

Position Statement

Role of the Oncology Pharmacy Team in Cancer Care

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Best Practice Recommendations to Support the Oncology Pharmacy Team (OPT)

The International Society of Oncology Pharmacy Practitioners (ISOPP) advocates that:

- the OPT be fully incorporated into the multidisciplinary healthcare team (MHT) to optimize patient care
- educational and healthcare institutions develop programs to continually educate OPT members
- regulatory authorities develop certification programs for pharmacists and technicians to recognize the unique contributions of the OPT

Oncology Pharmacy Practice as a Pharmacy Specialty

- Recognize and support the unique roles of the OPT in promoting effective, safe, and cost-efficient cancer patient care
- Define oncology pharmacy practice as a specialty in each individual country
- Determine the education and training requirements needed to become an oncology pharmacist and technician
- Determine the continuing education needs to ensure that oncology pharmacists and technicians maintain competency to practice in the evolving field of cancer care

Contributions to Patient Care

- Participate as an integrated, collaborative member of each patient's MHT
- Evaluate appropriateness of anticancer therapy doses, clinical indications, and eligibility for treatment
- Optimize patient adherence to anticancer therapy
- Monitor drug therapy adverse effects and pharmacovigilance-related activities
- Verify, review, and recommend strategies for food and drug interactions prior to and throughout therapy
- Implement patient-specific management of treatment-related adverse effects and ensure supportive care is planned and implemented
- Promote patient and caregiver advocacy

Oncology Pharmacy Practice Management

- Develop strategies to mitigate, manage, and prevent medication errors, drug-related problems, and drug-related morbidity
- Develop policies and standard operating procedures (SOPs) for oncology pharmacy practice

- Promote appropriate storage, handling, and preparation and dispensing of anticancer medications (and supportive care) in all clinical environments
- Ensure best practices for anticancer medications dispensed outside of a cancer center (eg, specialty pharmacies, community pharmacies)
- Certify pharmacy practice sites, policies, and procedures

Education and Training

- Provide patient-specific education for patients, families, and caregivers
- Educate and train members of the MHT

Contributions to Oncology Research and Quality Initiatives

- Manage investigational medications in oncology care
- Conduct and facilitate oncology-related research activities

Introduction

The Oncology Pharmacy Team (OPT), consisting of specialty-trained pharmacists and/or pharmacy technicians, is an integral component of the multidisciplinary healthcare team (MHT) involved with all aspects of cancer patient care. The OPT fosters quality patient care, safety, and local regulatory compliance. The International Society of Oncology Pharmacy Practitioners (ISOPP) advocates that 1) the OPT be fully incorporated into the MHT to optimize patient care; 2) educational and healthcare institutions develop programs to continually educate OPT members; and 3) regulatory authorities develop certification programs to recognize the unique contributions of the OPT. The specific roles of the oncology specialty-trained pharmacists and technicians will vary by institution and region based upon institutional policies and local regulations for each of these MHT members. ISOPP advocates that institutions take advantage of local regulations that allow for independent roles of pharmacists and technicians to facilitate optimal patient care.

Oncology Pharmacy Practice as a Pharmacy Specialty

Oncology pharmacy practice is the specialty of pharmacy that incorporates the knowledge, skills, and expertise of pharmacy practice with a focus in the area of hematology and oncology malignancies.¹ Currently, not all countries worldwide formally recognize oncology pharmacy as a specialty but recognize the benefits from the contributions of the OPT.

Oncology pharmacists and oncology pharmacy technicians:

- are an essential part of the cancer MHT, with a broad range of expertise, levels of practice, skills, and responsibilities²⁻⁸
- provide quality care to patients with cancer throughout their disease trajectory, including optimization of initial and subsequent treatments, supportive care, palliative care, and survivorship⁹
- support the prevention and screening of cancer⁹
- prepare and/or dispense anticancer and supportive care medications, utilizing safe handling principles^{1,9}

Common practice sites for the OPT include, but are not limited to:⁹

- ambulatory oncology clinics
- aseptic compounding companies
- cancer infusion centers and satellite oncology pharmacies
- community or specialty oncology pharmacies
- hospital inpatient clinical oncology

- investigational drug services
- practice management oncology

Preparation to practice in the specialty

Oncology pharmacists and pharmacy technicians represent a broad range of expertise, education and training of the oncology pharmacist and/or technician is varied, depending on the country, the requirements of an institution, and education pathways available.^{1,2,9-11}

