Recommendations for the safe use and handling of oral anticancer drugs in community pharmacy: A pan-Canadian consensus guideline

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Introduction

Availability and access to oral anticancer drugs (OACDs) is increasing and expected to continue, given the number of oral forms of therapy currently in development¹ and the use of these agents for nonmalignant indications (i.e., rheumatologic and immunologic disease). Despite this trend, few guidelines, if any, target the safe use and handling of OACDs in the community pharmacy setting. Moreover, despite the potential for serious patient harm if OACDs are used in error, fewer safeguards are in place to ensure the safe use and handling of OACDs than for intravenous (IV) forms of cancer drugs.² While this may be because of a general misconception that the risks associated with OACDs are lower than for IV chemotherapy, the hazards of occupational exposure through inhalation, dermal and/or oral contamination require appropriate controls to reduce risk. Moreover, OACDs are considered high-alert medications (<https://www.ismp.org/tools/highalertmedicationLists.asp>) because of the harm introduced when an error occurs.

This consensus guideline complements existing provincial and national legislation, regulation and professional practice standards and is intended to supplement mandatory legislative requirements. In the event of inconsistency or

conflict between the recommendations in this document and any mandatory or more restrictive requirements, the latter shall prevail. All applicable/mandatory legislative requirements must be adhered to.

It is recommended that a self-assessment of safety practices (with a specific focus on handling) be conducted at baseline (if this has not been done previously) and at regular intervals. The Medication Safety Self-Assessment for Community/Ambulatory Pharmacy tool (<https://www.ismp-canada.org/amssa/>) from the Institute for Safe Medication Practices Canada may be used for this purpose. Results from the self-assessment should be used to identify areas for quality improvement to ensure safe practices in community pharmacy settings.

Scope and relevance

Exposure to OACDs can occur at any point along the medication life cycle. As a result, this consensus guideline addresses packaging, labelling, receiving and unpacking, storage, drug preparation and handling, verification and dispensing, transportation, personal protective equipment, disposal, waste management and cleaning and incident reporting.

Environmental monitoring and medical surveillance were determined to be out of scope

for this document but may be revisited if compelling evidence emerges for their relevance in these often low-volume settings.

While it is believed that these recommendations are likely of relevance to health care providers working in settings other than community pharmacy, such as long-term care, compounding centres, penitentiaries, respite and other day facilities where OACDs may be used to treat cancer and other nonmalignant diseases, they are designed to address safe handling issues in the community pharmacy setting specifically. Individuals working in other environments with OACDs that are used for other nonmalignant indications or who handle other types of hazardous drugs are encouraged to assess the relevance of these recommendations in their own practice settings and to implement those that are relevant and applicable. Please see Appendix 1 (available online) for definitions of frequently used words in this document.

Hazardous drug definition

While there is no single list of hazardous drugs that is accepted worldwide, the National Institute of Occupational Safety and Health (NIOSH) produces and updates a list periodically that can be used as a guide from which to develop a workplace or setting-specific hazardous drug list based on an inventory of the drugs handled and the potential for exposure. Guidance on how these workplace-specific lists should be developed is available through NIOSH (<http://www.cdc.gov/niosh/index.htm>). OACDs are among the many drugs that are considered hazardous.

Definition of oral anticancer drugs

For the purpose of these recommendations, an OACD is a drug that is used to treat cancer (or other indications) and is given by mouth and includes some hormonal agents. The health risks associated with exposure to individual OACDs are typically assessed based on their potential for carcinogenicity, teratogenicity, genotoxicity, reproductive toxicity or organ toxicity. In addition, exposure risk should be evaluated based on modifying factors, including the packaging of the agent for oral consumption (i.e., blister vs loose), formulation (i.e., coated vs uncoated tablet; tablet or capsule vs liquid) and frequency of exposure, although the latter can be difficult to quantify. Information on the potential hazard level of a drug may be found in resources such as

the safety data sheets produced by drug manufacturers and the list of hazardous drugs maintained by NIOSH.

Types of exposure and hazard control

Exposure to OACDs can vary but typically occur by inhalation of dust, particles and/or droplets (if a product is aerosolized or if product vapour exists); dermal contact through direct primary contact with the drug or drug powders present on the outside of containers or on contaminated surfaces during preparation; administration or disposal of OACD waste and/or oral contact through hand-to-mouth exposure or inadvertent ingestion.

Currently, there are no recommended exposure limits for OACDs, permissible exposure limits or threshold limit values established for hazardous drugs in general (e.g., by groups such as NIOSH, Occupational Safety and Health Administration or the American Conference of Governmental Industrial Hygienists, respectively). The likelihood that a worker will experience adverse effects from hazardous drugs increases with the amount and frequency of hazardous drug exposure and the lack of proper work practices.

