to, the following:

- identification and immediate reporting of adverse drug reactions to the prescribing physician and pharmacy
- documentation in the patient's health record and the pharmacy medication profile
- evaluation of the adverse drug reaction to determine the cause-effect relationship
- regular reporting of adverse drug reactions to the designated Committee responsible for risk management
- reporting of adverse drug reactions to Health Canada and to the drug manufacturer, according to institutional policy
- notifying the patient of hypersensitivities detected and mechanisms to prevent repeat occurrence.

Standard 1.13 Resource Management

There should be sufficient staff, space, facilities, equipment, information technology and supplies to support the principal functions of the oncology pharmacy service and to ensure a safe working environment for personnel.

Guideline 1.13.1

All equipment used in the preparation, distribution and administration of oncology drugs should be appropriately identified and regularly serviced to ensure accurate and safe operations (annually or according to recommendations of the manufacturer or other authoritative agency).

Guideline 1.13.2

Oncology pharmacy operations should be adequately supported by computer software which provides comprehensive documentation to support oncology pharmacy functions in a timely manner.

Guideline 1.13.3

Library resources, online websites and technical support services should be available to assist staff in the provision of oncology pharmacy services. Information accessibility should include current drug information, cancer therapeutics, pharmacy practice and complementary and alternative remedies. The oncology pharmacy service should develop a system to facilitate rapid retrieval of information (manual or computerized).

Guideline 1.13.4

The scope and responsibility of the oncology pharmacy service should be adequately supported with an appropriate complement of pharmacists, pharmacy technicians and other support personnel and should be funded appropriately by the facility administration.

Standard 1.14 Financial Control

Financial management of the oncology pharmacy service should include direct involvement in budget preparation for all aspects of the service, including research and pharmacy education.

Guideline 1.14.1

Expenses should be monitored and the budget adjusted according to, but not be limited to, the following:

- workload and staffing requirements
- variance analysis reports
- cost effective use of oncology drugs
- impact of the cost of research

Standard 1.15 Cost Containment

The oncology pharmacist should consider the potential cost implications of the drug therapy for the individual cancer patient and for the funding agency to ensure the most beneficial and economical drug therapy is utilized.

Guideline 1.15.1

The oncology pharmacist should be aware of the cost implications related to wastage of oncology drugs and should avoid wastage whenever possible.

Guideline 1.15.2

Methods for cost containment should include, but not be limited to:

- formulary management
- application of evidence-based guidelines
- monitoring and managing budgets
- data collection and analysis
- inventory management
- pharmacoeconomics analysis to identify the most cost effective therapy within a class of competing treatments

Standard 1.16 Medication Use Evaluation

Medication Use Evaluation (MUE) encompasses goals and objectives of Drug Use Evaluation (DUE) with emphasis on improving patient outcomes and Quality of Life (QoL).

The oncology pharmacy service should co-ordinate, in co-operation with the oncology medical staff and the Oncology Drug Advisory Committee (or equivalent) and/or the Pharmacy and Therapeutics Committee, a system for ongoing evaluation of drug use within the oncology unit, which may include:

- development of oncology drug use criteria to promote optimal therapy using validated methods (e.g. physician academic detailing)
- evaluations of oncology drug use against the predetermined criteria
- identification of problem areas

- education to correct patterns of inappropriate drug use and evaluation of the impact of the educational programs
- adherence to established external standards (Professional practice regulations, Hospital/service Accreditation, provincial and federal laws).

Guideline 1.16.1

Problems detected during the evaluation process should be communicated to the responsible body. (MUE team or program)

Guideline 1.16.2

The frequency and depth of evaluation should be based on identified need for procedural modifications, as well as economic impact.

Standard 1.17 Reporting Systems

The oncology pharmacy service should include a comprehensive reporting system to assist with monitoring cost and evaluation of the specialty practice.

Guideline 1.17.1

Reports should include, but not be limited to, the following:

- workload data
- resource utilization (e.g. drug budget)
- staffing
- variance analysis
- quality improvement measures
- educational activities
- programs related to goals, objectives and new initiatives
- research program activities

Guideline 1.17.2

Information should include, but not be limited to, the following:

- number of inpatient admissions and information on length of stay for oncology patients on each inpatient unit
- number of patients who receive systemic therapy or visited the oncology clinic
- number of days each patient receives systemic therapy and associated supportive therapy
- total number of oncology (or anti-cancer drug) orders processed by the oncology pharmacy service and total number of oncology prescriptions processed each day
- total number of units prepared each day e.g. intravenous, oral, intrathecal, etc.
- total cost/drug, cost/regimen, cost/patient, cost/disease site group
- preparation of pumps for home care, identification of expiration dates and other inventory issues.
- incident reports regarding exposure, injury, medication spills
- such other data which may be required

SECTION 2 STANDARDS FOR AN ONCOLOGY PHARMACY DISTRIBUTION SERVICE

Standard 2.1 Oncology Pharmacy Distribution Services

The oncology pharmacy service should include a comprehensive anti-cancer drug service designed to meet the needs of cancer patients.

Guideline 2.1.1

All anti-cancer drugs used for treatment of cancer patients should be prepared and dispensed by the pharmacy service, optimizing safety, efficiency and economical use of anti-cancer drugs.

Guideline 2.1.2

Pharmacy personnel must demonstrate competency in sterile preparation technique prior to preparing parenteral admixtures. Additionally, pharmacy personnel involved in the preparation of anti-cancer drugs should be trained in and should satisfactorily demonstrate their knowledge of, and adherence to, all required safe handling and aseptic procedures through a certification program annually.

Guideline 2.1.3

Anti-cancer drugs, which are hazardous drugs, should have established written policies and procedures for safe handling and this documentation should be reviewed regularly.

Standard 2.2 Pre-printed Medication Orders

The use of pre-printed medication orders should be standard practice for an oncology pharmacy service, as they reduce potential errors and provide treatment information in a clear, consistent, uniform format.

Guideline 2.2.1

Preprinted medication orders should:

- include the name of the approved regimen and the cancer for which it is intended
- include each generic anti-cancer drug and supportive drug(s) where appropriate to the specific regimen
- include dosing and administration instructions for each drug as well as administration dates for each dose
- include a process to ensure accuracy of dose calculations
- include a process to identify potential drug interactions
- be approved individually by a multidisciplinary committee designated by the institution to be responsible for care delivery
- be reviewed annually and revised as necessary and include date of revision and reference
- have a copy that can be appended to the individual health record
- be authorized by the prescriber and individualized according to the patient's needs.
- be written according to institutional policies and procedures developed with a focus on medication error prevention

Guideline 2.2.2

Whenever possible, electronic order entry and decision support software identifying maximum and minimum allowable doses should be employed.

Guideline 2.2.3

Incorporation of other protocol elements such as laboratory tests, diagnostic imaging, radiation treatment consultations, etc into preprinted orders can enhance safe and consistent provision of treatment according to protocol.

Standard 2.3 Medication Order Review

The oncology pharmacist should verify the medication order against the treatment protocol, the patient's medication profile and the patient's health record prior to dispensing.

Guideline 2.3.1

Prior to dispensing any medication, the oncology pharmacist should verify the medication order against the treatment protocol, the patient's medication profile and the patient's health record. In the absence of a treatment protocol, the pharmacist should check the medication order against two independent literature sources. Where possible, the pharmacist who reviews the medication order should not be the same pharmacist involved in the final product verification. There should be at least three independent pharmacy checks built into the verification process for each anti-cancer drug order:

- Verification of the drug order
- Computer order entry and label review
- Manufacturing and final product check

Guideline 2.3.2

The following must be reviewed and verified by a pharmacist prior to dispensing parenteral, oral and topical cancer treatments:

- the patient's name, diagnosis, identification number, (e.g. Health Insurance Number, or hospital unique number) and location
- age, gender, allergy or medication intolerance, or history of adverse drug reaction
- height, weight and body surface area
- signature of authorized prescriber, either written or electronic
- critical laboratory values or clinical criteria which must be monitored (according to pre-defined criteria) to proceed with anti-cancer drug treatment
- the name of the medication, formulary status, and therapy protocol
- dosage, dosage interval and cycle number
- dosage form and route of administration
- frequency of administration, number of doses, cycle interval and complete directions for use
- duration of treatment, stop date
- cumulative doses of selected drugs
- date order was written, name of physician and license number
- date and time of treatment
- therapeutic duplication
- drug-disease incompatibility, drug compatibility
- significant drug-drug, drug-food or drug-herbal interactions

- use of support therapy (e.g. antiemetics, hydration etc.)
- the oncology pharmacist ensures that all appropriate prescriptions for medications for use at home are written (e.g. oral oncology drugs, corticosteroids, antiemetics, hematopoietic stimulating factors, etc.)
- laboratory results to determine adequate organ function, drug serum concentration (where appropriate) and need for dose modifications
- for parenteral admixtures: correct intravenous fluid, final volume and concentration, stability and potential incompatibilities and rate of administration
- name of anti-cancer drug regimen, or if a clinical trial: protocol and patient study number
- the pharmacist should document that they reviewed and verified the anti-cancer medication order on a permanent record.

Guideline 2.3.3

The oncology pharmacist should resolve any questions regarding the anti-cancer drug order with the prescriber and should document the resolution in the patient's health record.

Guideline 2.3.4

Telephone or verbal order for anti-cancer drugs should **not** be allowed or accepted. Orders must be written and signed.

Standard 2.4 Labels

The oncology pharmacist should use computer-generated labels, using a standardized format, terminology and generic nomenclature.

Guideline 2.4.1

Labels should include, but not be limited to:

- name of patient, identification number, area or unit
- generic drug name
- date of treatment, name of regimen and name of prescriber
- dose, drug volume, infusion solution, total volume of admixture, frequency and route of administration e.g. for intrathecal use only, irritant, vesicant etc.
- drug concentration, if applicable
- sequential IV solution bag number (e.g. Bag 1 of 2, Bag 2 of 2)
- for pumps – residual volume and rate and route of administration in mL/hour
- the 'beyond use' date and time
- initials of pharmacy personnel who checked the final preparation
- distinctive warning labels stating the contents are "hazardous" "and contents are to be disposed of properly
- appropriate auxiliary labels (e.g. warning: for intravenous use only)
- storage requirements (e.g. refrigerate, do not shake)

Standard 2.5 Checking Medication Preparation and Labeling

An independent check of the final product against the physician's order to ensure accuracy and completeness of the label is required.

Guideline 2.5.1

The oncology pharmacist/delegated oncology pharmacy technician should check all completed anti-cancer drug admixtures to ensure the correct ingredients (e.g. drug, diluent, infusion solution, infusion equipment) and the correct amounts have been prepared and labeled properly. This check should be recorded on a permanent record.

The delegated oncology pharmacy technician should complete the institution specific training program and achieve a specified level of accuracy before being delegated the responsibility for the final check.

Guideline 2.5.2

The oncology pharmacist and/or technician should inspect all completed anti-cancer drug admixtures for particulate matter, leaks, signs of incompatibility, degradation or contamination before dispensing for patient use in zip lock bags.

Guideline 2.5.3

There should be a standard procedure in place to retrieve the batch number and expiry of all drugs and diluents used in the preparation of parenteral admixtures of anti-cancer drugs.

Guideline 2.5.4

The oncology pharmacist or technician should check the label against the original order for accuracy and completeness.

Guideline 2.5.5

The oncology pharmacist and/or technician should affix the correct label to the completed anti-cancer drug dose using care not to cover solution levels.