- Pharmacists graduate from a school of pharmacy that allows for licensure. Licensure is often a requirement depending on the regulatory practices of a locality or country. It may include passing a licensure exam that assesses pharmacy knowledge gained during pharmacy school.¹ Practice experience, demonstrating knowledge in the laws of their jurisdiction, and/or completion of a practical or laboratory-based exam may be required.
- Pharmacy technicians have a diverse level of practice worldwide. Some may have some formal didactic education and/or experiential training related to medications with a specific emphasis on drug distribution. In some institutions and countries, pharmacy technicians have advanced training in compounding and are allowed to dispense in a supervised practice or are required to become licensed after taking a course, passing a national examination, and completing a practicum.¹²
- Specialization in oncology pharmacy practice, can be achieved in several ways.
 - Practice experience (eg, on-the-job training) and continuing education.^{1,9}
 - Competency training – this training may be offered by the institution or a professional organization. For example, the United States National Pharmacy Technician Association offers a chemotherapy technician certification course for technicians and the Hematology Oncology Pharmacy Association offers a Core Competency course for pharmacists.^{13,14} Training courses may be offered within healthcare institutions (eg, Belgium, Ethiopia, Germany, Malaysia), or by pharmacy associations (eg, TUKED, a public pharmacy society).^{11,15}
 - Pharmacists may also:
 - complete post-graduate formalized training programs that allows the licensed pharmacist to practice under the supervision of an experienced preceptor to gain more clinical experience and practice management (ie, residency program) or research experience (ie, fellowship).^{1,9} Residency programs vary in duration, and may require an examination following completion (eg, Hospital Pharmacy

Argentine Association exam) or portfolio assessment (eg, Ministry of Health Singapore) following completion.¹⁶ In some countries, a Master's degree in oncology pharmacy practice is required (eg, United Kingdom, Italy).¹⁷

- pass an established specialization exam (eg, USA board certification in oncology pharmacy [BCOP], Sociedade Brasileira de Farmaceuticos em Oncologia Brazilian Association of oncology pharmacists [SOBRAFO] exam, Board Certified Pharmacotherapy [BCP] of Thailand, Board-Certified Pharmacist in Oncology Practice [BCPOP] & Board-Certified Oncology Pharmacy Specialist [BCOPS] of Japan).
- Use a combination of these approaches (in some areas of the world). This can be done alone or following on-the job training or completion of a residency or fellowship program. To obtain BCOP, pharmacists must meet certain criteria, such as completion of an oncology residency program or work in an oncology pharmacy for 4 or more years as well as pass an examination that is designed to assess the level of knowledge and implied skill of the pharmacist in oncology.¹⁸ This BCOP is conferred by the Board of Pharmacy Specialties and the specialty has been recognized since 1996. Currently, 3000 pharmacists worldwide have obtained their BCOP. To become an oncology specialist in Brazil, pharmacists must have worked 3 or more years in oncology, completed a post-graduate program in oncology and passed an exam.¹⁹ Two types of board certification in oncology pharmacy exist in Japan.²⁰ The first is a board BCPOP. This certification first requires the pharmacist to be board certified as a hospital pharmacist and then complete the following requirements: 5 years of substantial time spent in oncology pharmacy practice, completion of a 3-month specialized residency at a select cancer center; attendance at 10 oncology lectures, presentation of 50 cancer case managements, and passing the examination. The designation of BCOPS, requires BCPOP status, 3 conference presentations and 2 peer-reviewed manuscripts for journal publication in oncology and passing an examination.

The true number of dedicated oncology pharmacists worldwide is unknown. Additionally, some oncology pharmacists work full time in cancer care whereas other oncology pharmacists practice in a combination of cancer care and other patient populations.

Reasons for the lack of a specialized certification for oncology pharmacists include:

- lack of global requirement(s) for oncology pharmacy certification
- current oncology pharmacy certification examinations may not reflect regional oncology care practices
- cost of obtaining and maintaining certification maybe prohibitory
- not all healthcare institutions require certification for oncology pharmacists
- pharmacists may have entered into the role of an oncology pharmacist before these programs were available
- pharmacists do not have access to these programs due to geographical location
- many of the certifications for oncology pharmacy are voluntary, and do not carry with them a clear career advancement or additional income

To promote safety and optimal care for individuals with cancer, pharmacy regulatory agencies and institutions who provide care and services to individuals affected by cancer should:

- recognize and support the unique and integral role of the OPT in promoting effective, safe, and cost-efficient cancer patient care
- develop strategies to define the roles of oncology pharmacy as a specialty in their institutions and country
- determine a minimum baseline educational requirement for pharmacists and technicians whose practice includes individuals with cancer, including those not participating in a traditional OPT, given that pharmacists and technicians across the spectrum may encounter patients with cancer (eg, community pharmacists)
- determine continuing education needs to ensure that oncology pharmacists and technicians who provide care to individuals with cancer maintain their competency to practice

Contributions to Patient Care

Participate as an integrated, collaborative member of each patient's MHT

The primary role of an OPT practicing within a health care system is to ensure safe and appropriate medication use for individuals with cancer.²¹ Safe and appropriate medication use encompasses clinical, pharmaceutical, and economic aspects of drug therapy for the individual with cancer. Studies conducted globally have confirmed the benefit of the integration of the OPT as part the MHT within a variety of settings in improving overall patient care.²²⁻⁵²

The OPT role includes the following, but is not limited to:

- assess medication safety in the context of therapeutic use, adverse effect profile, pharmacokinetics, pharmacodynamics and patient-specific characteristics
- assess medication safety in the context of patient tolerance and disease response, during and following the completion of therapy
- adjust drug dosage(s) relative to organ function, comorbidities and patient-specific factors
- verify the potency, purity, stability, and sterility of medications prepared for and administered to patients
- verify that medication prescriptions/orders include the correct drug, dose and regimen, route, and schedule, and are communicated in a clear and complete manner
- uphold successful behaviors for collaborative interdisciplinary practice including culpability, dependability, respect for others, attention to detail, and transparency⁵³

Regarding the contribution to the MHT, the OPT must:

- ensure safe and appropriate medication use
- assess product cost, therapeutic alternative selection, and adherence to institutional formulary or institutional guidelines (eg, Pharmacy/Drugs/Medicines and Therapeutics Committee, Medication Management Committee guidelines)
- provide medication information to MHT members
- counsel patients and caregivers about their anticancer therapy regimen and supportive care
- maintain primary responsibility for assessing and managing medication adherence in cancer patients
- perform medication therapy management⁵⁴
- proactively manage medications (including alternative/complementary medications and supplements) that are prescribed for managing non-cancer conditions to ensure that they do not adversely affect the efficacy of anticancer therapies
- prepare, deliver, and manage drug products used in the treatment of patients with cancer, including safe and appropriate compounding of drugs for specific situations (eg, nasogastric tube or pediatric administration)
- coordinate care of patients

Evaluate appropriateness of anticancer therapy doses, clinical indications and eligibility for treatment

The OPT is an essential checkpoint for verifying systemic anticancer therapy regimens.^{55,56} A culture supporting professional accountability, mutual respect, and interdisciplinary collaboration is necessary for successful verification of anticancer therapy regimens.^{55,57} Pharmacist-MHT collaboration ensures that a suitable regimen with appropriately dosed medications is prescribed/ordered.

To provide a stringent checkpoint for anticancer therapy prescriptions/orders the oncology pharmacist must verify :

- anticancer therapy selection and dosages/regimen in the context of
 - diagnosis, including appropriate biology of cancer (eg, actionable mutational alterations) and current extent of disease (eg, stage)
 - pharmacotherapy history
 - performance status, organ and bone marrow function, and comorbidities
 - concomitant drug therapy (including non-prescription medications and complementary therapies)
 - allergies and previous tolerance to therapies
 - validity of body descriptors and calculations for surface area- or weight-based anticancer therapy doses
 - appropriateness of regimen, which is supported by clinical guidelines, clinical evidence, or acceptable level of evidence
 - appropriateness for those individuals enrolled in a clinical trial by the clinical research protocol
 - requirements for appropriate medication administration (rate, duration, compatibilities, order of drug administration, administration requirement in relation to food, management of missed doses)
- appropriateness of medications used in conjunction with anticancer treatment
- appropriateness and frequency of clinical and laboratory monitoring

To provide a stringent safety checkpoint, institutions should recognize that the OPT must provide:

- a rigorous, independent verification of anticancer drug therapy prescriptions/orders that includes concurrent medications required to safely administer the anticancer agent(s)
- collaboration with MHT to ensure identified issues are addressed, clarified and rectified if appropriate, documenting this process in the patient record

- collaboration between pharmacists and technicians to support correct product preparation and documentation
- collaboration with patients, family, and caregivers to ensure optimization of drug therapy
- collaboration between the OPT, MHT, and caregivers to verify patient readiness for administration of the prescribed/ordered anticancer therapy

Optimize patient adherence to oral anticancer therapy

Medication adherence to oral anticancer therapy is a critical component to achieving optimal patient outcomes.⁵⁸ The OPT has a substantial role in improving adherence, and subsequently lead to improved care, better therapeutic outcomes, and lowering costs to both patients and health care providers.⁵⁹

The OPT should:

- facilitate anticancer therapy adherence and coordination of medication therapy with the patient and caregiver
- ensure safe and appropriate use of oral anticancer therapies as described in above sections.
- provide guidance on safe handling and disposal of anticancer therapies

Monitor drug therapy adverse effects and pharmacovigilance-related activities

Pharmacovigilance-related activities for cancer patients are very important. The oncology drug market is rapidly expanding and anticancer medications are being marketed with limited clinical experience or conditional approvals.⁶⁰ OPT members have specific expertise in implementing safety-monitoring and pharmacovigilance-related activities in this setting.

The OPT must :

- record adverse drug reactions (ADR) in patient records, report to institutional reporting systems and national reporting systems. Unique ADR case reports should be published²
- develop toxicity monitoring and reporting policies or SOPs for all anticancer and supportive care medications
- monitor drug toxicities (eg, cardiovascular, dermatologic, immune-related adverse events, toxicities related to targeted therapies) in a patient, disease, and medication-specific manner

Verify, review, and recommend strategies for food and drug interactions prior to and during therapy

The potential for food-related and drug interactions is high among oncology patients across different care settings due to the complexity of anticancer drug regimens and the background comorbidities of many cancer patients.⁶¹⁻⁶³ Pharmacists are responsible for the management of drug therapy, which includes an ongoing review and management of food and drug interactions as part of the pharmaceutical care provided to patients and have been shown to prevent potential drug interactions among cancer patients, thus improving medication safety.⁶⁴⁻⁶⁹ Multiple possible points of intervention exist, including during collaborative rounds, chart reviews, and direct patient medication reconciliation or verification of anticancer therapy prescriptions/orders.

