

Summary: Quality & Safety Recommendations for Enhancing the Delivery of Take-Home Cancer Drugs in Ontario

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TRAINING AND EDUCATION FOR PROVIDERS

Evidence Summary

- ✓ Errors relating to prescribing, dispensing and administration of THCD that result in patient harm are well documented in the literature. ^{1,2,10,3,4,4–9}
- ✓ The availability of a competent and skilled workforce is essential to ensure safe medication practices across the cancer care continuum.^{11–18}
- ✓ Providers involved with THCD delivery should have appropriate skills and qualifications in the management and treatment of cancer. ^{11–18}
- The treatment of cancer and the modalities employed are continually evolving. Insufficient training and education on new protocols can compromise safe delivery of treatment. ^{11–18}
- ✓ Health care organizations/employers have a responsibility to ensure staff maintain competency and meet continuing professional development requirements that reflect their role and responsibilities and are relevant to their current scope of practice. ^{11–17,19}

RECOMMENDATION 1: Health care providers involved in one or more of prescribing, handling, dispensing, patient education and/or monitoring take-home cancer drugs should have oncology specific training and demonstrate ongoing competency in oncology care.

RECOMMENDATION 2: Health care organizations/employers involved in one or more of prescribing, handling, dispensing, patient education and/or monitoring take-home cancer drugs should develop a plan to ensure that providers are appropriately trained and maintain the knowledge and skills required for their job function. The organizational plan should include methods for standardized oncology training and routine performance assessment. Health care organizations/ employers should also support health care providers to receive this initial training and continued professional education.

ACCESS TO CARE

Evidence Summary

✓ The impact that navigation programs have on improving clinical outcomes and overall patient experience in oncology are well documented in the literature.^{20–25}

RECOMMENDATION 3: Health care organizations/employers should offer assistance to navigate reimbursement options (e.g., oncology drug access navigators) to patients and/or caregivers to ensure that optimal therapy and/or treatment alternatives can be readily accessed. Members of the cancer care team should ensure that patients and/or caregivers understand the treatment and funding options available to them and facilitate prescription access/dispensing in a timely manner with minimum patient burden.

PRESCRIBING

Evidence Summary

- ✓ Lack of information, use of inconsistent terminology, and unrecognized abbreviations lead to misinterpretation of medication names, doses and dosage instructions and increases the potential for errors.^{10,13,33–37,16,26–32}
- ✓ Handwritten prescriptions and verbal orders increase the potential for errors.^{4,6,43,10,18,29,38–42}
- ✓ Standardization of the prescribing process and associated documentation reduces the likelihood of errors. ^{4,6,40–44,10,15,26,29,33,34,38,39}
- ✓ The use of computerized prescriber order entry (CPOE) to facilitate prescribing has demonstrated to improve safety.^{34,45–52}
- An independent double-check ensures that the prescribed treatment is accurate and consistent with the intended treatment, before sending it to the dispensing pharmacy. This process enhances safety by increasing the visibility of errors and thus, preventing errors from reaching patients. ^{14,16,26,53–56}

RECOMMENDATION 4: All prescriptions for initiating or renewing take-home cancer drugs should be generated using systemic treatment computerized prescriber order entry (CPOE) implemented in an evidence-based manner. Handwritten prescriptions and verbal orders are unacceptable. Telephone orders are never accepted for systemic treatment except to hold, delay or discontinue the treatment in which case, the instructions should be noted on the prescription followed by a counter signature/electronic signature by the prescriber.

RECOMMENDATION 5: In addition to existing laws, regulations, and professional practice standards in Ontario, prescriptions for take-home cancer drugs should include the content listed below. Organizations should also refer to CCO guidelines for systemic treatment computerized prescriber order entry (CPOE) to ensure their systems meet the minimum requirements.

→ Patient variables:

- At least two unique patient identifiers
- Current height (SI unit), weight (kg), and Body Surface Area (BSA) (values should be determined using only the Mosteller equation to reduce the risk of BSA calculation and dosing errors), as appropriate
- Allergies
- $\rightarrow\,$ Chemotherapy Protocol and Dosing Schedule:
 - Diagnosis or disease-specific indication for treatment
 - All of the drugs in the regimen
 - Use full generic name and use TALLman lettering (if applicable) according to ISMP Canada recommendations