Standard 2.6 Dispensing Anti-cancer Drugs for Oral Use

Provision of oral anti-cancer drugs to cancer patients requires the attention to detail that applies to the supply and distribution of all hazardous drugs.

Guideline 2.6.1

Prior to dispensing a prescription for oral anti-cancer drugs it must be screened by a pharmacist with experience in anti-cancer drug therapy who accepts responsibility for the clinical safety of the prescription.

Guideline 2.6.2

Prescriptions must state clearly the drug, dose, route and frequency of administration, intended start date, duration of treatment and when relevant, the intended stop date for each course of treatment.

Guideline 2.6.3

Pharmacists must have access to a documented treatment plan and a full copy of the relevant protocol.

Guideline 2.6.4

It is the responsibility of the oncology pharmacist to:

- ensure prescribed doses, treatment intervals and administration details are appropriate for the patients' demographics, tumour type, hematological and biochemical profile, organ function and chosen treatment protocol
- verify maximum and cumulative doses of all anti-cancer drug doses are not exceeded
- check that all anti-cancer drugs included in the protocol have been prescribed including those to be administered by other routes
- check that additional supportive drugs relevant to the treatment protocol are prescribed
- recognize the therapeutic and toxic effects of the prescribed drug(s) and identify the potential for interaction with other drugs
- verify with the original prescriber any discrepancies identified during the checking process. Incorrect or missing details must be corrected prior to dispensing

Guideline 2.6.5

Pharmacists should dispense one cycle of oral anti-cancer drug treatment at any one time. If more than one cycle or a repeat prescription is provided to the patient, clear protocol instructions must be in place to ensure predefined clinical parameters are evaluated and doses confirmed prior to treatment.

Guideline 2.6.6

Labeling should use generic terminology with clear dosing instructions.
"As Directed" should never be used.
Labels should specify:

- the intended period of treatment (number of days)
- start and stop dates
- total dose required and schedule for taking the prescribed drug
- auxiliary labels specifying appropriate storage requirements
- cautionary advisory labels as indicated
- see Standard 4.6 Patient Counseling

SECTION 3 STANDARDS FOR SAFE HANDLING OF HAZARDOUS ANTI-CANCER DRUGS

Standard 3.1 Handling Hazardous Drugs

The majority of anti-cancer drugs are identified as hazardous drugs and require safe handling practices.

The oncology pharmacy service should provide a practice site which ensures the safe handling and distribution of hazardous drugs.

Guideline 3.1.1

Hazardous drugs should be handled in a manner to ensure:

- the safety of personnel
- the accuracy and appropriateness of the drug and dose
- protection of the patient
- protection of the environment
- minimum exposure of hazardous drugs to pharmacy personnel, nursing staff, allied health staff and patients.

Standard 3.2 Policies and Procedures

Standardized policies and procedures for the safe handling of hazardous drugs and equipment should be established, documented and regularly reviewed. Polices should be multidisciplinary and multi-departmental to include all health-care workers who may handle hazardous drugs in their daily work. The oncology pharmacy should be the leaders and
work together with other disciplines in development of these policies.

Guideline 3.2.1

Written policies and procedures should be readily available to all personnel involved in handling hazardous drugs. Policies and procedures should be consistent with National and International hazardous drug safe handling standards (e.g. ASHP Guidelines on Handling Hazardous Drugs., Am J Health-Syst Pharm 2006; NIOSH Alert-Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings, NIOSH 2004; ISOPP Standards of Practice Safe Handling of Cytotoxics, 2007 and USP 797).

Guideline 3.2.2

Policies and procedures should be based on references providing detailed handling procedures and provincial guidelines for the handling and disposal of hazardous drugs. (e.g. Alberta Cancer Board Pharmacy "Training Manual for the Preparation of Parenteral Cytotoxic Admixtures", 8th Edition, June 2005 (updated June 2009) (see references); BC Cancer Agency Pharmacy Practice Standards for Hazardous Drugs, May 2009, *www.bccancer.bc.ca/HPI/CE/pharmacists/safehandling.htm*.

Standard 3.3 Clean Room

All hazardous drug admixtures should be prepared within a Biological Safety Cabinet (BSC) located in a clean room that meets the guidelines for preparation of sterile products in pharmacies of the Canadian Society of Hospital Pharmacists, 1996. Where feasible, clean room design and operation should meet the standards of the US Pharmacopoeia (USP) revised general chapter <797> pharmaceutical compounding – sterile preparations, June 2008.

Guideline 3.3.1

Clean room(s) should be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. The facility should also provide a comfortable and well-lighted working environment, which typically includes a temperature range of 18 - 22°C to maintain comfortable conditions for compounding personnel to perform optimally when attired in the required aseptic compounding garb and personal protective equipment.

Guideline 3.3.2

Environmental sampling may occur as part of a comprehensive quality management program and shall occur minimally under any of the following conditions:

- as part of the commissioning and certification of new facilities and equipment
- following any servicing of facilities and equipment
- as part of the re-certification of facilities and equipment (e.g. every 6 months)
- in response to identified problems with end products or staff technique
- in response to issues with compounded sterile products, observed compounding personnel work practices, or patient-related infections (where the product is being considered as a potential source of the infection)

The environmental sampling program to measure viable and nonviable particle levels should be developed based on a risk assessment of compounding activities performed.

Standard 3.4 Biological Safety Cabinet

Hazardous drug admixtures should be prepared in a Class II Biological Safety Cabinet (BSC) that meets provincial occupational health and safety requirements and NSF Standard 49 (National Sanitation Foundation and Regulatory Agencies), and any other national or provincial regulations governing these devices. Class II Type A cabinets are a minimum requirement and Class II Type B cabinets which are fully exhausted to the outside should be used whenever feasible. The BSC must be equipped with a continuous monitoring device to allow confirmation of adequate airflow and cabinet performance. The National Institute for Occupational Safety and Health (NIOSH) Alert statement is "The exhaust from these cabinets (biologic safety cabinets and containment isolators) should be HEPA filtered and whenever feasible exhausted to the outdoors (away from air intake locations). Additional equipment, such as closed system drug-transfer devices, glove bags, and needle-less systems will further protect workers from exposure when used properly."

Guideline 3.4.1

The BSC should be located in an area of the clean room where air turbulence is minimal. NIOSH states "While the need for asepsis is critical for many operations, this need should not require the sacrifice of worker safety and health".

Guideline 3.4.2

The BSC should be certified by an accredited technician when:

- initially installed
- the cabinet is physically moved or altered
- service work or repairs are completed
- at least annually

Guideline 3.4.3

Site specific procedures should be created and posted for workers so when gauges, lights or alarms indicate the BSC is not working properly or there is power interruption, the safety of personnel, the environment and the aseptic condition of the product (if possible) will be maintained.

Guideline 3.4.4

Operation of the BSC should include:

- operate the blower in the "turned on" position, 24 hours per day, 7 days a week
- keep the viewing window at the manufacturer's recommended operating position
- do not block intake or exhaust grills with paper or other materials
- check and document the magnetic gauge readings daily (e.g. to ensure the BSC pressure is adequate and the blower is operating properly)
- for an externally vented BSC, check that the exhaust flow gauge is operating in the normal range
- perform regular smoke pattern test (if there is a change in pattern an interim certification may be required as something may be occurring within the BSC)

Guideline 3.4.5

To maintain an aseptic environment and to protect against possible contact with hazardous drug particles, surfaces of the BSC should be cleaned with aqueous antibacterial solution and then disinfected with 70% alcohol regularly throughout the day. To keep interior surfaces of the BSC as clean as possible, they should be cleaned and disinfected at the beginning of the work day (all interior surfaces), after completing each preparation (work surface only), and at the end of the compounding session/shift (all interior surfaces).

The following procedure describes a method which may be used for daily cleaning and disinfecting the interior surfaces of the BSC:

- wash hands and wear protective clothing (e.g. gown, gloves, NIOSH approved respirator mask, safety goggles, and disposable hair and shoe covers as outlined by policy
- soak clean, low linting towels (wipes or gauze) with aqueous antibacterial solution and place on the work surface inside the BSC
- clean all surfaces of the BSC using one towel for each surface
- repeat the previous two steps using low linting towels moistened with seventy percent alcohol; do not use alcohol on the viewing window if it is made of plastic, as alcohol may cause permanent fogging
- place contaminated outer gloves and used towels in sealable bags inside the BSC and then dispose in a hazardous waste container outside of the BSC
- allow the BSC to purge for 15 minutes after cleaning

Guideline 3.4.6

The BSC should be thoroughly decontaminated:

- at least once a week
- after a hazardous drug spill has occurred in the BSC
- before turning the BSC off for maintenance, certification or servicing
- before and after the BSC is moved

The following procedures describe a method which may be used for decontaminating the BSC:

- wash hands and wear protective clothing (e.g. gown, gloves, NIOSH approved respirator mask, safety goggles, and disposable hair and shoe covers as outlined by policy
- soak clean, low linting towels (wipes or gauze) with aqueous antibacterial solution and place on the work surface inside the BSC
- clean all surfaces of the BSC using one towel for each surface
- wipe all interior surfaces of the cabinet with aqueous alkaline detergent solution (e.g. ceiling grill, back wall, fixtures, side walls, and work surface) working from top to bottom and back to front (e.g. from cleaner area to more contaminated area)
- lift the work surface tray and place against the back wall or have a second appropriately gowned person hold the tray against the wall, to decontaminate the lower portion of the BSC
- wipe the under surface of the working tray and the top and bottom of the front intake grill
- prevent suction of cleaning material up into the fan by maintaining a firm hold on cleaning material (e.g. BSC may have a screen on the fan to prevent material from being sucked up into the fan)
- wipe all surfaces underneath and above the work surface with low linting towels soaked with sterile water for irrigation USP to remove detergent residue
- pour (do not spray) alcohol on low linting towels and use to wipe all surfaces underneath and above the work surface: do not use alcohol on the viewing window if it is made of plastic, as alcohol may cause permanent fogging
- pull the viewing window down and clean both sides with aqueous alkaline detergent solution followed by sterile water for irrigation USP to remove any drip or touch contamination
- place contaminated outer gloves and used towels in sealable bags inside the BSC and then dispose in a hazardous waste container outside of the BSC
- allow BSC to purge for 30 minutes after decontamination
- record on the cleaning log when the weekly decontamination procedures were completed

Guideline 3.4.7

A horizontal laminar flow cabinet should not be used to prepare hazardous drugs because of the risk of aerosolized drug particles being propelled out of the cabinet on to personnel and into the room.

Potential infectious agents (e.g. BCG vaccine) and hazardous drugs should not be prepared in the same BSC, due to the possibility of cross contamination, A closed system preparation device should be used for preparation of BCG vaccine on the counter top or in an alternate designated BSC.

Standard 3.5 Equipment for Parenteral Hazardous Drug Preparation

Hazardous drugs should be prepared using appropriate equipment to ensure product sterility and optimal protection for the health care worker and should address the following:

- sterile disposable supplies are used for all hazardous drugs and doses
- luer-locking devices should be used, whenever possible
- polyvinyl chloride-free (PVC-free) equipment is required for certain drugs
- closed-system drug transfer devices offer additional protective benefits to workers for both preparation and administration of hazardous drugs
- closed-system drug transfer devices may be used in conjunction with a BSC to prepare hazardous drugs, but should not be used as a substitute for a BSC

Guideline 3.5.1

Closed-system drug transfer devices should be used whenever possible for transfer of hazardous drugs from primary packaging (e.g. vials) to dosing equipment (e.g. infusion bags, bottles, pumps or syringes). Closed-system drug transfer devices have been demonstrated to limit potential aerosol generation and reduce potential worker exposure to sharps. Closed-system devices may not be used as a substitute for a BSC (see NIOSH Alert).