The OPT should:

- evaluate the potential for drug interactions between anticancer and supportive care medications, in addition to interactions between other medications the patient is taking and food interactions
- collaborate on appropriate management strategies with the prescriber and MHT to discuss management of clinically significant drug interactions
- counsel the patient and caregivers about potential food and drug interactions to avoid potential occurrence
- provide strategies for management of drug interactions that may occur during the course of care (eg, communication of complete medication list to MHT, reduce dose, therapeutic drug monitoring, separating administration of medications by several hours, alternative medication)
- document recommendations implemented and evaluate patient outcomes

Implement patient-specific management of treatment-related adverse effects and ensure supportive care is planned and implemented

Anticancer therapy is associated with a wide-range of toxicities, such as nausea and vomiting, myelosuppression, and febrile neutropenia. Anticancer drug therapy, such as targeted therapy and immunotherapy, also have complex supportive needs.^{70,71} The oncology pharmacists role is to participate in the design and implementation of patient-specific management of treatment-related side effects and ensure that evidence-based supportive care is adequately planned and implemented in a timely manner to ensure anticancer treatment is delivered with minimal and tolerable toxicity.

The OPT should:

- be involved in designing and implementing patient-specific supportive care therapies for cancer patients receiving anticancer therapy. These strategies are based both on ever evolving evidence-based recommendations and individualized based on patient-

specific consideration. These strategies should ideally be included in the anticancer therapy prescriptions/orders (eg, antiemetics, hydration, rescue medications)

- identify and regularly analyze common and severe toxicities that are associated with each treatment protocol regularly employed in their institution
- assist with developing treatment and monitoring protocols to manage these adverse effects
- ensure that with each anticancer drug therapy regimen, the appropriate supportive medications and laboratory tests have been ordered concurrently and obtained when appropriate
- review patient history prior to each new cycle of anticancer therapy to ensure that supportive care provided is adequate or require recommendations/actions to be implemented
- independently manage ancillary therapies (wherever regulations allow)

Promote patient and caregiver advocacy

The OPT is ideally situated within the healthcare system to be a patient and caregiver advocate and bring the patient's and public's concerns about cancer to decision makers.⁷² The OPT is uniquely placed to optimize their skills as health care providers, from grassroot levels to global change, by prioritizing the needs of the patient and driving the profession forward.^{72,73} Patient advocates and medical professionals from all spheres have a common goal, to address the needs and concerns of people with cancer, ultimately accelerating progress against cancer.⁷⁴ Advocacy has an essential role to play in increasing cancer awareness and prevention, incidence, care and outcomes of patients, and addressing the ever-increasing cancer burden on the world's aging population.⁷⁵ The OPT has a role in promoting advocacy at the individual patient level and globally.

Therefore, the OPT should work with other disciplines to promote patient care by:

- serving as a liaison for the patient and family to secure medications that have restricted distribution programs and/or are price prohibiting
- collaborating and/or leading education programs supporting cancer prevention and screening
- advancing cancer research
- negotiating legislative and regulatory matters
- raising public awareness of cancer and its management
- providing support to those individuals living with cancer

- serving as liaison for access to cancer care and clinical trials
- responding to the needs created by drug shortages
- assessing value and quality in cancer care⁷⁶

Oncology Pharmacy Practice Management

Develop strategies to mitigate, manage, and prevent medication errors, drug-related problems, and drug-related morbidity

Medication error prevention is of utmost importance in cancer patient care and exists as a consistent theme permeating all aspects of oncology pharmacy services. The OPT, being specially trained and qualified in medication safety, is an integral component of the MHT involved with medication error prevention in cancer patients. Pharmacists use education, training, and practice skills to collaborate with the MHT and patients in the safe use of medications by assessing that the right drug at the right dose reaches the right patient at the right time, and by the right route.⁷⁷⁻⁷⁹ Pharmacists educate patients on the safe use of their medications, assessing for allergies, potential drug interactions and identifying and managing potential medication-related problems.⁸⁰ Pharmacy technicians have several years of education and/or on the job training related to medications with a specific emphasis on drug distribution. As pharmacists' roles continue to evolve pharmacy technicians have moved into the key operational role of dispensing medications and have a vital role in medication error prevention.^{1,81}

Specific roles of the OPT to promote medication safety in cancer patients include:^{1,15,56,77-94}

- overseeing and managing safety strategies related to the procurement and storage of the physical drug products
- ensuring safe medication use at all points in the medication-use system including prescribing, pharmacist validation, compounding, dispensing, administration, and monitoring
- overseeing quality and risk assessments related to cancer medication use as part of institutional committees (e.g. Pharmacy/Drug/Medicines and Therapeutics Committee, Medication Management Committee)
- being involved in developing international, national, and institutional policies and procedures for safe anticancer medication use
- educating other health care professionals and patients about medications and their safe use

Develop policies and standard operating procedures (SOPs) for oncology pharmacy practice

The OPT is often called upon to use their clinical knowledge to provide policy and procedure development and support for other oncology- and medication-related issues. A strong knowledge of oncology therapeutics; safe preparation, administration, and disposal of anticancer therapies, many of which are considered hazardous drugs; and supply, cost, and reimbursement for anticancer therapies is crucial in developing collaborative institutional guidelines and practice-based decisions.