Protection from hazardous drug exposure depends on adherence to safety programs established by employers and followed by workers. A comprehensive approach to eliminate or minimize worker exposure should be part of a safety and health program that includes safe work practices, proper engineering controls, personal protective equipment and training appropriate to the employee's job function, skill and knowledge.

There is limited literature to quantify the magnitude of contamination within the various workspaces of a community pharmacy. Similarly, the long-term health effects on those working in the community setting is largely unknown because the focus has traditionally been on staff within a hospital pharmacy, where the frequency and volume of exposure are substantially greater. Until evidence specific to the community pharmacy setting is available, a basic occupational health approach applying a hierarchy of controls to eliminate or minimize exposure should be applied. This includes, in order of hierarchy, limiting exposure through elimination of the hazard or substitution to replace the hazard with a less hazardous drug (often not feasible in health care), engineering controls to isolate workers

from the hazard (i.e., containment cabinet, use of unit-dose packaging), administrative controls to change the way people interact with their environment (i.e., storing OACDs in a segregated, labeled space to visually remind workers that special handling precautions are required) and, as the last line of protection, personal protective equipment (i.e., chemotherapy gloves, chemotherapy gowns, respiratory protection if risk of inhalation exists). In developing this consensus guideline, the hierarchy of controls was carefully considered and incorporated.

Approach to the development of a consensus guideline in a low-volume setting

There is a paucity of evidence regarding the potential health impacts associated with the often infrequent, short-term and low-volume exposure to OACDs in the community pharmacy setting. Few, if any, minimum thresholds for “safe” levels of occupational exposure of OACDs or other hazardous drugs have been established.

The recommendations in this consensus guideline were deliberately designed to be pragmatic and to introduce a moderate approach that would encourage a systemwide and gradual change in community pharmacy policy and practice.

Recommendations

Packaging

The manner in which manufacturers or distributors package OACDs, as well as other hazardous drugs, may be an influence on the degree of exposure (Table 1).

Receiving and unpacking

Within the community pharmacy setting, space is limited and pharmacy tasks may be shared among the pharmacy dispensary and nondispensary staff (Table 2). Pharmacy managers must take steps to develop and implement work practice policies and procedures to ensure that unintentional occupational exposure to OACDs is avoided. Education and tools (e.g., visual aids and/or checklists) must be provided so that receiving and unpacking occurs safely. Furthermore, policies and procedures for managing damaged shipments must be developed to avoid confusion about whether the pharmacy or the manufacturer/distributor is responsible for the cost of replacement product if a product package has been damaged during transport.

Storage

Distinctive labels and physical separation of OACDs from nonhazardous drugs is commonly recommended as an occupational health and safety measure to limit staff exposure, lower the risk of a medication error through incorrect selection of medication and visually indicate that special handling precautions are required (Table 3).

Drug preparation and handling

While the dispensing volume of OACDs in community pharmacies may be low, the potential for exposure supports the need for vigilance (Table 4). Where exposure limits exist (i.e., American Conference of Governmental Industrial Hygienists, NIOSH or province-specific resources such as Ontario *Regulation 833—Control of Exposure to Biological and Chemical Agents*), the employer must ensure compliance.

Evidence-based standards vary regarding the use of containment cabinets and personal protective equipment when the prescribed dose of an OACD is not commercially available and compounding of nonsterile hazardous drugs is required. Additional recommendations provided by NIOSH state that in the absence of a containment cabinet, the compounding of nonsterile hazardous drugs may be performed using alternative safe-work practices while wearing personal protective equipment in a low-traffic, designated area of the pharmacy.

Finally, the use of any other readily available material or equipment to further reduce inadvertent OACD exposure or spread should be considered very carefully along all points in the dispensing process, especially activities related to nonsterile compounding without the use of a containment cabinet (e.g., “Dissolve-a-Dose” containers, crushing tablets [using a mortar] and splitting tablets inside an enclosed clear, resealable bag, wetting a tablet prior to crushing to minimize aerosolization of particles).