Guideline 3.5.2

When closed-system drug transfer devices cannot be used, all devices for transfer and parenteral delivery of hazardous drugs should be equipped with luer-locking connections to reduce the potential for spillage subsequent to accidental disconnection.

Guideline 3.5.3

In order to minimize patients exposure to the plasticizer DEHP [di-(2- ethylhexyl)phthalate] which may be leached from PVC infusion bags or sets, some hazardous drugs should **not** be administered in equipment that contains PVC. For these drugs (e.g. paclitaxel, docetaxel, etoposide), non-PVC equipment should be used for drug preparation and drug administration according to the manufacturers guidelines.

Standard 3.6 Personnel

Strict procedures to ensure personnel safety should be followed in the preparation and handling of all anti-cancer drugs identified as hazardous drugs.

Guideline 3.6.1

Preparation, reconstitution, administration and disposal of hazardous drugs should be performed by trained personnel to protect the handler, the drug and the environment.

Guideline 3.6.2

Workers should follow protective guidelines, use protective equipment and wear protective clothing in order to minimize the release of particles into the parenteral preparation environment leading to possible contamination of the final product(s) and to decrease the possibility of personal exposure to hazardous drugs.

Recommended protective clothing includes:

- two pairs of disposable, powder-free protective gloves which are long enough to reach – one pair under the cuff of the gown and the other pair over the cuff of the gown
- protective gloves should be changed every 30 minutes or immediately if they are torn, punctured or contaminated
- a long sleeved, back closure, low permeability, disposable protective gown with solid front and tight fitting cuffs
- protective gown is changed daily or when contaminated and is not worn outside the hazardous drug preparation area
- disposable hair covers, including facial hair covers, surgical masks and shoe covers should be worn at all times during preparation of hazardous drugs in the sterile preparation area
- goggles are recommended when any projection risk is present. In most cases the viewing window of the BSC should offer adequate protection against any possible spray of solutions during hazardous drug preparation. Goggles and a mask should be worn when cleaning a spill and when decontaminating the BSC.
- NIOSH approved respirator type masks (e.g. N95) should be worn when the viewing window of the BSC is raised, when cleaning a hazardous spill and when decontaminating the BSC both inside and outside the BSC

Guideline 3.6.3

There should be no eating, drinking, chewing gum, applying cosmetics or storing food in or near the preparation area. Personnel working in the hazardous drug sterile preparation area should remove body jewelry that can interfere with the fit of gloves, gowns, and any visible body piercing above the neck.

Guideline 3.6.4

An eye wash station should be located in the anteroom and a safety shower should be readily accessible. Eyes that become contaminated should undergo sustained irrigation with either a commercial eye irrigation solution or sodium chloride (0.9%). Due to the potential for water pressure damage to the eye, it is not recommended to irrigate the eye directly with running water from a tap (ISOPP Standards of Practice 2007).

Guideline 3.6.5

Employees who are pregnant, attempting to conceive or father a child, or are breast feeding may request to be transferred to alternate duties, which do not involve handling hazardous drugs. A policy should exist to provide direction for personnel in these situations.

Guideline 3.6.6

Whenever possible, personnel with upper respiratory infections, conjunctivitis, cold sores or cutaneous infections should be excluded from preparing anti-cancer drug admixtures. Personnel receiving immunosuppressive therapy should be informed they have the option to be excluded from preparing anti-cancer drug admixtures.

Guideline 3.6.7

Staffing must be sufficient to allow for adequate breaks for those working in the hazardous drug sterile preparation room. Often staff work in isolation and sufficient breaks must be provided to maintain concentration. It is recommended that no more than two hours be spent working at the cabinet or isolator without a break (ISOPP Standards of Practice 2007).

Standard 3.7 Receiving and Storage of Hazardous Drugs

Strict procedures to ensure personnel safety should be followed for the receipt, transportation, handling and storage of hazardous drugs in the institution.

Guideline 3.7.1

The multi-departmental policies and procedures on safe handling of hazardous drugs should include guidance for receipt, transport and storage of these products.

Guideline 3.7.2

Any person who opens a container to unpack or handle hazardous drugs should wear two pairs of protective gloves. Staff should wash their hands after handling hazardous drug vials. Wearing protective gloves is not a substitute for hand washing.

Hazardous drugs requiring refrigeration should be unpacked and refrigerated immediately upon receipt.

Packages with visual signs of damage should be quarantined immediately and the supplier should be contacted. It is not advisable to return damaged hazardous drug vials to the supplier. The damaged vials should instead be disposed of appropriately into hazardous waste.

Guideline 3.7.3

Hazardous drugs should be stored as follows:

- separate from other inventory in a manner that prevents hazardous drug contamination and exposure to personnel
- in properly labeled containers, shelves, and bins
- with barriers and other design features on bins and shelves to contain accidental leakage and reduce the chance of drugs falling to the floor
- refrigerate hazardous drugs in individual leak and break-proof bins separate from non-hazardous drugs

Access to areas where hazardous drugs are stored should be limited to authorized personnel.

Standard 3.8 Preparation of Hazardous Drugs

Hazardous drug preparation should involve a specific technique to ensure the integrity of the product and personnel safety. Personnel should be trained as per Standard 2.1.2.

Guideline 3.8.1

Each institution that prepares hazardous drugs should maintain a current list of hazardous drugs available at their site.
A list of hazardous drugs requiring special handling is available in the NIOSH Alert 2004-165 or on the website at *www.cdc.gov/niosh*.

Guideline 3.8.2

Three basic criteria should be met when hazardous drugs are prepared:

- protection of the product
- protection of personnel
- protection of the environment

Guideline 3.8.3

Hazardous drugs should be prepared in a properly equipped area in the pharmacy (or pharmacy satellite) of the organized health facility by staff trained in the special techniques to optimize the basic criteria listed in Guideline 3.8.2.

Guideline 3.8.4

The following procedures describe a method for the preparation of injectable hazardous drugs. There are 3 principles to respect:

- place all the necessary items for manipulation in the hood to minimize movement in and out of the BSC
- do not overload the working area
- work six (6) inches away from the grill and sides of the BSC

General

- wash hands thoroughly with soap and water as per local guidelines/procedures before gloving and after gloves are removed
- clean the interior surface of the BSC as described in Guideline 3.3.4
- take care to avoid puncturing of gloves and possible self-inoculation
- wipe vials with 70% alcohol to remove hazardous drug contamination before placing inside the BSC
- wipe or spray outer wrapping of supplies with 70% alcohol prior to placement inside the BSC
- keep outer wrapping away from the viewing window to avoid disruption of air flow
- use only luer-locking syringes and devices, except with some pediatric doses
- minimize coring by using each needle for a maximum of three (3) punctures (e.g. reduce risk of needle becoming dull)
- minimize cross-contamination by using each alcohol swab for a maximum of three (3) swipes
- use syringes with sufficient capacity to avoid filling more than 75% of the barrel length of the syringe, but small enough to measure the contents with acceptable accuracy, as follows:
  - 3 mL syringe no more than 2.3 mL
  - 5 mL syringe no more than 3.8 mL
  - 10 mL syringe no more than 7.5 mL
  - 20 mL syringe no more than 15 mL
  - 30 mL syringe no more than 22.5 mL
  - 60 mL syringe no more than 50 mL

- check reconstituted solutions to ensure complete dissolution before withdrawal from the vial/ampoule or when storing for future use
- adjust solution volume and/or eliminate any air bubbles in the syringe before taking the needle out of the vial
- cap needles upon filling using a hands-free system or attach a luer tip. The plunger should be drawn back to remove any hazardous drug from the hub of the needle and a fresh needle should be attached before injecting into IV bags or before delivery to nursing station (if applicable). Syringes should contain no excess hazardous drug solution.
- close attached intravenous sets and secure from any hazardous drug leakage
- check reconstituted solutions to ensure complete dissolution before withdrawal from the vial or ampoule
- visually inspect the final product for particulate matter, physical incompatibility or leaks. In some provinces, a licensed pharmacist must inspect the final product. Pharmacists should routinely inspect all products for intrathecal use with the aid of a lamp. Literature is available which indicates intrathecal injections should be routinely filtered prior to final dispensing (Hosp Pharm).
- prepare only one patient's treatment at a time and limit preparation in the workspace of the BSC to one drug at a time

<u>Reconstitution of Vials</u>

- expose rubber stopper and wipe with a fresh sterile alcohol swab and allow to fully air dry. At least 10 seconds is required for maximum cell kill. Vial surface should be dry, to avoid introduction of alcohol into the vial
- reconstitution devices that eliminate pressure gradients may be used to admix and/or withdraw hazardous drug solutions from the vial. Minimize coring by using each needle for a maximum of three (3) punctures
- after removal of the solution aliquot, wipe the top of the vial with an alcohol swab to remove any droplets of hazardous drug

<u>Handling Ampoules</u>

- ensure contents of ampoule are below the neck of the ampoule before opening
- tap ampoule with finger to remove fluid from upper section
- file around neck if necessary
- wipe neck of ampoule with an alcohol swab
- use ampoule breaking device or wrap swab around neck, grasp with thumb and index finger and snap open using a motion away from you
- discard head of ampoule into sharps container
- for dry ampoule, slowly add diluent down inside ampoule wall; tilt and rotate the ampoule to ensure wetting of all powder; agitate slowly to dissolve
- withdraw solution from the ampoule using a filter needle or a filter straw that has a using a 5-micron particulate filter. Adjust to volume after removal of filter. Do not use this filter for teniposide or for the solvent used for amsacrine and diaziquone reconstitution
- remove trapped air in syringe or adjust volume by capping needle, tapping syringe, drawing back on plunger, then advance until solution appears in needle hub. Adjust to correct volume by returning excess solution to ampoule.
- dispose of solution in ampoule by drawing into a syringe, capping syringe and disposing in hazardous drug waste (sharp) container. If the hazardous drug is stable for more than 24 hours and will likely be used, transfer remaining hazardous drug into a sterile pyrogen free vial and label and date appropriately

Preparation of Anti-Cancer Drug Dose Admixtures in Small Volume Syringes

- techniques and devices used in the safe and accurate withdrawal of hazardous drugs from a vial should support minimizing the production/release of hazardous drug aerosols and vapours, maintaining the sterility of hazardous drugs and preventing leakage/spillage
- whenever possible, hazardous drugs should be drawn into syringes using closed-system drug transfer devices with locking connections
- if a closed- system drug transfer device cannot be used, luer-lock syringes should be used and dispensed with a leur lock syringe cap

Preparation of Anti-Cancer Drug Dose Admixtures in Large Volume Parenteral Solutions

- large volume parenteral solutions of hazardous drugs should always be mixed inside the BSC
- hazardous drug transfer from the vial should be carried out using closed-system drug transfer devices whenever possible
- closed-system drug transfer devices that achieve dry connections between the administration set (IV line) and the final admixture container allow for spiking the container with a secondary IV set and priming the IV line using backflow from the primary, non hazardous solution to safely occur on the nursing unit. This eliminates the potential contamination of the IV set within the BSC and the risk of dislodging the IV set during transport between the BSC and the nursing unit

Preparation of Anti-cancer Drug Dose Admixtures in Ambulatory Infusion Devices

- fill the infuser with the calculated volume of diluent
- remove the winged, leur-lock cap from the delivery tubing to allow the line to prime with diluent (non-drug) solution. Priming of the IV administration tubing with non-hazardous drug solution reduces potential for spillage and hazardous drug exposure at the time of administration
- hold the distal end of the tubing above an alcohol swab until three drops of diluent flow from the tubing to confirm that the contents of the infuser system are flowing through the tubing and the tubing is clear of air and primed to the end of the line
- add the calculated volume of hazardous drug to the infuser
    i. closed system drug transfer devices are recommended at all steps of hazardous drug dose preparation to prevent the release of hazardous drug aerosols and vapours
    ii. leur-lock fitting should be used for connections made during manipulation of hazardous drugs when closed drug transfer devices are not available

Standard 3.9 Administration of Hazardous Drugs

Included for reference information only.