Oncology pharmacists are involved not only in the development of clinical practice guidelines, such as the prevention and management of treatment-related complications, but also in other aspects of safe medication use and oncology practice (eg, safe and administration handling of hazardous drugs, ensuring appropriate supply of anticancer drugs). Oncology pharmacists are important members of their institutional committees that make formulary recommendations on the efficacious, safe, and cost-effective use of oncology drugs.

The OPT assess drug inventory, ensure that drug waste is minimized, maintain an adequate but not excessive supply of drugs, and minimize exposure to hazardous drugs. With the ongoing crisis of drug shortages, OPT have become a critical component of drug management strategies and are relied on for their ability to optimize dosing and alternate therapies. Additionally, knowledge of local or national medication quality standards (see Appendix II); local rules and legislation; and international consensus guidelines is necessary for institutional pharmacies to maintain compliance with pharmacy regulations that protect patient and staff safety.^{76,83,85-100}

Key global responsibilities for the OPT regarding policy and SOP development include:

- designing, implementing, evaluating, and modifying pharmacy services appropriate to the needs of patients across the continuum of care
- establishing and modifying systems to ensure the safe use of medications
- ensuring that oncology-related pharmacy services comply with established regulations, standards, and best practices
- ensuring that care is consistent with appropriate clinical practice guidelines.
- incorporating patient rights and ethical standards into pharmacy policies and procedures (eg, confidentiality, age-appropriate informed consent, right of refusal)
- developing appropriate anticancer medication use policies in collaboration with other providers or agencies

Regarding specific institutional policies and procedures, the OPT, as part of an MHT approach, should be involved with:

- defining the roles and responsibilities of oncology pharmacists and oncology pharmacy technicians
- managing or serving as a consultant for the anticancer and supportive care medication formulary
- developing institution-specific drug use standards
- developing quality improvement strategies (eg, processing of anticancer therapy prescriptions/orders, protocol reviews)
- managing drug product shortages
- overseeing expanded access/compassionate use drug supply programs

As government and private insurers develop disease management programs and initiatives to address both quality and cost of care, oncology pharmacists have the drug therapy knowledge and experience to help determine safe and effective ways to meet the goals of these initiatives. Regarding specific global policies and procedures, organizations and regulatory agencies should include the OPT in development and modifications of :

- clinical, professional, and/or regulatory guidelines for cancer patient care (See Appendix II)
- standards related to cancer care such as safe handling and patient safety for anticancer therapy administration (See Appendix II)

Promote appropriate hazardous medication handling for anticancer medications (and supportive care) in all clinical environments

Many anticancer medications are hazardous drugs. Exposure to hazardous drugs can lead to both acute effects like skin rashes and chronic effects like adverse reproductive events or cancer.^{96,97}

Furthermore, measurable amounts of hazardous drugs have been found in urine of health care workers who prepared or administered hazardous drugs with appropriate protection. Because of this occupational hazard, the OPT are often the most knowledgeable about hazardous medications and safe handling regulations and should play a pivotal role in developing the safe handling system for their institution. The roles of the OPT include, but are not limited to:

- serving as the designated people responsible for developing and overseeing the hazardous drug program to ensure compliance with all applicable regulations

- developing policies and procedures for the safe handling program
- developing competency programs for preparation and administration of hazardous drugs
- assuming responsibility for oversight of monitoring the facility and maintaining reports of testing/sampling performed
- serving as the institution's expert to maintain the hazardous drug list by classifying approved and investigational medications as hazardous medications
- developing education programs for nurses and physicians for safe handling during hazardous drug administration
- developing the institution's system for hazardous drug disposal

Ensure best practices for anticancer medications dispensed outside of a cancer center (eg, specialty pharmacies, community pharmacies)

The term “specialty pharmacy” is defined in some areas of the world as the pharmacies created to manage the handling and service requirements of select (or specialty) pharmaceuticals, including dispensing, distribution, reimbursement, case management, and other services specific to patients with rare and/or chronic diseases.^{1,100,102} In some countries, some medications used for cancer patient care are distributed by specialty pharmacies. In other countries, specialty pharmacies may be used only for patients with private insurance and in others may be used for distribution of anticancer medications before full public availability (ie, compassionate care programs).