- Route, dose and frequency
- Total quantity prescribed (Mitte)
- Delays, dosing modifications, omissions and rationale, where applicable
- Methodology used to calculate the dose (BSA, weight or other) i.e.,100mg/m² or 5mg/kg
- Cycle number out of total planned cycles (e.g. C3D1, cycle 3 day 1), where applicable
- Clear dispensing instructions on intended start date, cycle days, timing, duration (e.g., Days 1 to 5; start date Dec 1, 2017)
- Denote "please do not request refills (i.e., e-renewals, fax authorizations)" as the default statement
- → Clinically relevant information/additional instructions for the dispensing pharmacist, where applicable (e.g., concurrent radiation, additional prescriptions, dispensing calendars, compliance aids)
- → **Drug Coverage Status/Application** (e.g., Limited Use code listed, or application/approval for drug coverage under the Exceptional Access Program)
- \rightarrow Prescriber information:
 - CPSO#
 - Direct contact information

RECOMMENDATION 6: All prescriptions for take-home cancer drugs should undergo an independent double-check. This procedure involves two licensed health care professionals clinically verifying the prescription separately (Refer to R7) and then another two licensed health care professionals completing the technical/dispensing/final product check separately

RECOMMENDATION 7: At least one oncology health professional (excluding the prescriber and preferably a pharmacist with oncology training) should follow the key steps listed below when verifying the prescription before it is sent to the dispensing pharmacy and there should be a sign-off that the verification has been completed.

\rightarrow Patient Variables:

- Verify patient identity using two identifiers
- Check current height (SI unit), weight (kg), and BSA (BSA values should be determined using only the Mosteller equation to reduce the risk of calculation and dosing errors), as appropriate
- Confirm and check for additional allergies
- Confirm diagnosis or disease-specific indication
- \rightarrow Regimen:
 - Identify the treatment as new or ongoing
 - Verify that the regimen is appropriate for disease-specific indication
 - Verify full generic drug name and correct dose to be given
 - Check for drug interactions between regimen and patient's concurrent medications

- Verify that the routes of administration are correct
- Verify that the schedule is appropriate for the regimen
- Verify the administration instructions
- Check for toxicities or intolerances from the previous cycle, if applicable
- Verify the intended start date and the exact duration of treatment

\rightarrow Dose:

- Verify that the prescribed dose is appropriate for the drug, the disease-specific indication, and the patient
- Verify that the calculated dose is correct as per the patient's current BSA or weight, if applicable
- Verify that the quantity prescribed is sufficient to cover the patient for the intended time frame and that no refills have been added
- Review original laboratory data including the most recent results and trends over time, where available
- Check for modified dose, when applicable (e.g., renal impairment, hepatic impairment, other comorbidities, treatment-related toxicities like myelosuppression)

\rightarrow Patient Care:

- Verify pre-, post- and supportive care medications as ordered
- Verify that the prescriber/drug access navigator has secured coverage or funding assistance on behalf of the patient
- Provide patient and/or caregiver education (refer to R8)
- Identify psychosocial aspects/barriers to adherence, if any (refer to R9, R10)

PATIENT AND/OR CAREGIVER EDUCATION

Evidence Summary

- Adverse events have been associated with patients misinterpreting instructions and inadvertently taking an incorrect dose or continuing therapy beyond that prescribed.^{34,57–62}
- ✓ Patients and/or caregiver should have the knowledge and skills necessary to enable self-care and self-management safely outside the hospital environment.^{32,63–66}
- ✓ Prior assessment of a patient's and/or caregiver's educational needs and learning abilities allows providers to choose suitable methods of teaching, and ensure that that patients and/or caregivers receive the type of information that is desired and relevant for them.^{67–70}
- ✓ Patients and/or caregivers who received a structured program of information during the course of treatment reported significantly less disruption in usual activities before and after the therapy.^{63,66–72}

RECOMMENDATION 8: Members of the cancer care team should develop an education plan for initial and follow-up visits. Establish a process to determine who in the cancer care team provides which piece of information listed below (verbally and in writing) to the patient and/or caregiver. The health care professional(s) should document the counselling session(s), and the patient and/or caregiver should certify that they received and understood the information.

<u>RECOMMENDATION 9</u>: Use a standardized tool [e.g., Multinational Association for Supportive Care in Cancer (MASCC) Oral Agent Teaching Tool (MOATT)] to facilitate the following:

- Assess patient and/or caregiver knowledge of the diagnosis, treatment plan and current medications.
- Assess the patient's and caregiver's ability to obtain and administer take-home cancer drugs
- Provide general teaching instructions (e.g., storage, handling, disposal, strategies to remember to take medications)
- Provide drug-specific information (e.g., dose, schedule, side effects, potential interactions)
- Ascertain understanding of the information provided (e.g., teach back method) and address information gaps
- Determine the level of support that the patient needs to ensure the best outcomes within the context of their psychosocial situation.