Safety precautions should be followed during the administration of all hazardous drugs to prevent undue exposure of the health care worker and the patient.

Guideline 3.9.1

Protective clothing as described in 3.6.2 should be worn during the administration of all hazardous drugs to offer the nurse protection from possible hazardous drug exposure (two pairs of protective gloves and a protective gown).

Guideline 3.9.2

Whenever possible, a closed-system should be used for administration of parenteral hazardous drugs. If closed-system devices are not available, luer-lock syringes may be used. Infusion pump fittings with luer-lock connections should be used to minimize leakage and separation of the fittings. All Y site connections should be taped securely.

Guideline 3.9.3

During administration, a plastic-backed absorbent pad should be placed under the administration set. The pad will minimize the spread and protect the patient's skin in the event of an accidental leakage.

Guideline 3.9.4

Production of aerosols should be avoided. Tubing should never be removed from an IV bag containing a hazardous drug. Do not disconnect tubing from the patient until the tubing has been thoroughly flushed with a non hazardous drug solution. Remove the IV tubing and bag intact and dispose into hazardous waste.

Guideline 3.9.5

Use of a needle-safe system is recommended and is legislated in some provinces.
If needle-safe technology is not utilized, to avoid accidental skin punctures, needles should **not** be recapped or clipped after use, but should be discarded directly into the designated hazardous drug sharps container. If the needle must be detached from the syringe or replaced with a new needle, proceed with caution. The one-handed method for needle capping is recommended.

Guideline 3.9.6

Gowns should be discarded on leaving the anti-cancer drug administration area. Protective gloves should be worn and discarded after each use and hands washed thoroughly.

Guideline 3.9.7

Personnel administering anti-cancer drugs should be trained in procedures to manage accidental skin or eye contact with hazardous drugs. Training should include the proper disposal of hazardous drug contaminated supplies and materials.

Guideline 3.9.8

Infusion pumps should be made available for use in inpatient or ambulatory care as required. Policies and procedures should be made available for preparing and handling mechanical and electronic devices**.**

Standard 3.10 Transport of Hazardous Drugs

Procedures for transporting hazardous drugs should be developed and maintained to protect and secure delivery of hazardous drugs.

Guideline 3.10.1

Three basic criteria should be met when hazardous drugs are transported from the pharmacy department:

- protection of the product
- protection of personnel
- protection of the environment

Guideline 3.10.2

Hazardous drugs should be easily identifiable by all personnel involved in their handling. Special precautions should be followed to prevent breakage, minimize exposure and contain spills when transporting hazardous drugs within the health care facility. Hazardous drugs should be placed in 4 mil sealable plastic bags or leak proof, puncture resistant containers. They should then be securely transported to minimize the possibility of a hazardous drug spill.

Guideline 3.10.3

All individuals involved in the transportation of hazardous drugs should have quick and reasonable access to a spill kit and be trained in methods to handle hazardous drug spills.

Guideline 3.10.4

Pneumatic tubes or other mechanical transport systems should **not** be used to transport hazardous drugs.

Guideline 3.10.5

All of the above apply to transportation outside the health care facility. Appropriate packaging materials should be used to provide cushioning. Packaged hazardous drugs should be properly labeled for transportation to alert the handler to hazards of the package contents. Compliance with federal Transportation of Dangerous Goods Acts and Regulations are required, when applicable.

Standard 3.11 Hazardous Drug Waste

Written policies governing the identification, containment, collection, segregation and disposal of hazardous drug waste materials should be established and maintained.

Guideline 3.11.1

All hazardous drug waste should be separated from general waste. All hazardous waste should be separated between breakable and non breakable and placed in specially marked thick plastic bags or leak-proof containers specifically labeled containers labeled with the hazardous drug hazard symbol. Receptacles should be kept in all areas where hazardous drugs are prepared or administered.

Guideline 3.11.2

Contaminated needles, syringes, ampoules, broken glass, vials, intravenous sets and tubing, intravenous and intravesical catheters should be placed into designated leak-proof and puncture proof sharps containers that clearly and visibly display the hazardous drug symbol. They are placed in the BSC as needed, and when full, are transferred to the oncology waste container.

Guideline 3.11.3

Non-breakable contaminated materials including disposable gowns gloves, gauzes, masks, intravenous bags etc. should be placed in 4 mil thick, sealed plastic bags, hard plastic or hazardous drug containers that clearly and visibly display the hazardous drug hazard symbol. When full, they are placed in the oncology waste container.

Guideline 3.11.4

Institutional procedures should be in place to ensure hazardous drug waste is collected, stored and removed from the facility in an appropriate manner.

Guideline 3.11.5

Hazardous drug waste should be disposed in accordance with all applicable provincial, federal and local regulations for the handling of hazardous and toxic waste.

Guideline 3.11.6

Hazardous drug waste should not be mechanically or manually compacted.

Guideline 3.11.7

Hazardous drug waste should be destroyed in an incinerator approved for the destruction of hazardous drugs. If access to an appropriately licensed incinerator is not available, transport to and burial in a licensed hazardous waste dump is an acceptable alternative.

Guideline 3.11.8

Un-reconstituted or unopened vials, ampoules, or bottles should be returned with permission to the distributing agent.

Standard 3.12 Hazardous Drug Spills

Hazardous drug spills should be cleaned up immediately by properly trained personnel following established policies and procedures for spill management and clean up.

Guideline 3.12.1

Spill kits, containing all materials and equipment necessary to clean a spill, should be available and readily accessible at each area where hazardous drugs are received, stored, prepared and administered.

Guideline 3.12.2

Spill kits may be assembled or purchased. Key components of a spill kit include:

- 2 pairs of protective gloves
- impermeable protective gown, hair and shoe covers
- safety glasses or splash goggles
- NIOSH approved respirator mask
- absorbent plastic backed sheets or spill pads
- incinerable absorbent material (e.g. gauze pads, spill towels, absorbent polymer)
- decontaminating agent (e.g. detergent and water or commercial equivalent decontamination towelettes)
- at least 2 sealable plastic waste bags marked "Hazardous Drug Waste"
- warning sign and plastic "caution tape" (e.g. to quarantine spill area)
- disposable scoop (e.g. for collecting glass fragments)
- puncture-resistant container (e.g. for glass fragments)
- instructions on the management of a hazardous drug spill
- institutional report forms for recording the spill incident

Guideline 3.12.3

All individuals who routinely handle hazardous drugs should be trained in proper spill management and cleanup procedures and should be required to demonstrate competence in spill management. Training and competency assessment should be documented.

Guideline 3.12.4

The circumstances and handling of each hazardous drug spill should be documented. Health care personnel exposed during spill management should complete an incident report or formally document the hazardous drug exposure.

Standard 3.13 Handling Hazardous Drugs for Oral Use

Safe handling of oral and topical anti-cancer drugs requires the application of all the principles that apply to the supply and distribution of all hazardous drugs.

Guideline 3.13.1

Hazardous drugs for oral use must be handled in a manner which avoids skin contact, the liberation of aerosols or powdered drug into the air and cross-contamination with other drugs. Preference should be given to manufacturers that package tablets and capsules in protective strip packaging.

Guideline 3.13.2

Additional precautions include:

- use of protective gloves to dispense oral hazardous drugs is recommended.
- hands must be washed thoroughly after each dispensing
- designated counting trays should be used and cleaned after each use
- counting machines must not be used
- suitable containers for dispensing must be used to avoid any adverse storage effects on the hazardous drug

- childproof caps must be used when dispensing non-blister packs of containers of oral chemotherapy for use outside the health care setting. Childproof caps can be omitted when requested by the patient, because they are unable to open them
- crushing or cutting tablets and opening capsules must not be carried out in the pharmacy outside a Class II BSC because of unacceptable risk of exposure
- all layers of packaging and containers must have a hazardous warning label
- oral hazardous drugs must be stored in a designated area of the pharmacy and clearly labeled with hazardous warning labels

SECTION 4 STANDARDS FOR A CLINICAL PRACTICE IN ONCOLOGY PHARMACY

Standard 4.1 Professional Knowledge and Skills

Oncology pharmacists should acquire and be able to apply a broad integrated knowledge in caring for cancer patients and meeting the requirements for pharmaceutical care of the cancer patient.

Guideline 4.1.1

To meet the societal, professional and practice responsibilities the oncology pharmacist requires the knowledge and insight gained from a broad background in the pharmaceutical, medical, research, management, basic and social sciences, humanities and population health areas of expertise.

Guideline 4.1.2

In order to provide a desired level of care for cancer patients the oncology pharmacist should function as the patient's advocate and develop the required skills necessary for communication, collaboration, problem identification and resolution, critical thinking, self assessment, ethical decision making, knowledge of carcinogenesis and essential aspects of molecular biology.

Oncology pharmacists should use the principles of scientific inquiry and be prepared to think analytically, clearly and critically while solving problems during daily practice. They should be able to systematically find, appraise and apply information to make informed, evidence-based decisions.

Guideline 4.1.3

Each oncology pharmacist is responsible for ensuring their own initial and continuing competence in this specialty practice area.

Guideline 4.1.4

The oncology pharmacist should apply the necessary retrieval techniques to access the required information and to critically appraise and analyze the information including adequacy of research design, statistical testing, relevance, applicability, accuracy, reliability, validity and generalizability. The oncology pharmacist should be able to integrate new information with existing information to establish recommendations for appropriate drug use.

Standard 4.2 Team Work

The oncology pharmacist should work as a member of the health care team. The establishment of a good working relationship with medical, allied health and nursing staff, as well as community health professionals is fundamental. Each health worker is responsible for sharing information with other providers to ensure patient safety and optimal treatment outcomes.

Guideline 4.2.1

Oncology pharmacists should maintain a visible, presence on the health care team. Participation in the team may occur during patient care rounds, multidisciplinary team conferences or during informal discussions.

Guideline 4.2.2

When feasible, assignment of oncology pharmacists to specific disease sites is encouraged.

Standard 4.3 Medication Reconciliation

Medication Reconciliation is an Accreditation Canada Standard (2008) with an explicit focus on the safe management of medications. It includes an effective process to reduce errors and harm associated with loss of medication information during transitions of care. It is a collective and collaborative, multidisciplinary and professional responsibility.

Guideline 4.3.1

A complete list of a patient's current medications, allergies, and medication sensitivities should be obtained and documented upon admission to the organization in all relevant sites of care. This information is updated at all visits whenever medications are prescribed and administered so an assessment of the potential effect of medications on the patient's treatment can be evaluated.

Guideline 4.3.2

All new medications prescribed or administered should be reconciled against the patient's medication list during the patient's care. Patients transferred between services or levels of care should have all medications reconciled. If a new medication is prescribed (or changes are made to the current regimen), the patient's medication list in the health record should be updated and a copy of the updated list provided to the patient.

Guideline 4.3.3

A complete list of medications should be given to the patient upon discharge, and communicated to the next known provider or service when the patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization.