Verification and dispensing

The dispensing of OACDs should be accomplished in a manner that minimizes contamination to the surrounding area, both in the workplace and in the patient’s home (Table 5). This includes dispensing these agents in original packaging if tablets are packaged by the manufacturer or distributor in full-cycle packaging or individual unit dosing. When this is not available, package in a manner that prevents/

TABLE 1 Manufacturer packaging

1.1	<p>Manufacturers of oral anticancer drugs should:</p> <ul style="list-style-type: none"> • Package the exact number of tablets needed for one cycle of therapy or, if there are multiple strengths or concerns about rapidly changing treatment recommendations, use individual unit-use packages (i.e., blister package).³ • Package oral anticancer drugs in durable packaging that is able to contain any accidental leakage during handling and transport of liquid formulations and is tamper proof. • Provide instructions for compounding liquid formulations.³ • Take all necessary precautions to reduce contamination on the outside of containers that contain oral anticancer drugs. • Affix safe handling warning labels on all layers of packaging for oral anticancer drugs, indicating that special handling and disposal precautions are necessary. The labels should be recognizable to individuals who handle or come into physical contact with oral anticancer drugs, including those responsible for transportation from the manufacturer or distributor to hazardous waste disposal.^{4,5}
1.2	<p>Distributors of oral anticancer drugs should:</p> <ul style="list-style-type: none"> • Take all necessary precautions to reduce contamination of oral anticancer drugs to surrounding containers to the lowest achievable level (e.g., packaging all oral anticancer drugs in a sealed plastic bag for shipping with other drugs). • Affix safe handling warning labels on all layers of packaging for oral anticancer drugs, indicating that special handling and disposal precautions are necessary. The labels should be recognizable to individuals who handle or come into physical contact with oral anticancer drugs, including those responsible for transportation from the distributor to hazardous waste disposal.^{4,5}
1.3	Those responsible for supply chain management and oral anticancer drug procurement in the community pharmacy setting may preferentially consider manufacturers and distributors whose practices promote delivery of a product that minimizes potential occupational exposure by handlers along the supply chain. ⁶⁻⁸

TABLE 2 Receiving and unpacking

2.1	Best practice recommends that receiving and unpacking of shipments that contain oral anticancer drugs should be in a separate room. If that is not possible, receiving and unpacking should be in a designated, low-traffic area. ^{6,7,9-11}
2.2	The task of receiving and unpacking drug deliveries that contain oral anticancer drugs should be the responsibility of specific individuals. These individuals should be given this responsibility only after completion of job-specific training. ^{6,9} A process should be in place to ensure adequate staff coverage in instances where the primary individual is absent.
2.3	The outside of cartons is examined for possible damage or leakage prior to unpacking in the event they contain oral anticancer drugs. ^{4-7,9,11}
2.4	Deliveries containing oral anticancer drugs where the integrity of the original manufacturer's package has been compromised, leading to the potential for occupational exposure to a hazardous drug, should be dealt with in the same manner as a spill. See Table 8. ^{6,7}
2.5	When an oral anticancer drug is received without appropriate warning labels, the pharmacy manager or other designated member of the pharmacy team should notify the originator (i.e., distributor, group purchasing agent or other) and reinforce the importance of affixing warning labels to indicate to those handling the delivery that special handling precautions are required. ⁵

TABLE 3 Storage

3.1	Oral anticancer drugs should be stored in a designated area, separate from nonhazardous drugs, and labelled with warnings that indicate the need for special precautions. If stored in a separate room or area, it should be clearly marked. ^{3,5-10,12,13}
3.2	Access to areas where oral anticancer drugs are stored should be restricted to staff who have received appropriate training. See Table 9, section 9.2. ^{6,9}

TABLE 4 Preparation and handling

4.1	Employers must take every reasonable precaution to limit individual staff member exposure to oral anticancer drugs so as not to exceed occupational exposure limits when these limits exist or, when they do not, to levels as low as reasonably achievable. ^{8,14}
4.1.1	<p>Nonsterile compounding of oral anticancer drugs should be done in a Class I biological safety cabinet (BSC).^{14,15} When nonsterile compounding of oral anticancer drugs in a containment cabinet is not possible, community pharmacies not equipped with a containment cabinet should consider:</p> <ul style="list-style-type: none"> • redirecting the patient or transferring the prescription to a pharmacy where compounding in a containment cabinet is possible^{10,16} or • contacting the prescriber to round doses up or down according to available strengths and body surface area/weight requirement or to determine if alternate-day dosing to make up the total weekly dose would be appropriate.^{8,17} <p>If it is not feasible to redirect or change the dose and the nonsterile compounding of a drug is deemed to be necessary and in the best interest of the patient, prepare the drug using personal protective equipment (see Appendix 2, available online), including 2 pairs of chemotherapy gloves (ASTM standard, see Appendix 2), a nonpermeable gown and respiratory protection (i.e., N95 or better) in a low-traffic area. If there is a risk of splashing, eye protection should also be used.^{3,8,12,18-22}</p>
4.1.2	Dedicated preparation equipment (i.e., counting trays) should be used to count oral anticancer drugs that do not require compounding. This equipment should be labelled for anticancer agent use only. ⁹
4.1.3	<p>The following should not be used when dispensing oral anticancer drugs:</p> <ul style="list-style-type: none"> • blister pack filling machines for uncoated tablets,¹³ • automated counting machines,^{3,4,8,9,11-13,19-21,23} or • an open mortar, if crushing tablets unless performed in a containment cabinet (e.g., biological safety cabinet or compounding aseptic containment isolator [CACI])²⁰ or additional measures are taken to limit exposure (e.g., enclosing open mortar in a plastic bag).
4.1.4	A list of hazardous drugs, including oral anticancer drugs, should be readily accessible to any individual who may come in contact with them in their work environment. ³ This list should be reviewed and updated periodically to ensure continued relevance.