RECOMMENDATION 10: Supportive care management plans should be established for all patients receiving take-home cancer drugs; however, adherence aids, educational/organizational interventions, and additional supportive plans which include caregivers or home/community care, may be required for patient populations where safety is a particular concern (e.g., complex treatment, literacy, cognitive issues).

COMMUNICATION PLAN

Evidence Summary

- ✓ Communication failures during clinical hand-offs can result in poor continuity of care, increased risk of medication errors, compromise patient safety and an overall lead to poor patient experience and quality of care.^{15,18,34,73–76}
- ✓ The roles and responsibilities of each multidisciplinary team member should be defined and expectations should be clarified about how each discipline will communicate and work collaboratively to provide treatment.^{15,18,34,73–76}
- ✓ A plan improves safety in the delivery of treatment and ensures consistent communication to all providers that encounter the patient. ^{15,18,34,73–76}

RECOMMENDATION 11: A communication plan should be established by the prescribing institution and shared with the patient and/or caregiver and all members of the cancer care team, across the cancer treatment continuum, to facilitate an integrated approach to care.

DISPENSING

Evidence Summary

- ✓ The hazards of occupational exposure anti-cancer medications through inhalation, dermal and/or oral contamination, require appropriate controls to reduce risk.^{2,15,77–82}
- Standardized and thoughtful drug labeling practices need to be a part of an overall strategy to improve medication adherence and reduce inadvertent medication errors.^{18,26,32,37,58,61,62,83,84}
- ✓ High pill burden can contribute to a patient's anxiety, confusion and subsequent nonadherence.^{85–87}

RECOMMENDATION 12: Follow regulatory standards and provincial/national guidelines for the safe handling of hazardous drugs including packaging, receiving, unpacking, storage, preparation, transportation, administration, equipment for personal protection, spill management, environmental cleaning and waste disposal.

RECOMMENDATION 13: Dispense the fewest number of tablets when there are multiple dose strengths of take-home cancer drugs, as clinically appropriate.

<u>RECOMMENDATION 14</u>: In addition to labelling requirements, each take-home cancer drug prescription vial/prescription container must:

- Specify "no refills" and part-fills (e.g., 90 tablets of 360 tablets every 30 days), where appropriate
- Include the before use date and storage conditions, if applicable
- Be affixed with the appropriate auxiliary label(s) to indicate required precaution(s). At minimum there should be a label to indicate cytotoxic drug

PATIENT MONITORING

Evidence Summary

- ✓ Toxicities are common and may cause disruptions in treatment, impaired healthrelated quality of life, and unplanned health care service use.^{88,89}
- ✓ Suboptimal adherence is associated with diminished therapeutic efficacy with lower exposure to drug, influencing risk for recurrence and mortality.^{86,90–92}
- ✓ Proactive monitoring prevents escalation of symptoms and delayed contact with clinicians.^{10,93–98}
- ✓ Proactive monitoring creates opportunities to answer questions and to reinforce key patient safety messages.^{10,93–98}

RECOMMENDATION 15: When initiating a new therapy, a proactive monitoring plan (i.e. the schedule for follow-up contact/visits) should be put in place and communicated to the patient and/or caregiver. The plan should be tailored to specific patient groups and drugs/protocols. The plan should be reassessed and dose modified, if necessary. Patients and/or caregivers and other health care providers should report back to the cancer care team promptly if there are:

- Adverse drug reactions
- Medication-related incidents
- Problems with adherence
- Potentially severe near misses
- Change in patient- and condition-related factors (e.g., cognitive decline)

INCIDENT REPORTING

Evidence Summary

- ✓ Not all incidents are reported, even when actual harm occurs, but especially when no harm occurs and the incident is a close call or near miss.^{99–104}
- More effective organizational learning from potential and lower severity incidents could lead to system improvements that will reduce the risk of adverse events.^{15,26,99,105,106}

RECOMMENDATION 16: Near misses and/or medication-related incidents should be reported to incident-based reporting systems [e.g., local reporting systems, Assurance and Improvement in Medication Safety (AIMS) Program, Canadian Medication Incident Reporting and Prevention System (CMIRPS) Program, safemedicationuse.ca].

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