Standard 4.4 Pharmaceutical Care

Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes to improve the patients' quality of life. Oncology pharmacists, in partnership with cancer patients, their families and other health care providers, should use their specialized knowledge and skills to meet the drug-related needs of cancer patients. To provide continuity of care to individual cancer patients the oncology pharmacist should be responsible for seamless pharmaceutical care, regardless of service provider. Each oncology pharmacist should be accountable and responsible to the cancer patient.

Guideline 4.4.1

In provision of pharmaceutical care for cancer patients, oncology pharmacists require basic knowledge related to:

- tumour type
- epidemiology
- clinical features of the cancer disease
- natural history of the cancer disease

- diagnosis including pathology and histologic subtypes
- how treatment may differ by subtype, staging and grade
- treatment options including the risks and benefits of various therapies

Guideline 4.4.2

Pharmaceutical care is based on a process by which drug-related problems are identified, solved and prevented. In oncology, unlike other areas of practice, adverse drug events are common and usually predictable. Many anti-cancer drugs are administered at a maximum tolerable dose, the upper limit of which is usually defined as unacceptable toxicity (side effects). Pharmaceutical care of the oncology patient should concentrate on identification of unexpected or unusual drug-related problems and on optimal supportive measures when any drug-related problem occurs. Whenever possible, supportive measures should be considered to help prevent expected drug related problems (e.g. appropriate antiemetic).

Guideline 4.4.3

Pharmaceutical care requires the oncology pharmacist to establish a covenantal relationship with the cancer patient and family. Every cancer patient is eligible for pharmaceutical care and he/she can autonomously consent to the degree in which they receive this care. Consequently, the oncology pharmacist is able to prioritize the cancer patients based on the need for pharmaceutical care.

Guideline 4.4.4

If it is impossible to provide pharmaceutical care for all patients some criteria for identifying cancer patients who would most benefit from pharmaceutical care include:

- patients whose clinical state or condition may affect medication absorption or disposition, alter dosage requirements, or predispose them to adverse drug reactions or medication toxicity
- patients with organ dysfunctions which may affect anti-cancer drug metabolism or elimination (e.g. hepatic or renal dysfunction)
- patients with comorbidities which may limit drug dosing (e.g. cardiac dysfunction and anthracycline drugs) or which may affect outcome from systemic therapy (e.g. diabetes, COPD)
- populations (e.g. geriatrics, pediatrics) where age, weight, or physiologic parameters are important considerations in determining appropriate medication therapy
- patients on multiple drug therapy (in addition to the many drugs used for cancer treatment)
- patients taking non-cancer medications with a narrow therapeutic index (such as aminoglycosides and digoxin) or drugs with a high likelihood for drug interactions with the cancer treatment drugs
- patients taking investigational, special access or compassionate release medications
- patients taking medications in doses greater or less than recommended in the treatment regimen or by the manufacturer or other recognized references
- other regimen specific criteria

Guideline 4.4.5

The oncology pharmacist should interview cancer patients for the purpose of obtaining medication histories and medication reconciliation.

The medication history should contain information relating to:

- adverse drug reactions, including allergies
- past and currently prescribed medication therapy including the name of the drug, dose, frequency of administration, indication and duration of therapy
- the patient's usual laboratory, in order to obtain or verify laboratory tests as needed
- non-prescription medication use
- use of alternative/complementary therapies
- compliance with prescribed medication regimens
- name of physician and community pharmacy

Guideline 4.4.6

The oncology pharmacist should identify, prevent and resolve drug-related problems including, but not be limited to:

- taking or receiving a non-cancer treatment medication without valid indication
- needing pharmacotherapy, not yet prescribed, especially for supportive care of predictable treatment-related toxicities
- taking a medication for an inappropriate indication
- taking an inappropriate dose of an indicated medication
- experiencing an adverse drug reaction, including drug-induced disease or drug sensitivity
- therapeutic duplication
- experiencing a drug-drug, drug-food, drug-lab test interaction, or allergy to a drug or class of drugs
- not taking or receiving the drug prescribed or non-compliance, due to lack of understanding or a lack of financial resources
- drug dependency
- other habits or practices which may lead to medication-related problems

Guideline 4.4.7

It is understood that the primary responsibility for selection of anti-cancer therapy resides with the oncologist (or other physician) in agreement with the patient. Other outcomes may be determined by the oncology pharmacist. The oncology pharmacist should establish these desired outcomes of drug therapy in discussion with the physician, the patient or delegate, and other health care professionals as required.

Guideline 4.4.8

The oncology pharmacist should monitor the outcomes from drug therapy and if necessary and possible, plan revisions to better achieve the desired outcomes.

Guideline 4.4.9

The oncology pharmacist should assess the patient for development of drug-related problems throughout the entire treatment protocol and beyond. The oncology pharmacist should evaluate:

- the cancer patient's response to drug therapy and achievement of the therapeutic outcomes in particular the symptom management drug therapies associated with anti-cancer treatment
- adverse effects from drugs including allergies and toxicities in particular serious/life threatening or unexpected toxicities from anti-cancer drugs

- changes in the clinical condition of the cancer patient (e.g. altered kinetics of drug absorption, distribution, metabolism, or excretion) which necessitate an alteration in drug therapy or dosage
- changes in patient status leading to delay or discontinuation of therapy and the possibility of hospitalization

Guideline 4.4.10

When a cancer patient is transferred from one service to another in hospital or is discharged from the hospital to the community, the oncology pharmacist covering the sending service should communicate a summary of the patient's medication history and specific outcome monitoring parameters to the pharmacist and physician covering the receiving service.

The communication may be in written or verbal form or a discharge summary sheet to facilitate desirable outcomes including:

- enhanced consistency of care
- fewer drug related problems
- improved quality of life

Guideline 4.4.11

The oncology pharmacist should document provision of pharmaceutical care in the patient health record in accordance with institutional (clinic) and pharmacy policies and procedures.

Standard 4.5 Patient Care Consultation

Oncology pharmacists should be available for all patient care consultations requested by cancer patients, their agents, physicians, nurses or other patient care staff.

Guideline 4.5.1

Patient care consultations should involve the tasks of patient education, medication histories and reconciliation, or a complete pharmaceutical care evaluation.

Standard 4.6 Patient Counseling

Anti-cancer drugs are medications with a high probability of toxicity and it is essential cancer patients adequately understand their correct use. The oncology pharmacist should counsel cancer patients and their family members to address any concerns about the drug therapy, to provide specific drug information required for safe and appropriate drug therapy, to offer suggestions for the prevention or management of potential side effects and to promote compliance.

Guideline 4.6.1

Oncology pharmacists should be sensitive to the emotional aspects of the burden of cancer when planning for patient counseling and education.

All patients should be seen at least once by the oncology pharmacist for patient counseling.

Guideline 4.6.2

Verbal instructions should be supplemented with written information; (such as medication information sheets) and other aids as required, (e.g. audiovisual and compliance aids).

Guideline 4.6.3

The pharmacist providing medication counseling should provide written information to the patient on the following aspects of medication use:

- the name of the medication and its purpose (which may be specific to the patient's treatment regimen)
- physical appearances and storage
- route of administration, dose and duration of therapy
- possible side effects and precautions with the medication
- action to be taken in the event of a dosage omission
- possible adverse or toxic drug reactions and methods for prevention
- special considerations:
  - potential drug-drug interactions
  - drug-laboratory interactions
  - drug-food interactions
  - drug-disease interactions
  - drug-herbal interactions
- prescription refill information (included on the label)
- when to call the physician or go to the emergency department of the local hospital (e.g. when a potentially serious adverse drug reaction occurs or an important side effect persists greater than 24 hours).
- patients should be provided with details of how to contact medical, nursing and pharmacy staff to whom they can direct questions. Questions on compliance, treatment tolerance and adverse events should be addressed on each visit to the pharmacy

Guideline 4.6.4

Cancer patients should be advised of the following additional recommendations, as applicable to their situation:

- patients should be made aware of the importance of seeking urgent medical treatment, for signs of infection (fever greater than 38.5 degrees C for more than one hour, chills and cough with phlegm,, lethargy, unusual bleeding, bruising, mucositis, severe nausea or vomiting, or any other severe adverse effects which may be potentially life-threatening
- anti-cancer drugs are usually prescribed as a course of therapy and should be taken strictly as directed by the prescriber
- to minimize nausea and vomiting, oral anti-cancer drugs should be taken after meals unless otherwise specified
- when feasible, oral medication should be taken at the same time every day
- patients should be advised to always wash their hands after handling their oral anti-cancer drugs
- patients should be made aware of what to do if they vomit after taking a dose
- patients should be advised when to take supportive medication such as antiemetics
- the use of aspirin, medications containing aspirin and other non-steroidal anti-inflammatory drugs should be avoided unless otherwise advised by the prescriber
- the use of suppositories should be avoided unless on the recommendation of their treating specialist

- advice on contraception may be necessary, as pregnancy is usually contraindicated while taking cancer drug therapy. For females, oral contraceptives are usually not adequate contraception, since many cancer treatment drugs may interact to reduce contraceptive efficacy. Male patients should be counseled, where appropriate, to practice barrier contraception while taking these drugs.
- breastfeeding should be avoided, unless otherwise advised by the prescriber
- oral anti-cancer drugs should be stored in a secure, cool, dry place (unless otherwise indicated) and protected from exposure to direct sunlight
- tablets should not be crushed, and capsules should not be opened. Mixtures should be prepared according to accepted standards

Guideline 4.6.5

Patients should be informed of procedures for handling anti-cancer drug therapy waste products at home. A patient information sheet on "Hazardous Drug Waste Management in the Home" should be provided to assist with the process. Advice on the disposal of hazardous drugs should be offered. As a guide, patients should keep all waste, unwanted anti-cancer drugs or materials used in the application of topical anti-cancer drugs in a strong walled container. Pharmacies should accept patient returns of such hazardous materials and dispose of them in accordance with accepted standards.

Guideline 4.6.6

Oncology pharmacists should use discretion and consent when counseling cancer patients, particularly regarding adverse effects (e.g. it is important to inform without frightening).

Guideline 4.6.7

The oncology pharmacist should evaluate the effectiveness of counseling on the patient's medication knowledge through questioning and/or follow-up. When possible, the oncology pharmacist should reinforce the medication knowledge through repeat counseling on later visits.

Guideline 4.6.8

The oncology pharmacist should document the occurrence of the medication consultation in the health record.

Standard 4.7 Drug Information

The oncology pharmacist should provide patient specific drug information to health care personnel through the integration of pathophysiological, pharmacotherapeutic, pharmacokinetic, pharmacodynamic, economic and ethical considerations. Drug information needs to be sustained by evidence-based medicine, whenever possible.
This is a fundamental professional responsibility.

Guideline 4.7.1

The oncology pharmacist should be able to retrieve and evaluate the relevant literature and integrate new information with existing information to establish recommendations for appropriate drug use. Critical appraisal skills are required by the oncology pharmacist to integrate information and evidence with individual patient medication decisions.

Guideline 4.7.2

The oncology pharmacist should provide information on drugs used in cancer care by:

- responding to drug-related questions posed by oncology staff and patients
- providing information related to a specific patient's pharmacotherapy
- recommending oncology drug-related references and patient counseling materials
- providing an oncology drug-related newsletter to oncology staff
- providing in-service presentations based on demonstrated need or request
- participation in journal club activities within the pharmacy or with other oncology services
- participation in activities of the Pharmacy and Therapeutics Committee and participation in other oncology based committees as appropriate
- advising providers on medication related policies and procedures
- communicating knowledge of Pharmacy and Therapeutics Committee (or equivalent) decisions regarding approved drug therapy per disease site
- liaison with the Pharmaceutical Industry and the health care team
- liaison with University Students/ Residents (education projects)

Guideline 4.7.3

The oncology pharmacist should act as a resource for the dissemination of oncology related drug information. This includes collaboration with other professionals and the public in addressing public health issues as they relate to oncology pharmacy practice. The dissemination of oncology related drug information should also include the education of nursing, medical and allied health staff, as well as colleagues and pharmacy students.