minimizes contamination or access by unintended individuals.

In addition to safe handling dispensing practices below, other parameters that promote patient safety should be considered, including those outlined in the Canadian Association of Provincial Cancer Agencies' document, *Oral Cancer Drug Therapy Safe Use and Safe Handling Guidelines*.²⁴ Pharmacy team members should be aware of and follow recommended practices, including but not limited to dispensing only one cycle of OACDs at a time and ensuring that both dispensing and cognitive verification checks are conducted by individuals who are knowledgeable and trained to accept responsibility for the clinical safety of the prescription.

Clinical verification of OACDs in community pharmacy settings can be a difficult task to fully complete. Often community pharmacists have limited access to patient medical records. They may also have limited training related to cancer

treatment and little exposure to OACDs due to low dispensing volumes. As a result, it is recommended that OACD prescriptions be reviewed by a pharmacist with experience and training in cancer treatment. When this is not possible, it is important that a network be established such that a pharmacist with experience and training in cancer treatment is available for consultation and the use of a checklist is implemented to facilitate clinical verification.^{25,26} Additionally, telephone orders should not be allowed, as they can introduce errors, especially if a pharmacist is not familiar with cancer treatment regimens.

Concerns about the safe handling of OACDs by community pharmacists may multiply when prescriptions are delivered directly to a patient without the benefit of any in-person pharmacist and patient interaction. While direct-to-patient delivery offers advantages for patients, including fewer visits, less travel and improved convenience, it simultaneously reduces the

opportunity for face-to-face education and toxicity and adherence assessment, among other relevant and important issues. While there are programs designed to offer telephone counseling to patients or caregivers prior to direct-to-patient courier prescription delivery and call-back programs to provide adherence and toxicity monitoring after delivery, these programs are not consistently available and may be inadvertently omitted if patients are on multiple medications, including non-OACDs. Without this additional due diligence, direct-to-patient courier delivery is not considered ideal and is not recommended until after the initial OACD prescription is dispensed to the patient in person.

Personal protective equipment

Hazards exist in most workplaces, and in a pharmacy environment, whether community or otherwise, workers are likely to come in contact with hazardous drugs. Although there are other more effective controls to protect against exposure to hazardous drugs (e.g., controlling a substance at its source [elimination], substitution, engineering controls and administrative controls), personal protective equipment (PPE) remains the last and possibly the *only* line of defense when other controls are not in existence or are not obtainable, are rendered ineffective because of a temporary breakdown or as an interim control measure while engineering and administrative controls are being implemented (Table 6).

Gloves. The gloves used to handle hazardous drugs must be powder free, made of latex or nitrile (polyurethane or neoprene are also acceptable) and comply with ASTM standard D-6978-05 (standard for chemotherapy gloves). Due to the allergenic properties of latex, other materials are often used. Vinyl gloves are not recommended, as they are more permeable to hazardous drugs. Gloves may be sterile or nonsterile. Workers should change both sets of gloves every 30 minutes or less in the event of contamination, spillage or breakage of oral solutions. All gloves have some degree of permeability to hazardous drugs. This permeability increases over time, but 30 minutes is an appropriate average time that ensures protection.⁷ A pragmatic approach was taken with the consensus guideline, and 2 pairs of chemotherapy gloves are recommended to avoid confusion when trying to recall the number of gloves to wear when handling OACDs.