Specialty pharmacy distribution models should facilitate methods to ensure optimal communication between patients/caregivers and cancer care teams that enhance adherence to medications, identify potential safety issues, and allow for the timely administration in accordance with prescriber directives. Alternatives that allow face-to face interaction between the pharmacist and patient should be explored.

The roles of the OPT in specialty pharmacy include:^{103,104}

- participate in establishing purchasing process for medications distributed by specialty pharmacies
- implement dispensing process guidelines for specialty pharmaceuticals
- establish the most appropriate model (e.g. outsourced, integrated, or hybrid) for their setting
- counsel patients at transitions of care (eg, at discharge or admission) and perform follow-up visits in the ambulatory setting

Certify pharmacy practice sites, policies, and procedures

Hazardous drugs must be handled in facilities that promote patient safety, worker safety and environmental protection. Compliance with occupational health and safety, regulatory and practice standards ensures that products compounded are of acceptable quality and that the safety of the staff, patients and environment is promoted.

Different jurisdictions have varying requirements for accreditation, validation and/or certification of pharmacy units handling hazardous drugs. Certification programs are largely voluntary. The ISOPP standards recommendation is that whenever possible, all equipment and processes used for hazardous drug preparation which affect product sterility or product attributes should be validated and/or certified.⁸³ The ISOPP standards recommend qualification for the room and equipment a four-step process which includes:

- design qualification
- installation qualification
- operational qualification
- performance qualification

National organizations also provide guidance (see Appendix II). For example, the Pharmacy Board of Australia provides guidelines on compounding of medicines and gives specifications for the facility, working environment and equipment. The public pharmacy society in Turkey, TUKED, provides both clinical and safe handling guidance, including guidance on hazardous drug facilities.¹⁵ The Joint Commission International has both standards and measures to assess and improve performance related to hazardous drugs.¹⁰⁵ The Joint Commission Medication Compounding Certification is open to all organizations performing medication compounding and offers a voluntary certification program for compounding pharmacies seeking an independent evaluation and recognition of compliance with United States Pharmacopeia [USP] <797> and <795> and shall include chapter <800> once implemented.¹⁰⁶ In other countries, such as the UK and Indonesia, hospital production unit is required to be licensed by the regulatory agency as part of quality assurance.^{107,108} Certification is meant to improve the quality of staff training, products and pharmacy environment. In the US, the Pharmacy Compounding Accreditation Board (PCAB) provides a voluntary accreditation program that assesses pharmacies that compound medications whether in the retail, hospital, mail order, or closed door setting by conducting an extensive on-site survey conducted by an independent expert and annual verification to ensure compliance with the non-sterile and sterile pharmacy compounding process defined by USP standards.¹⁰⁹

The role of the OPT in pharmacy certification is to:

- ensure that compounding is done in premises that are adequately designed, equipped, maintained and resourced
- ensure that the design, installation, operation and performance of facilities, systems and equipment is suitable for the intended purpose and is in line with local regulations and best standards
- conduct risk assessment to determine specific facilities and equipment required for compounding different medicines
- review, approve and sign off certificates issued during certification and or validation of pharmacy facilities and equipment
- ensure that certificates of validation are retained in accordance with practice standards and regulations
- ensure that equipment and facility maintenance logs relating to routine maintenance and certification are retained in accordance with practice standards and regulations
- document compliance with nonsterile compounding, sterile compounding, and handling of hazardous drugs standards and to record standard operating procedures

Education and Training

Provide patient-specific education for patients and caregivers

Pharmacists are a critical part of the MHT caring for patients with cancer throughout their care in both inpatient and outpatient settings. At each point of interaction, pharmacists and technicians are responsible for providing appropriate education to patients and their caregivers on their anticancer and/or supportive care regimen, as well as establishing important steps to ensure the safe handling of hazardous medications. The education of patients and caregivers on the use of medications has long been a core responsibility within the practice of pharmacy, with perhaps the strongest origins in community practice or the outpatient setting. Strategies may include drug utilization review, direct patient / caregiver counseling, and development of education standards, and maintenance of patient profiles. Pharmacists also play a role in the education of patients, caregivers, and healthcare professionals on the appropriate use of anticancer therapy including, but not limited to, the impact of pharmacogenomics on medication therapy, drug-related toxicities, and therapy outcomes. Pharmacists are well-recognized and valued by patients, caregivers, and other healthcare professionals for their knowledge and patient counseling. Additionally, pharmacist-led education improves the patient's

understanding of their drugs and/or regimen or ability to manage side effects, improves quality of life, decreases anxiety and depression.^{24,28,29,110-112}

Regarding patient and caregiver education, the OPT are essential for:

- assessment and educational supplementation, as needed, of basic knowledge about their cancer diagnosis
- provision of education related to drugs, including:
 - current understanding of the mechanism(s) of action of therapy(s)
 - common adverse effects including mitigation strategies, self-monitoring, and triaging of questions regarding adverse effects
 - importance of medication adherence and strategies to promote adherence
 - sources of reliable information regarding drug therapy
 - safe handling and disposal of hazardous medications in non-clinical settings (eg, home)
 - instructions for strategies and duration of contraception during and following treatment based on drug therapy
 - instructions for breastfeeding during and following treatment based on drug therapy
 - health promotion activities during and following treatment
- development of practice-specific written resources for pharmacists and healthcare providers who counsel oncology patients and their caregivers that reflect cancer care practices within a region (eg, language, terminology, availability of drugs, regional guidelines)

Educate and train members of the MHT

The OPT plays an important role in the education and training of other members of the MHT. This includes core training in programs to provide the critical education required for the evolution of cancer care. The scope of education includes all members of the MHT including physicians, advanced practice providers, nurses and allied health professionals, and other pharmacists and pharmacy technicians. In addition, interprofessional health education is increasingly offered to facilitate the effectiveness of the MHT.^{113,114}

The OPT should provide:

- informal medication information regarding pharmacotherapy optimization and safe handling of hazardous drugs
- formal education including participation in
 - medical, nursing, pharmacy, and other allied health school curriculum in cancer care

- post-graduate education in oncology care for non-oncology and oncology-focused training (eg, medical residency)
- post-graduate fellowship training in oncology care
- continuing education programs in cancer and cancer care
- informal training including:
 - collaboration on publication development
 - education through patient care discussions (eg, rounding, tumor boards, clinics)
 - participation in journal clubs
 - participation in the development of institutional practice care guidelines

Contributions to Cancer Drug Development and Oncology Research

Manage investigational medications in oncology care

Clinical trials using investigational medications, or established medications in a new way, are an integral part of cancer patient care. As protocols and therapies increase in number and complexity cancer research the OPT can support the IDS for cancer clinical trials.⁸⁴

The OPT should:

- be involved in the establishment, management and oversight of the IDS involved in cancer drug development
- be actively involved in the study design and protocol development for oncology clinical trials. This include particular attention to issues related to drug source/supplier; storage; preparation; dispensing; returns and disposal; stability and compatibility; administration; contraindications; adverse effects; and drug interactions
- assist with developing institutional SOPs and policies unique to investigational medications used in cancer patients that support Good Clinical Practice (GCP) and global ethical requirements and are compliant with all applicable regulations
- establish appropriate safety measures to inform all staff involved in oncology clinical trials
- be a resource to assess whether an investigational anticancer agent should be included on the institution's hazardous medication list
- facilitate the development of patient education material for investigational medications in oncology clinical trials
- be a resource to develop and/or review electronic prescriptions/order sets to facilitate safe anticancer drug use process (including compounding [eg, type and volume of fluids], dispensing

[eg, light protected, refrigerated], and administration [eg, anticancer order administration, administration rate])

Conduct and facilitate oncology-related research

The OPT role in anticancer drug development is broad and encompasses aspects of translational science, clinical trial conduct, and facilitation of research activities. As an example, the Cancer Therapy Evaluation Program of the National Cancer Institute in the US recognizes pharmacists and other clinicians as non-physician investigators, with the opportunity to be leaders on studies conducted through cooperative group and other mechanisms.¹¹⁵ Other organizations have provided guidance and support for pharmacists as principal investigators on grants and trials. The American College of Clinical Pharmacy (ACCP) has published and updated evidence for pharmacists as leaders of research in multiple areas, demonstrating increases in federal funding, publications, and listing as principal investigators on ClinicalTrials.gov.¹¹⁶ These data and other experiences support the role of pharmacists as investigators driving research in cancer and other diseases. Additionally the OPT is often responsible for participating in institutional review, ethics or data safety monitoring boards and provides guidance on clinical trial availability and treatment plans.

The OPT may lead, participate and/or facilitate cancer research activities including:

- contribute to institutional and collaborative research and scholarly activities such as:
 - leading laboratory research programs for anticancer agent discovery, development and correlative studies (eg, pharmaco-analytical assays for concentration measures)
 - conducting practice-based research or pharmacoeconomic evaluations
 - serving as principal and/or co-investigators on clinical trials and participating in conduct of research (eg, recruiting, enrolling, data collection, data analysis)
 - conducting well-designed scientific studies in the most cost-effective manner
 - disseminating research findings, which include the following and not limited to: presentation of findings within own institution, presentation of findings at a national, regional or international meeting, and publishing
- support patients by referring and finding clinical trials for enrollment
- facilitate clinical trial conduct by creating treatment prescriptions/orders and pathways
- counsel patients on investigational and standard agents used in trials
- participate and lead in committees and groups that review, approve, and oversee trials including scientific review committees at cancer centers, institutional review boards, and data

safety and monitoring committees, both at the institutional level and broader collaborative or consortium level

- participate in regulatory agency preparation and conduct of clinical trials and/or review of data for licensing

Conclusions

The OPT has a unique role in the MHT in caring for patients with cancer. Because of their expertise, they are able to promote effective, safe and cost-efficient care. Additionally, they have an essential role in patient and caregiver education. OPT are instrumental in the training of the healthcare team, including healthcare professionals and trainees. OPT play an integral role in the design and implementation of cancer drug development and oncology research. Furthermore, they are key personnel responsible for ensuring the prevention of medication errors, appropriate handling of hazardous medications and overseeing certification and other policies related to hazardous drugs and anticancer drug use. To optimize patient care, ISOPP recommends that countries around the world recognize and support the unique role of the OPT in oncology patient care, define oncology pharmacy as a specialty, and offer initial and ongoing education and training that prepares the pharmacist and technician.