Standard 4.8 Clinical Trials Research

Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and are consistent with Good Clinical Practice (GCP) and the applicable regulatory requirements. Guidance documents may be found on Health Canada's website at *www.ctg.queensu.ca/private/pharm_net/Pharmacist_Network_Manual/Revised_PN_2009Feb.pdf*.
The oncology pharmacist should be involved in clinical trials and should be familiar with all aspects of trials including design, approval, implementation and regulations governing the conduct of clinical trials in Canada.

Guideline 4.8.1

Oncology pharmacists have developed a support network through the National Cancer Institute of Canada - Clinical Trials Group Pharmacists' Network (NCIC-CTG PN). A pharmacy staff member who works at a NCIC CTG participating centre is eligible to become a member. Members have access to many essential documents on the website, including the Pharmacist Network Manual at *www.ctg.queensu.ca/private/pharm_net/Pharmacist_Network_Manual.2009Feb.pdf*.
The manual provides guidance for oncology pharmacy staff that can be used for all clinical trials at their practice site.

Specific requirements for pharmacists involved with clinical trials at their practice site include:

- follow the standard pharmacy department policies and procedures for management of clinical trials. Oncology trials often study drugs in earlier phases of development and include more toxic drugs than found in clinical trails in other medical disciplines

- it is important to involve the oncology pharmacist in the cognitive review of each oncology clinical trial, but technical issues may incorporated into general pharmacy operations or may be managed by a pharmacy technician or other designate as determined by the institution
- where possible, the oncology pharmacist should ensure written informed consent has been obtained from the patient prior to initiation of study treatment. The document of informed consent must be presented to the patient in an unbiased manner the risks and benefits of participating in the study. The document must clearly state that the patient's care should not be affected if they decline participation in the study. Lastly, financial or other inducements must not be offered to the patient for study participation
- the oncology pharmacist should critically review the full protocol, the pharmaceutical sections and the investigators' brochure following the protocol review guidelines as outlined
- when pharmacy is in possession of code-breaking information (randomization lists), the procedure for revealing the treatment code should be clearly outlined in department trial procedures
- oncology pharmacists should provide drug information in the form of a data sheet on all investigational drugs used at the practice site
- the oncology pharmacist or designate should ensure that clinical trials drugs are received, stored and dispensed by the institutional pharmacy whenever possible. The oncology pharmacist or designate should maintain an accurate record of drug dispensed, returned to the sponsor or destroyed
- oncology pharmacists should monitor clinical trial patients with respect to dosing, adverse effects, compliance and concomitant medications using the Pharmaceutical Care Model of patient care and should take part in Oncology clinical trials and Tumour board meetings.
- all information pertaining to a particular trial should be organized in a format which allows for easy set-up and retrieval of information, either computerized or manual
- the oncology pharmacist or designate should evaluate overall pharmacy fees for reading the protocol and establish the cost/patient for pharmacy budget refunds within the pharmacy department standard procedures
- oncology pharmacists involved in oncology clinical trials should participate actively in the NCIC CTG PN or pharmacy group of the relevant Clinical Trials consortium. Additional information can be found within the NCIC CTG website at *www.ctg.queensu.ca*.

Guideline 4.8.2

Clinical trials are a significant component of oncology pharmacy practice at many cancer treatment centres. When necessary, the oncology pharmacist should develop methods to ensure continuity of care between the accrual site and secondary follow-up sites (seamless care). However, secondary sites may or may not be allowed to accrue new trial patients or to deliver the investigational medication(s), depending on the trial procedures. Patients may be required to visit the trial site for certain treatments or trial/clinic visits.

Guideline 4.8.3

There should be a formalized process to review the resource impact of clinical trials on the oncology pharmacy service, as well as educational and training needs.

Standard 4.9 Oncology Pharmacy Research

Oncology pharmacists are encouraged to initiate clinical and health services research appropriate to their practice, recognizing this as an important contribution to the knowledge base of oncology pharmacy and the development of oncology pharmacy practice.

Guideline 4.9.1

To facilitate this research initiative the oncology pharmacist should possess knowledge of epidemiology, statistical analysis, research protocol development and critical appraisal of published literature. In situations where the oncology pharmacists research expertise may be limited (e.g. determination of study sample size or the statistical analysis plan) the identification and recruitment of external expert personnel should be undertaken (e.g. statistician).

Guideline 4.9.2

Oncology Pharmacist initiated research should be compatible with the goals of the institution, with a focus on patient centred health outcomes, such as: improvement of quality of life, appropriate and cost effective drug research, survival (including disease-free, progression-free and relapse-free survival) and improved response rates.

Guideline 4.9.3

Presentation and publication of research results should be considered an integral component of the research process. The findings of any pharmacy initiated research should be published within two years of study completion to ensure relevance. The oncology pharmacist should retain publication rights from the study sponsor, regardless of outcomes.

Standard 4.10 Education and Staff Development

Each oncology pharmacist should be encouraged to participate in formal and informal education programs to develop, maintain and expand their specialized knowledge of oncology pharmacy practice.

Guideline 4.10.1

All staff involved in oncology pharmacy services should be provided with education and staff development programs. These programs should be based on a needs assessment that addresses the development, maintenance and improvement of professional competence.

Guideline 4.10.2

Regular attendance of the oncology pharmacist at oncology/oncology pharmacy specialty conferences and education meetings should be encouraged to maintain currency of the oncology pharmacist's specialist knowledge. New information should be shared with colleagues. Liaison with special interest groups in oncology and the Canadian Association of Pharmacy in Oncology (CAPhO) is recommended.

Guideline 4.10.3

When feasible, financial support should be provided by the oncology pharmacy department to enable this education.

Guideline 4.10.4

Oncology pharmacy specialists may be encouraged to obtain formalized accreditation (e.g. Board Certified Oncology Pharmacist (BCOP)) and post-graduate education in oncology pharmacy practice (e.g. Oncology Pharmacy Residency).

Standard 4.11 Clinical Pharmacy Practice in Pediatric Oncology

Pediatric oncology pharmacists should offer pharmaceutical care that takes into consideration the unique clinical characteristics of the child and their diagnosis that may impact on drug side effects and acute and long term toxicities. Pediatric cancer patients are distinct from their adult counterparts in that the majority of children (approximately 80%) will be cured of their cancer. Pediatric malignancies rank second only to breast cancer in terms of potential years of life saved. Increasing attention and emphasis is being placed on issues in long term survivors of pediatric cancer (e.g. health-related quality of life, second malignancies). In addition, the overwhelming majority of children are treated within the context of multi-centered clinical trials.

Guideline 4.11.1

All of the Standards for a Clinical Practice in Oncology Pharmacy documented in Section IV are applicable in the pediatric setting. Customization of certain parameters will be required to meet the needs of the pediatric oncology patient.

Guideline 4.11.2

Qualitatively, the diagnosis of cancer in a child impacts on the immediate family and society as a whole. Families are extensively involved in the treatment of their dependent children. For these reasons, the family should be included in all treatment related discussions and are important partners in achieving desirable pharmaceutical care outcomes.

Guideline 4.11.3

Pharmaceutical care in the child with cancer seeks to maximize both short and long term outcomes.

Guideline 4.11.4

Dosing accuracy is especially important in the treatment of infants and children. The pediatric oncology pharmacist should understand the importance of dosing guidelines and tracking the cumulative doses of all anti-cancer drugs.

Guideline 4.11.5

The pediatric oncology pharmacist should contribute to the care of pediatric oncology patients by determining appropriate dosages, delivery techniques, formulations and routes of administration for drugs used in treatment of childhood cancers, as well as assuring the safe handling of hazardous drugs.

Guideline 4.11.6

The pediatric oncology pharmacist should understand the importance of age and organ function and how they influence both acute and long-term drug toxicity and adverse reactions. The pediatric oncology pharmacist should be involved in the management of all cancer and drug related complications (e.g. nausea, infection, pain etc. in pediatric oncology patients).

Guideline 4.11.7

The pediatric oncology pharmacist should monitor blood counts and relevant organ function and adjust the pharmaceutical care plan accordingly

Guideline 4.11.8

For the child with cancer, seamless care is important since patients often move from the clinic/community setting and hospital over the course of the child's treatment program.

GLOSSARY OF TERMS

Adverse Event – All negative or unexpected responses to medicine.

Anti-cancer Drugs – refers to the wide range of drugs (therapeutic options) used in the treatment of malignant diseases, including categories such as hazardous drugs, immunotherapies, targeted drug therapies, hormonal treatments, etc.

BCOP – Board Certified Oncology Pharmacist, certification awarded by the American Board of Pharmaceutical Specialties.

Best Practices - A Best Practice is a technique or methodology that through experience and research has proven to reliably lead to a desired result. A commitment to best practices is a commitment to using all the knowledge and technology at one's disposal to ensure success. Best Practices have 5 key components: Best skills, Best processes, Best solutions, Appropriate resources and Continuous improvement.

Biohazard – An infectious agent presenting a real or potential risk to humans and the environment.

Biomedical Sciences – Content in anatomy, biochemistry, biostatistics, immunology, microbiology, molecular biology, physiology and pathophysiology.

Body Surface Area (BSA) – A mathematical calculation using weight and height to measure the surface area of an individual. This measure is used to more accurately calculate the dosing of some toxic medications because it is a more precise measure of metabolic ability than weight alone.

Carcinogen – any cancer producing substance.

Chemotherapy – The treatment of disease by chemical means and currently used to describe drug (chemical) therapy of cancer.

Children's Oncology Group (COG) – The Children's Oncology Group (COG) is a North American research organization with international affiliations across the world. The primary objective of COG is to conduct collaborative clinical trials on new therapies for childhood cancer. At each member institute, patients with specific cancer diagnosis are treated exactly the same way, according to detailed protocols. Information about treatment is then pooled so that knowledge about childhood cancer can progress quickly and efficiently.

Clinical Trial – An investigation with human subjects intended to discover or verify the clinical or pharmacological effects of a drug or medical product. Phase I = efficacy, Phase II = safety, Phase III = Efficacy and safety, Phase IV = adverse events post marketing. Clinical Trials are sometimes referred to as clinical research.

Clinical Trial Protocol - A document that describes the rationale, objective(s) design, methodology, statistical considerations and organization of a clinical trial.

Closed System Drug Transfer Device – A drug transfer device is leak proof and air tight. The device mechanically prohibits the transfer of environmental contaminants into the device as well as prohibits the escape of hazardous drug or vapour concentrations out of the device..

Contamination – The deposition of potentially dangerous material where it is not desired particularly

where its presence may be harmful or constitute a hazard.

Cytotoxic – Possessing a specific destructive action on certain cells. Commonly used in referring to antineoplastic drugs that selectively kill dividing cells.

Decontamination – refers to the inactivation, neutralization, or removal of toxic agents (hazardous drugs), by mechanical or chemical means from all exposed surfaces using disposable cleaning materials and recommended or approved cleaning agents.