Gown. The gowns used when handling hazardous drugs should be disposable; made of lint-free, low-permeability fabric; have long sleeves with adjustable cuffs and tie or fasten in the back. Polypropylene gowns coated with polyethylene or vinyl are recommended when handling oral solutions. Workers should change gowns in the event of contamination, spillage or breakage of containers with oral solutions. The supplier must be able to certify that the gown protects against hazardous drugs. It is not recommended to reuse gowns.⁷

Disposal and waste management

Notwithstanding the low volume of OACDs dispensed by community pharmacies, the importance of disposing of hazardous waste in accordance with legislation, regulation and best practice remains a vital operational issue not only for environmental reasons but also to ensure that worker exposure during this end process is also limited (Table 7). Regardless of the low volume of OACDs dispensed by community pharmacies, the corporate entities to which they belong should establish and internally disseminate organization-wide policies about disposal and waste management, and individual stores and individual practitioners should be expected to demonstrate compliance.

Spill protocol

Spills may occur at any stage of the OACD process, from receiving, storage, dispensing, to waste management. A policy, procedure or guideline should be established to handle any spill situation (Table 8). There is insufficient evidence at this time to recommend a spill kit for patients taking OACDs only in the home.

Training and education

Staff training and education on the safe handling of OACDs is critical to a safe practice (Table 9). Policies and procedures should be developed centrally. Training programs should reflect these policies, procedures and legislative requirements and should be drug specific where appropriate. Training programs should be current and standardized across pharmacies within a corporation.

Education for patients and caregivers must be provided according to professional practice standards and should include pertinent information to enable safe and effective use of OACDs in the home. This information should be assessed

TABLE 5 Verification and dispensing

5.1	<p>When dispensing oral anticancer drugs, community pharmacy staff should:</p> <ul style="list-style-type: none"> • Dispense them in original packaging if tablets are packaged by the manufacturer or distributor in full-cycle packaging or individual unit dosing,^{8,14} and when tablets have not been provided in either of these formats, dispense in containers with childproof lids.^{8,10,12,17} • If easy-open lids are required, reinforce the importance of avoiding inadvertent exposure to children or pets.¹⁷ • Count and repackage tablets/capsules in a manner that avoids skin contact, as well as minimizes aerosolization and cross-contamination of other drugs.^{8-10,12,17,20} • Dispense liquids in bottle or vial packaged in a clear, closed, resealable plastic bag.⁴ • Dispense in ready-to-use formulation (no crushing or splitting required on the part of the patient).^{4,21} • Label oral anticancer drugs as “do not cut or crush.”¹⁰
5.2	<p>When oral anticancer drugs cannot be dispensed in person and direct-to-patient courier delivery is being considered, the dispensing pharmacy should recommend that at least the initial filled prescription be reviewed in person to enable provider-to-patient discussion, training and education to supplement that provided by the patient’s cancer care team.</p>
5.2.1	<p>When direct-to-patient courier delivery does occur, all national and provincial standards must be met. In addition, the delivery of an oral anticancer drug should only occur when it has been confirmed that someone is available to receive the delivery. The receiver of the delivery should be able to assume accountability for the delivered package.</p> <p>The delivery process should include a chain of signatures to assist with delivery tracking. Packages of oral anticancer drugs should not be left on a doorstep or in a mailbox. As best practice, a documented follow-up call should occur to confirm the patient has received the delivery and understands how to take the medicine and to answer any questions that arise.</p>
5.3	<p>Ensure the traceability of a dispensed product that is aligned with legislative requirements, where they exist. At minimum, the batch/lot number, along with expiry date (and other required information), should be documented in the medication management system in the event of a product recall. The use of barcoding may assist with this process.</p>

and reviewed at each dispensing encounter as appropriate.

Staffing

Determining appropriate pharmacy staffing levels is the responsibility of pharmacy managers and is beyond the scope of this document (Table 10). However, there are fundamental principles that should be carefully considered in determining the optimal and appropriate staffing mix or size. It is well known from the field of human factors that workplaces and work processes have a profound effect on the risk of medication incidents. Given the busy environment, frequent distractions and complex processes within a community pharmacy, pharmacy managers and individual pharmacy team members should be aware of the impact of things like prolonged periods of work without break and frequent interruptions when working with high-alert medications. Human factors experts may be called upon to assist with

the design of pharmacy work processes with changes, such as segregating OACDs in a pharmacy. Finally, there are few data to confirm that the time required to provide patient education regarding OACDs may be longer than the time required for other dispensed products, and it is a reasonable area to explore. If correct, a process to evaluate current dispensing fees for OACD products, even if only for the initial dispense, should be explored.