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Appendix II. Oncology Standards and Guidelines

Clinical, professional, and/or regulatory guidelines for cancer patient care

- American Society of Clinical Oncology (<https://www.asco.org/research-guidelines/quality-guidelines/guidelines>)
- European Society of Medical Oncology (<https://www.esmo.org/guidelines>)
- Multinational Association of Supportive Care in Cancer (MASCC) (<https://www.mascc.org/clinical-guidelines>)
- National Comprehensive Cancer Network [NCCN] (https://www.nccn.org/professionals/physician_gls/default.aspx)
- Society for Immunotherapy of Cancer (SITC) (<https://www.sitcancer.org/research/cancer-immunotherapy-guidelines>)

Safe handling and patient safety for anticancer therapy administration

- International Society of Oncology Pharmacy Practitioners [ISOPP] Standards of Practice (<https://www.isopp.org/education-resources/standards-practice>)
- American Society of Clinical Oncology [ASCO]/Oncology Nursing Society [ONS] Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology (<https://www.ons.org/ascoons-chemotherapy-administration-safety-standards>)
- British Columbia Cancer Agency Pharmacy Practice Standards for Hazardous Drugs (<http://www.bccancer.bc.ca/health-professionals/clinical-resources/pharmacy/safe-handling-manual>)
- British Oncology Pharmacy Association (<https://www.bopa.org.uk/resource-types/guidelines/>)
 - Cancer Pharmacy Education & Training Standards
 - Guidance on the contents of a Systemic Anti-Cancer Therapies (SACT) protocol
 - Guidance on the use of H₂ antagonists for the prevention and management of hypersensitivity
 - Guidance on the Oral Anticancer Medication (OAM) Review Service by Community Pharmacy
 - Standards for Pharmacy Verification of Prescriptions for Cancer Medicines
 - Standards for Reducing Risks Associated with Electronic Prescribing and Medicines Administration Systems (ePMA) for Systemic Anti-Cancer Therapies (SACT)
- Canadian Association of Provincial Cancer Agencies Oral Cancer Drug Therapy Safe Use and Handling Guideline (<https://capca.ca/wp-content/uploads/2020/10/En-Oral-Chemotherapy-Guideline-Final-11-May-2015.pdf>)

- Canadian Association of Provincial Cancer Agencies Safe Use and Handling of Oral Anti-Cancer Drugs in Community Pharmacy Guideline (<https://capca.ca/wp-content/uploads/2020/10/Safe-Use-and-Handling-of-Oral-Anti-Cancer-Drugs-OACDs-2017.pdf>)
- Clinical Oncological Society of Australia [COSA] Guidelines for the Safe Prescribing, Dispensing, and Administration of Cancer Chemotherapy (https://www.cosa.org.au/media/1093/cosa_guidelines_safeprescribingchemo2008.pdf)
- Hematology/Oncology Pharmacy Association (HOPA) Guidelines (<https://www.hoparx.org/resources/guidelines-standards-summaries>)
 - Best Practices for the Management of Oral Oncolytic Therapy: Pharmacy Practice Standard
 - Dose Rounding of Biologic and Cytotoxic Anticancer Agents
 - Further Defining the Scope of Hematology/Oncology Pharmacy Practice
 - HOPA Investigational Drug Services Best Practices Standards
 - Oncology Pharmacy Technician Guidelines
 - Scope of Hematology/Oncology Pharmacy Practice
- Institute for Safe Medication Practices Canada (ISMP Canada) (<https://www.ismp-canada.org/index.htm>)
- Pan American Health Organization Safe Handling of Hazardous Drugs in Limited Resource Areas (<https://iris.paho.org/handle/10665.2/28554>)
- Pharmaceutical Inspection Co-Operation Scheme (PIC/S) (<https://picscheme.org/en/publications>)
- Quality Standard for the Oncology Pharmacy Service [QUAPOS from the European Society of Oncology Pharmacy) (https://esop.li/wp-content/uploads/2020/01/QuapoS_english-6.pdf)
- Standard of practice in oncology and haematology for pharmacist services. *J Pharm Pract Res.* 2020;40:528-454. doi: 10.1002/jppr.1686
- TUKED. Guideline on safe working with hazardous drugs and pharmacy practices in oncology. Ankara: TUKED, 2016. (<http://tuked.org/en/tuked-activities/publications/>)
- United States Pharmacopeia [USP] Compounding Standards (including <795>, <797> and <800> standards) (<https://www.usp.org/compounding>)