Decontamination of the BSC - Where parenteral hazardous drug admixtures have been prepared – refers to the removal of chemical contaminants from all exposed surfaces using disposable cleaning materials and recommended or approved cleaning agents. Training Manual for the Preparation of Parenteral Hazardous Drug Admixtures, Alberta Cancer Board Pharmacy, 8th ed May 2005 (see reference).

Designated pharmacist responsible for – Is the pharmacist most responsible for the administrative aspects of the service. Terms frequently used to describe this position may include manager, director, professional practice leader, or division head.

Disinfection – removal of viable organisms from surfaces using 70% alcohol or other appropriate disinfectant prior to and during the compounding of sterile hazardous drugs.

Drug Related Problems – A drug related problem is an actual or potential sign or symptom related to drug therapy and is undesirable to the patient.

Drug Use Evaluation (DUE) – The prospective or concurrent analysis of the patterns of use of drugs against a predetermined set of criteria, followed by assessment, implementation of corrective action and reassessment.

Extravasation – The escape of a vesicant or irritant hazardous drug from a blood vessel into surrounding tissues resulting in damage to the tissue.

Goals – define end results to be achieved

Guidelines - Guidelines are a derivative of a particular standard and are provided for guidance and interpretation of the Standard's intent and purpose. Guidelines are also presented to illustrate ways and means of complying with Standards.

Hazardous – Dangerous; risky; representing a health risk.

Hazardous Drugs – A hazardous drug is defined as a drug that due to its inherent toxicity presents a danger to health care personnel. These drugs are identified by one or more of six characteristics: carcinogenic; genotoxic, teratogenic; cause reproductive toxicity; cause organ toxicity at low doses in animal models or treated patients and structure; toxicity in new drugs that mimic existing drugs determined to be hazardous by the above criteria.
Hazardous drugs include anti-cancer drugs, some hormones, antiviral medications, immunosuppressants, and some monoclonal antibodies.

Health Services Research – is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structure and processes, health technologies, and personal behavior affects access to care, the quality and cost of health care, and ultimately our health and well-

being. Its research domains are individuals, families, organizations, institutions, communities and populations.

Hospital Pharmacist – one who meets the requirements of a regulatory body in Canada and practices in a facility approved or designated by a federal, provincial or territorial government, in accordance with the appropriate laws to provide health services treatment to persons suffering from disease or illness (may also refer to other organized health care settings.

Medication Incident – An event where an error in the drug process is identified and corrected before reaching the patient and which does not involve the actual administration or omission of a drug to a specific patient.

Medication Error – A patient related event which involves the incorrect administration or omission of a medication to specific patient.

Medication Misadventure – The unintentional, negative outcomes associated with drug therapy which are largely preventable.

Medication Profile – An ongoing record of patient specific information used to monitor drug therapy. This record includes all medications prescribed and dispensed to the patient.

Medication Reconciliation – is the process of identifying the most complete and accurate list of medications a patient is taking and using this list to provide correct medications for the patient anywhere within the organization. The process includes comparing prescriber's medication orders at the interfaces of care to that list, bringing discrepancies to the prescriber's attention and, if appropriate, making changes to the orders including omissions, duplications, interactions and name/dose/route confusion. Other steps in medication reconciliation include updating the medication list as orders change during the episode of care and communicating the updated list to the patient and next known provider of care.

Medication Use Evaluation (MUE) – A criterion-based, systematic process for evaluating the use of medication to ensure they are used appropriately, safely and effectively.

Medication Use Evaluation Program – a multidisciplinary Team and Practice Program conducted on behalf of patients by the Health Team and Administration.

Mission – A mission statement defines the long range purpose which oncology pharmacy practice strives to sustain.

Objectives – refer to those relatively short-term conditions to be achieved within a given period of time and are measurable evidence of progress leading to the achievement of the goals of the oncology pharmacy service.

Oncology Drugs – includes all classes of drugs employed specifically for treatment of the cancer patient e.g. hazardous drug, biological response modifiers, monoclonal antibodies, steroids etc.

Oncology Pharmacist – The oncology pharmacist delivers care to cancer patients, and meets all criteria for practice in the local setting (e.g., licensure, practice privileges).

Oncology Pharmacy – addresses the drug-related care of patients with cancer.

Oncology Pharmacy Program - encompasses education (residency, university) and research programs as well as patient care.

Oncology Pharmacy Service – embraces all aspects of contemporary pharmacy practice and applies it to the direct and indirect care of the patient with cancer.

Oncology Pharmacy Specialist - the oncology pharmacy specialist promotes optimal care of patients with various malignant diseases and their complications. These specialists are closely involved in: recognition, management and prevention of unique morbidities associated with cancer and cancer treatment; recognition of the balance between improved survival and quality of life as primary outcome indicators; and provision of safeguards against drug misadventures in a treatment area where novel and experimental drug therapies are frequently employed.

Outcomes – established performance descriptions that are quantifiable and measurable.

Pharmaceutical Care – is the direct responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.

Pharmaceutical Sciences – content in medicinal chemistry, pharmacology, toxicology and pharmaceutics (physical/chemical principles of dosage forms and drug delivery systems, biopharmaceutics and pharmacokinetics), and behavioral, social and administrative pharmacy (epidemiology, health care economics, pharmacoeconomics, practice management, history of pharmacy, ethical foundations of practice, and social and behavioral applications).

Pharmacy Practice – content in clinical laboratory medicine, clinical pharmacokinetics, communications applicable to pharmacy, complementary and alternative medicines, computer applications, delegated prescribing authority, disease-state management, drug distribution and drug administration, drug information and literature evaluation, emergency first-care, geriatrics, gerontology, health promotion and disease prevention, laws pertaining to practice, nutrition, outcomes documentation, pediatrics, patient evaluation, pharmacotherapeutics, physical assessment and prescription processing.

Practice sites - may include the primary care site, general hospital, a cancer centre and oncology specialty settings (e.g. blood and marrow transplant unit in a tertiary care hospital).

Pre-printed Orders – templates that specify the medicines and procedures required by a protocol. Pre-printed orders are intended to ensure accurate and consistent treatment of all patients on a protocol.

Professional Competencies – professional qualities including knowledge, skills, abilities, and attitudes necessary for the specialized practice of oncology pharmacy.

Protective gloves – minimum thickness of 0.1mm (=4mils), made of latex, nitrile, neoprene, or polyurethane and preferably latex-free due to increasing incidence of latex allergies, powder-free and with length sufficient to cover cuff of protective gown.

Protective gown – non-linting, closed-front, back fastening, long sleeves with tight-fitting cuffs, disposable and made of material that is sufficiently impermeable to hazardous drugs.

Protocol – a formal written document describing a standard treatment or regimen. Components of a protocol include patient eligibility, baseline and treatment tests, premedications, treatment delivery

details, dose modifications, precautions and the evidence supporting the treatment.

Randomization - is the allocation of treatment to a patient included in a study.

Regimen – see protocol.

Research – see clinical trial or health services research.

Roadmap – an abbreviated treatment plan which provides a visual representation of the tests, treatments and required observations produced by COG for each clinical trial. The document accompanies the protocol and contains the salient information about the drug, dose, route of administration and frequency. This document may be referred to as a synopsis, schema or treatment plan.

Seamless Care – is the desirable continuity of care delivered to a patient in the health care system across the spectrum of caregivers and their environments. Pharmaceutical care is carried out without interruption such that when one pharmacist ceases to be responsible for the patient's care, another pharmacist or health care professional accepts responsibility for the patient's care.

Standard – is a statement that defines the performance expectations, structure or process that must be in place for an organization to provide safe and high quality care, treatment and service.

Standards of Practice - reflect expectations essential to the contemporary practice of oncology pharmacy. The use of the word **"should"** indicates CAPhO considers an attribute necessary to ensure an optimal oncology pharmacy service.

Sterile preparation room/area – a room/area containing a BSC in which chemotherapy is prepared. The concentration of airborne particles is controlled/minimized to meet a specified airborne particulate cleanliness class

Systemic Therapy - Treatment using substances that travel through the bloodstream, reaching and affecting cells all over the body. National Cancer Institute (NCI)

Transport Containers – are classified as: primary, inner or outer.

Primary transport container: includes dispensing containers such as an intravenous solution bag, an elastomeric infuser, syringe, vial, ampoule, ointment jar, sealable poly bag, blister card, manufacturer supplied packaging or a prescription vial.

Inner transport container: typically a zippered or heat sealed plastic bag; should be sealed, leak-proof and see-through.

Outer transport container: should be suitable to enclose the hazardous drug product and robust enough to withstand normal conditions of transport and handling, e.g. a hard shell plastic box with a secure lid for transport within the facility; molded foam or corrugated cardboard for transport outside of the facility or a padded envelope.

Tumour Board – is a multidisciplinary group that reviews individual cases and recommends methods of treatment. The Tumour Board may be general or sub-specialized to specific types of cancer (e.g. breast cancer tumour board). In some provinces, the Tumour Board may be called Cancer Site Teams or Disease Site Group.

USP Chapter 797 – US Pharmacopeia (USP) revised general chapter <797> pharmaceutical compounding – sterile preparations. USP Chapter 797 is an enforceable standard that came into force in the United

States as of January 2004, and was revised as of June 2008. The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official USP articles or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations. In Canada, compounding of drugs is practiced primarily by pharmacists as an integral part of their profession and is regulated by the respective regulatory authorities in each province/territory. Standards similar to USP 797 do not come from Health Canada. However, compliance with USP Chapter 797 is becoming best practice for compounded sterile products in Canada.

REFERENCES

1 Accreditation Standards and Guidelines for Pharmacy Professional Programs in Canada: Canadian Council for Accreditation of Pharmacy Programs; 2006.

2 American Society of Clinical Oncology Policy Statement: Oversight of Clinical Research. Journal of Clinical Oncology 2003;21:2377-86.

3 Anon, Clinical Pharmacy Services in a Pediatric Hematology/Oncology Clinic – A Needs and Impact Assessment; 1995.

4 ASHP Guidelines on Clinical Drug Research. Am J Health-Syst Pharm 1998;55:269-73, Reviewed 2003, still appropriate.

5 ASHP guidelines on clinical drug research. Am J. Health-Syst Pharm 1998;55:369-76.

6 ASHP Guidelines on Handling Hazardous Drugs. Am J Health-Syst Pharm 2006;63:1172-93

7 ASHP guidelines on handling hazardous drugs. Am J Health-Syst Pharm 2006;63:1172-93.

8 ASHP Guidelines on Medication Use Evaluation. Am J Health-Syst Pharm 1996;53:1953-5.

9 ASHP guidelines: minimum standard for pharmaceutical services in ambulatory care. Am J Health-Syst Pharm 1999;56:1744-53.

10 ASHP statement on pharmaceutical research in organized health-care settings. Am J Health-Syst Pharm 1991;48:1781.

11 ASHP statement on standards-based pharmacy practice in hospital and health systems. Am J Health-Syst Pharm 2009;66:409-10.

12 ASHP Statement on the Roles and Responsibilities of the Pharmacy Executive. 2009;3:289-91.

13 ASHP. Suggested definitions and relationships among medication misadventures, medication errors, adverse drug events and adverse drug reactions. Am J Health-Syst Pharm 1998;55:165-6.

14 Beavers MB. Specializing in pediatric hematology and oncology. Am J Health-Syst Pharm 2007;64:812-13.

15 Berman, NJ. The Canadian Strategy for Cancer Control – A collaborative intersect initiative. Oncology exchange 2003;2:24-9.

16 Bourret JA, Demers RF, Wordell D, Irania M, Baker J, and Evangelista C. Medication Use Review Process and Information Systems Utilized for Oncology Chemotherapy Quality Improvement. Pharm Pract Manage Q 1996;16(1):1-17.