Incident reporting

Quality improvement is a key component of delivering safe and high-quality care. Incident learning allows the profession to learn from both near-miss or actual events with the goal of implementing quality improvement initiatives to improve safety (Table 11). Unfortunately, mandatory incident reporting is not consistent across the provinces in Canada, which limits the opportunity to analyze aggregate incidents across the community pharmacy system as a

TABLE 6 Personal protective equipment

6.1	Appropriate personal protective equipment (PPE) should be available and worn wherever oral anticancer drugs are handled (i.e., unpacking, storing, dispensing and disposing). PPE shall be removed before leaving the dispensary. ^{6,7,10-12,18,20}
6.1.1	No PPE is required: <ul style="list-style-type: none"> • During transport or receiving as long as there is no evidence of an exposure hazard (e.g., leak, powder residue) • When handling oral anticancer drugs in their final dosage form (i.e., original bottles, prescription vials or blister packages) • If boxes are stored as received (not opened)
6.2	When unpacking or placing oral anticancer drugs into storage area, 2 pairs of chemotherapy gloves (ASTM standard, see Appendix 2) should be worn. ^{6,15}
6.3	During collection and transport of hazardous waste and when waste is in an open container, a protective gown (i.e., impermeable) should be worn in addition to 2 pairs of chemotherapy gloves (ASTM standard), and if there is a risk of a splash or spill, a protective gown, respiratory protective equipment (i.e., N95 or better) and protective eye wear should be worn.
6.4	During cleaning of the designated preparation area or when repackaging nonsterile oral anticancer drugs (i.e., liquid oral solutions, uncoated tablets), 2 pairs of chemotherapy gloves should be worn (ASTM standard), and if there is a risk of a splash or spill, a protective gown, respiratory protective equipment (e.g., N95 or better) and protective eye wear should be worn. ^{6,7,24}
6.5	When cleaning the containment cabinet, 2 pairs of chemotherapy gloves (ASTM standard), a protective gown, respiratory protective equipment (e.g., N95 or better), protective eye wear, a hair cover and shoe covers should be worn. ^{6,7,15}
6.6	When handling damaged packages containing oral anticancer drugs or if a spill occurs, full PPE should be worn, including 2 pairs of chemotherapy gloves (ASTM standard), a protective gown, shoe covers, eye protection and respiratory protective equipment (e.g., N95 or better) if there is a risk of aerosolization of drug residue. ⁴ Facilities with access to a biological safety cabinet should open damaged packages inside the containment cabinet. ^{14,15}
6.7	All PPE should be changed in accordance with the manufacturer's directions after use, immediately if contaminated or if contamination is suspected. Disposable PPE should be disposed of in an appropriate hazardous waste container. Reusable PPE, such as protective eye wear, should be cleaned with soap and water after use and allowed to air-dry before reuse or storage. ²⁷
6.8	Hands should be washed with soap and water after removing PPE. ^{3,7,8,17,21,27}

whole. Without these data, it is difficult to identify root causes and patterns, especially given that incidents are likely to occur infrequently. In this largely data-free zone, identifying and implementing approaches to mitigate the risk of further events will remain a difficult, if not impossible, task.

Implementation

It is anticipated that full adoption of these recommendations may be challenging because of the complexity of some of them, the novelty with respect to established practice and the

infrastructure to support implementation.³⁵

When considering implementation pacing, the most important factor should be ensuring the safety of pharmacy staff and patients. Practically, the speed of implementation will depend on a number of factors. The more than 30 individuals and organizations that responded to the external review of this consensus guideline commented on the anticipated speed of implementation (Figure 1). While it is understood that existing legislative requirements should already be in place, the variable pacing of recommendations included in this consensus guideline will create

TABLE 7 Disposal and waste management

7.1	The dispensing pharmacist should instruct the patient to return unused medication to dispensing or other pharmacy for disposal and not to dispose with household waste. To minimize inappropriate disposal in the home, pharmacies should accept oral anticancer drugs for disposal <i>even if</i> dispensed at another pharmacy. This should be reinforced in written material given to the patient. ^{17,21}
7.2	<p>Hazardous waste containers should:</p> <ul style="list-style-type: none"> • Be placed in the receiving and unpacking area and in the dispensary^{6,7} • Be rigid and leak- and puncture-proof^{6,7,9-12,17} • Be placed away from drains and areas where food is stored or eaten²³ • Have a sealable lid and foot pedal to open when needed⁶ • Be double-bagged, sealed and removed when three-quarters full^{7,10} • Have a cytotoxic label affixed in a visible location on the outside of the container^{6,7,12,27}
7.3	Segregate hazardous waste as soon as it is generated. ²³
7.4	Hazardous waste pickup should be scheduled for pickup and delivery to a facility that incinerates hazardous waste, avoiding peak activity in the pharmacy. ^{6,7,10}
7.5	<p>Dispensing equipment (e.g., tray, spatula) and hard surfaces (e.g., counter) that come in contact with oral anticancer drugs should be:</p> <ul style="list-style-type: none"> • Cleaned after each use using soap and water and allowed to air-dry before reuse¹³ • Decontaminated periodically (at least once per month¹⁵) with hypochlorite solution (e.g., 2.4% bleach) to denature hazardous drugs. After being decontaminated and allowed to sit for a few minutes, surfaces should be washed with soap and water and dried with a disposable towel.^{10,13,20} Sodium hypochlorite is not suitable for all oral anticancer drugs and will corrode stainless steel surfaces. Instead, sodium thiosulfate or a germicidal detergent (e.g., Surface Safe) should be used to remove/neutralize these agents and surfaces.¹⁵ <p>Isopropyl alcohol should <i>not</i> be used as a cleaning solution, as it can dissolve and spread drug residue instead of removing it.¹³</p> <p>Carpets are not easily cleaned and should be avoided in the pharmacy area.⁴</p>

opportunities to learn from and build on implementation efforts across the system. Given how important local factors are in determining implementation pacing, these timelines are intended to provide a starting point for discussion.

The external review process validated the assumption that accessible tools (e.g., pharmacy verification checklist, patient information regarding safe handling and disposal of OACDs, spill management training video) and information will be invaluable. Further consideration should be given to ensuring that this kind of support and resources are available.

Limitations

This consensus guideline was informed by both evidence and expert opinion. A systematic review of the literature was conducted, but it is recommended that literature, guidance documentation or other information released since the publication of this consensus guideline should be reviewed and considered as part of a

comprehensive approach to addressing OACD safe use and handling.

In an attempt to ensure that the recommendations remained relevant, the community pharmacy sector was actively involved in every step of this consensus guideline development process. However, because we were unable to engage 100% of the community pharmacy chains in Canada and because we were unable to find an adequate mechanism to engage with independent pharmacy store owners, it is possible that there are views that have not been incorporated.

Next steps

Feedback submitted during the external review of this consensus guideline suggests that pharmacy team members would benefit from the availability of tools (e.g., verification checklists) and that patients and their caregivers would value additional information not only about the drugs they are taking but also the questions they may wish to consider asking their community

TABLE 8 Spill protocol

8.1	<p>A policy, procedure or guideline should be in place that specifies:</p> <ul style="list-style-type: none"> • Assignment of accountability for spill management to individuals with appropriate training • Spill simulation exercise (annual basis or more frequently)⁷ • Appropriate personal protective equipment (PPE), as described in Table 6, section 6.6, and in Appendix 2^{4,10,13} • Cleaning requirements that include instructions to: <ul style="list-style-type: none"> ○ Clean from least to most contaminated.^{4,7,20} ○ Absorb liquid spill with an absorbent towel or pad (e.g., Chemosorb pad) before cleaning with water and soap. ○ Clean with detergent and water from area of most to least contaminated. Decontamination with sodium hypochlorite (left for approximately 10 minutes) may be considered for a large spill (>30 mL), followed by further cleaning of the area with detergent and water.^{7,13} ○ Cover spills involving powder with a wet towel or pad to prevent aerosolization of the product. The absorbent side of a plastic-backed pad can be used to pick up most of the product.^{10,13} ○ Dry the area with a disposable towel.¹⁰ ○ Dispose of all materials used in spill management (including PPE) in a plastic bag labeled “cytotoxic” and dispose plastic bag in a hazardous waste container.^{4,7,10,13} ○ Wash hands with water and soap after the spill has been cleaned.^{4,10,20} <p>The safety data sheets for products used for cleaning and decontamination must be made available onsite and be easily accessible.⁷</p>
8.2	Spill kits should be clearly labelled and available in all areas where oral anticancer drugs are handled and stored. ^{4,7,10-12,27}
8.3	<p>The spill kit located in community pharmacy should include:</p> <ul style="list-style-type: none"> • Policy, standard operating procedure or guideline^{12,13,20,28} • Cytotoxic/hazardous drug spill signage^{7,12,13,20} • List of supplies and PPE^{12,20,28} • Absorbent materials (disposable)^{12,13,28} • Small scoop or scraper to collect glass/other fragments^{10,12,27} • PPE including 2 pairs of chemotherapy gloves (ASTM standard, see Appendix 2), protective gown, respiratory protective equipment (e.g., N95 mask or better), protective eye wear and shoe covers • Sharps or robust puncture-proof container • Hazardous/cytotoxic waste bags^{12,13,20} • Cleaning agents (soap and water)^{12,20,28} • Incident report form(s)^{20,28} • Outside label clearly identifying contents (i.e., “Spill Kit”)

pharmacy team. Organizations that have a mandate in pharmacy practice and in patient and medication safety should explore how to address these opportunities. Furthermore, an evaluation of the degree of congruence between this consensus guideline and community pharmacy practice should be undertaken at regular intervals.