17 Canadian Cancer Statistics 2009: Canadian Cancer Steering Committee: Canadian Cancer Society; 2009.

18 Canadian Society of Hospital Pharmacists . Guidelines for Preparation of Sterile Products in pharmacies. 1996.

19 Chambers C, et al. Training Manual for the Preparation of Parenteral Hazardous Drug Admixtures, Alberta Cancer Board Pharmacy. 8th edition 2005.

20 Chemotherapy Policy and Procedures Manual. London Health Sciences Centre; 2001.

21 Cheo Recommendations of the Special Protocol Review Committee. Children's Hospital of Eastern Ontario; 2003.

22 Cohen MR, Anderson RW, Attilo N, Green L, Muller RJ, and Pruemer JM. Preventing medication Errors in cancer chemotherapy. Am J Health-Syst Pharm 1996;53:737-46.

23 Competency framework for specialist oncology pharmacists – inserted with the December, 2004 BOPA (British Oncology Pharmacy Association) newsletter. *www.bopawebsite.org/tiki-page.php?pageName=Position+Statements*

24 Connor TH, Anderson RW, Sessink PJ. and Spivey SM. Effectiveness of a closed system device in containing cyclophosphamide and ifosfamide in an IV admixture area. Am J Health-Syst Pharm 2002;59(2):

25 Cousins David. Current status of the monitoring of medication practice. Am J Health-Syst Pharm 2009;66(Suppl 3):549-56.

26 CSA Standard Z316,6-07 Evaluation of single-use and reusable medical sharps containers of biohazardous and hazardous drug waste. 2007.

27 CSA Standard Z317.10 Handling of waste materials in health care facilities and veterinary health Care facilities. 2008.

28 CSHP Position Statement on Medication Reconciliation, approved by CSHP Council, March 2009.

29 Curtiss FR, Fry RN, and Avey SG. Framework for Pharmacy Services Quality Improvement - A Bridge to Cross the Quality Chasm. J Manag Care Pharm 2004;10(1):60-78.

30 Executive summary of petition requesting specialty recognition of oncology pharmacy practice. Task Force on Specialty Recognition of Oncology Pharmacy Practice; Am J Hosp Pharm1994;5(1):219-24.
31 Finley R. The Influence of Clinical Practice Guidelines on Professional Practice and Decision Making. Highlights in Oncology Practice 1993;17(2):
32 Finley RS. Clinical Guidelines: Enhancing Patient Care versus Restricting Practice Autonomy. Highlights in Oncology Practice 1999;17:2
33 Gardner B, and Graner K. Pharmacists' Medication Reconciliation- Related Clinical Interventions in a Children's Hospital. Jt Comm J Qual Patient Saf 2009;35(5):278-82.
34 German Society of Oncology Pharmacy. Quality standard for the oncology pharmacy service with commentary. January 2003
www.esop.eu *(Library, Newsletter Nr.1/2004 Quapos.pdf)*
35 Grinded KA, Chambers CR, and Hicks J. Updating a survey for medication error prevention. Journal of Oncology Pharmacy Practice 2002;8(4):105-17.
36 Guide for Pharmaceutical Care in Oncology. Association des Pharmaciens des établissements de Sante du Québec (A,P.E.S,); 2002.
37 Guidelines for Counseling Patients Receiving Drugs Used in the Treatment of Neoplastic Disease: a Pharmacists Guide to Advisory Labels and Patient Information. Committee on Specialty Practice in Oncology; The Society of Hospital Pharmacists of Australia: The Australian Journal of Hospital Pharmacy 2001;31:1.
38 Guidelines for the Handling and Disposal of Hazardous Pharmaceuticals (including Hazardous Drugs): 1997.
39 Hepler CD. Clinical Pharmacy, Pharmaceutical Care, and the Quality of Drug Therapy. Pharmacotherapy 2004;24(11):1491-8.
40 ISOPP (International Society of Oncology Pharmacy Practice) standards of practice: safe handling of hazardous drugs. J Oncol Pharm Practice Supplement 2007;13:1-81.
41 Jacobson JO, Polovich M, McNiff KK, LeFebvre B, Cunnings C, Galioto M, Bonelli KR, and McCorkle MR. "American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards" Journal of Clinical Oncology,2009;25(Sept 28):1264.
42 Jaehde U, Lieweg A, Simon S, and Westfeld M. Minimising treatment-associated risks in systemic cancer therapy. Pharm World Sci 2008:30:161-68.
43 Kapty D. Pediatric Considerations, Appendix 7: Pediatric Cancer Drug Manual, B.C. Cancer Agency; 1994.
44 Knapp KK and Ray MD. A pharmacy response to the Institute of Medicine's 2001 initiative on quality in health care. Am J Health-Syst Pharm 2002;59:2443-50.
45 Kohler DR, Montello MJ, Green I, Huntley C, High JL, and Goldspiel BR. Standardizing the expression and nomenclature of cancer treatment regimens. Am J Health-Syst Pharm 1998;55:137-44.
46 Levesque L. Module 1. Reading Evidence Clearly to Guide Decision Making. The Clinical Critic: Oncovox Continuing Health Communication 2002; (GSK).
47 Levesque L. Module II. Statistics for the Non-Statistician. The Clinical Critic: Continuing Health Communication 2003; (GSK).
48 Liekweg A, Westfeld M, and Jaehde U. From oncology pharmacy to pharmaceutical care: new contributions to multidisciplinary cancer care. Support Care Cancer 2004;12:73-79.
49 Maerin-Calero MJ, Machuca M, Murillo MD, Casino J, Gastellurrutia, and Faus MJ. Structural Process and Implementation Programs of Pharmaceutical Care in Different Countries. Current Pharmaceutical Design 2004;10:3969-85.
50 McElhiney LF. Establishing a Quality-Assurance Program for Hospital Compounding. International Journal of Pharmaceutical Compounding 2008;12(2):
51 Medication Reconciliation, University of Wisconsin Hospital and Clinics. Hospital Administrative Manual, Patient Support Policy 7.60 April 3, 2007
52 Model Standards of Practice for Canadian Pharmacists. National Association of Pharmacy Regulatory Authorities (NAPRA); 2009.
53 National Institute for Occupational Safety and Health (NIOSH) Alert: Preventing Occupational Exposure to Antineoplastic and other Hazardous Drugs in Healthcare Settings. Cincinnati, OH, US Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, DHHS (NIOSH) Publication No 2004-165.
54 NIOSH Alert-Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings, NIOSH 2004

55 NIOSH Workplace Solutions: medical Surveillance for health care Workers Exposed to Hazardous Drugs. Cincinnati, OH. US Department of Health and Human Services, Centers for Disease Control and Prevention, NIOSH, DHHS (NIOSH) Publication No 2007-117.

56 NIOSH Workplace Solutions: Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs. Cincinnati, OH, US Department of Health and Human Services, Centers for Disease control and Prevention, NIOSH, DHHS (NIOSH) Publication No 2009-106.

57 Oncology Pharmacy Specialty Certification Examination. BPS Specialty Council on Oncology Pharmacy Outline: American Board of Pharmaceutical Specialties; 2009.

58 Pediatric Oncology Mission Statement. New York Medical Centre; 2002.

59 Perez A, DolorescoF, Hoffman JM, Meek PD, Touchette DR, Vermeulen LC, and Schumock GT. Economic Evaluations of Clinical Pharmacy Services: 2001- 2005. Pharmacotherapy 2009;29(1):128.

60 Pharmaceutical Care Standards of Practice: London Health Sciences Centre; 2001.

61 Polovich M. Safe Handling of Hazardous Drugs. Online Journal of Issues in Nursing. 2004;9(3):1172-91.

62 Power LA. Handling hazardous drugs: Are our safety programs effective? Am J Health-Syst Pharm 2006;63(12):1130.

63 Prevention Guide - Safe Handling of Hazardous Drugs. Association paritaire pour la santé et la sécurité du travail du secteur affaires sociales (ASSTSAS) 2008
http://www.asstsas.qc.ca/_cms/plugins/recherche/default.aspx (search = 'hazardous drugs')

64 Professional Standards for Hospital Pharmacy Practice: Canadian Society of Hospital Pharmacy; 2000.

65 Quqpo5 2000 Quality Standards for the Oncology Pharmacy Service with Commentary. Institute for Health Care Sciences for the German Section of the International Society of Oncology Pharmacy Practitioners (ISOPP) as the result of the 7th North German Cytostatics Workshop (NZW) January 1999, Institute for Applied Healthcare Sciences (IFAHS e.V.)

66 Rogers K, Tierney M. Singh A, and McLean W. Assessment of a Seamless Care Prescription/Discharge Notes Form. Can J Hosp Pharm 2003;56:14-23.

67 Seamless Care Workshop – A Joint Initiative. Canadian Society of Hospital Pharmacists and Canadian Pharmacists Association; 1998.

68 Sessink, Paul JM, Rolf MA, and Ryden N. Evaluation of the PhaSeal Hazardous Drug Containment System. Hospital Pharmacy 1999;34(11):

69 Shah S, Dowell J, and Greene S. Evaluation of Clinical Pharmacy Services in a Hematology/Oncology Outpatient Setting. The Annals of Pharmacotherapy 2006;40(9):1527-33.

70 SHPA Standards of Practice for Clinical Pharmacy. Committee of Specialty Practice in Oncology; The Society of Hospital Pharmacists of Australia: J Pharm Pract Res 2005;35(2):122-46.

71 SHPA Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer. The Society of Hospital Pharmacists of Australia: J Pharm Pract Res 2007;27(2):147-52.

72 SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments. Committee of Specialty Practice in Oncology; The Society of Hospital Pharmacists of Australia: J Pharm Pract Res 2005;35(1):44-52.

73 SHPA Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments. Committee of Specialty Practice in Oncology; The Society of Hospital Pharmacists of Australia: J Pharm Pract Res 2007;37(3):234-5.

74 Standards for Accreditation of Pharmacy Technician Programs in Canada: Canadian Council for Accreditation of Pharmacy Programs; 2007.

75 Standards for Hospital Pharmacists: Ontario College of Pharmacists, Pharmacy Connection; 2003.

76 Taylor, Suzanne C. Malfair, Developing evidence-based guidelines, B.C. Cancer Agency, Vancouver, B.C. ISOPP VIII; 2002.

77 Training Manual for the Preparation of Parenteral Cytotoxic Admixtures, 8th Edition, Alberta Cancer Board Pharmacy, June 2005 (updated June 2009)
www.cancerboard.ab.ca moving to www.albertahealthservices.ca in 2010

78 US Pharmacopeia (USP) revised general chapter <797> pharmaceutical compounding- sterile preparations. June 2008.

79 Vanbdenbroucke J, and Robay H. How to protect environment and employees against hazardous agents, the UZ Ghent experience. J Oncol Pharm Pract, 2006;6(4):146-52.

80 Weingart SN, Cleary A, Seger A, Ene TK, Saadeh M, Gross A, and Shulman LN. Medication reconciliation in ambulatory oncology. Jt Comm J Qual Patient Saf 2007;33(12):750-7.

81 Wood AM. BCOP Oncology Clinical Practice Guidelines. Highlights in Oncology Practice 1999;17(2):2791-994.

Mission

To promote the practice of oncology pharmacy in Canada, by conducting educational events, maintaining appropriate professional practice standards, facilitating communication between oncology pharmacists and other interested health professionals, and developing oncology pharmacy as an area of specialty practice

Canadian Association of Pharmacy in Oncology (CAPhO)