Conclusion

Safe delivery of care must be the constant in an ever-changing, always improving cancer delivery system. Regardless of whether patients are treated in an outpatient environment or receive and self-administer their OACDs in the community, the safeguards should be as similar as would

be considered reasonable and prudent. Similarly, whether care providers are working in a hospital, outpatient setting or community pharmacy, they have the right to know that their employer adheres to existing legislation regarding workplace health and safety and that they are taking every reasonable precaution under the circumstances to protect their occupational health and well-being. The growth in availability and use of OACDs when combined with preliminary and self-reported data from the community pharmacy sector suggests a wide degree of variation in terms of the safe use of these drugs. This finding warranted the development of a setting-specific set of recommendations that are practical and,

TABLE 9 Training and education

9.1	Policies, procedures and/or guidelines regarding safe handling of oral anticancer drugs should be developed, implemented and regularly revised and evaluated. ^{6,12,29}
9.2	All members of the community pharmacy team involved in handling, or who may come in contact with oral anticancer drugs or related waste products, should have training and education that is appropriately detailed to their job function, prior to commencement of assigned duties and when new classes of oral anticancer drugs are introduced or procedures change. Standardized competency testing and regular reevaluation would be beneficial. ^{9,10,20}
9.2.1	Initial and regular training for dispensing pharmacists and pharmacy technicians should include but not be limited to information about the following ^{3,9,10,20,23} : <ul style="list-style-type: none"> • Safe work practices and procedures when handling or disposing of oral anticancer drugs, including appropriate use of personal protective equipment (PPE) as detailed in Table 6 and Appendix 2 of this document • Work hazards and potential risks of exposure to oral anticancer drugs and related waste • Legislative requirements for waste management • Management of a spill (including potential spill simulation exercises) • Mandatory reporting for accidental exposures, where required • Any other legislative training (e.g., Workplace Hazardous Materials Information System [WHMIS]). Supplemental resources should be made accessible on site, either online or in print.
9.2.2	Training programs should be regularly evaluated and updated. ^{9,10,23}
9.3	In addition to professional practice standards, when dispensing oral anticancer drugs, community pharmacies should provide patient education including, at a minimum, the following ^{3,7,8,10,12,17,20,21,24,27,30-32} : <ul style="list-style-type: none"> • Special storage, handling and disposal instructions. Specifically, patients should be made aware of any recommendations regarding PPE use when opening dispensed packaging and administering or applying medication, storing medication away from children and pets, and returning unused medication to a pharmacy, ideally the dispensing pharmacy. • Instructions for use, handling missed doses, managing side effects, importance of adherence, breastfeeding and reproductive precautions (as applicable) for men or women thinking of or preparing to have children. In addition, early and periodic adherence monitoring and toxicity assessment either by phone or other means of communication is important.

TABLE 10 Staffing

10.1	Factors and work processes that influence how safely pharmacy staff perform their work, including frequent rest breaks, task rotation and opportunities for uninterrupted work space when dispensing high-alert medications (e.g., oral anticancer drugs), should be carefully considered and implemented wherever possible. ⁹
10.2	Community pharmacies that employ staff who are planning parenthood, are pregnant or are breastfeeding should consider policy options to limit exposure to oral anticancer drugs, including the possibility of protective reassignment. Information or counselling regarding the potential reproductive health risks from exposure to hazardous drugs should also be provided. ^{6,9,20,27}

TABLE 11 Incident reporting

11.1	All medication incidents and close calls should be reported through incident reporting systems, such as the National System for Incident Reporting (NSIR), safemedicationuse.ca, Individual Practitioner Reporting Program and/or Community Pharmacy Incident Reporting (CPhIR) system. If incidents are reported through a corporate community pharmacy incident reporting system, anonymized data should be shared by the company with ISMP Canada or another expert group to ensure opportunities to learn and reduce the risk of future events. ^{24,33,34}
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FIGURE 1 Expected implementation by external review respondents ($n = 32$)

relatively speaking, easy to follow. This consensus guideline, developed through partnership with the community pharmacy sector, demonstrates a commitment to strive for best practice. In reality, the ability to implement will be tempered by several factors, including space, business planning and the ability to pace recommendations to focus on those with the greatest impact first while

working towards fuller implementation over time. Uneven pacing is expected, and as long as the perspective of addressing these recommendations is focused on a journey of quality improvement and safe care, rather than a destination, we should all be reassured that the system is moving in the right direction on behalf of patients and all Canadians. ■

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