Guidelines for outpatient cancer care by community pharmacists

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Introduction

The pharmacotherapy of cancer is changing. Systemic therapy, using high-risk intravenous (IV) drugs administered in hospitals, continues to be a key tool in cancer treatment. IV systemic therapy has been joined by a growing number of new agents, many of which are taken orally and dispensed by the community pharmacist.

Many new treatments are designed to target very specific steps in the intracellular pathways used by cancer cells to ensure their continued propagation. The indications for use of these new agents are often very specific to patients with particular cancers, expression of certain biomarkers and/or designated genetic mutations. For many new agents, this translates to very small populations of eligible patients, often as low as 1 or 2 per 100,000 population. With 4 to 6 new drugs approved annually and at least 3 dozen drugs in clinical trials,¹ it is not reasonable to expect the community pharmacist to be knowledgeable about this rapidly developing therapeutic area. Studies in individual jurisdictions^{2,3} and across Canada⁴ have demonstrated that community pharmacists lack the necessary knowledge or confidence when providing these medications to this subset of patients. Yet these treatments are as hazardous to patients as many IV systemic therapies.^{5,6}

Community pharmacists indicated that they understood that hospital-based clinicians exclusively handled medication management with oral cancer drugs. In a study examining human factors issues with oral systemic therapy drugs,⁷ it was identified that different levels of patient support were offered by different hospital-based

clinicians, but most offered no order verification or ongoing management beyond the physician visit. Ordering and dispensing oral systemic therapy is considered a high patient care risk practice, and solutions have been designed (pending funding) for the necessary additional resources. Even if these processes were fully implemented, there remains a critical role for community pharmacists to assist in providing the level of care appropriate to these hazardous drugs.

Cancer Care Nova Scotia (CCNS) determined that an alternate approach was required to enable community pharmacists in our province to provide appropriate clinical care to cancer patients receiving these oral systemic therapy agents. The traditional approach of “just-in-case” education was not shown to be effective, as demonstrated in the practitioner surveys conducted.²⁻⁴ The relative rarity of patients who qualify for these drugs is so low that many pharmacists seldom or never see these drugs in their practice. Instead, a “just-in-time” process was developed. Using the public website supported by CCNS,⁸ a set of drug-specific tools was developed and implemented to support community pharmacists (and community nurses and other health care practitioners). The process and associated tools are described in detail below. Although community pharmacists receive no specific reimbursement for the activities proposed, we believe that the clinical care provided by the community pharmacist is crucial to optimal patient care and, if proven effective, could result in additional service reimbursement by insurers as a cost-saving initiative.

*Lead author Larry Broadfield passed away a few months before publication of this article. See longer note at end of article.

TABLE 1 Content components of the Pharmacy Toolkit

Instructions for the pharmacist <ul style="list-style-type: none"> • Prescription “rules” • Drug interactions • Safe handling issues • Counselling tips • Adherence issues • Adverse drug reaction checking reminder • Follow-up planning • Communication with cancer care team • Drug indications • How drug is given 	Patient counselling: initial and follow-up calls <ul style="list-style-type: none"> • Follow-up plan Adverse effects: prevention and management suggestions <ul style="list-style-type: none"> • Which adverse drug reactions can be managed by the pharmacist and which require referral to the cancer care doctor • Which should be managed in the emergency department? Drug interactions <ul style="list-style-type: none"> • List of important drug-drug interactions • Other online drug-drug interaction checking resources (free)
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To find the Pharmacy Toolkit for a specific drug, go to www.cancercare.ns.ca. Click the Health Professionals tab at the top. On the left-side list, click on Systemic Therapy and select Systemic Therapy Manual. You can then search drug by name. Click on the Pharmacy Toolkit tab for a pdf.

A different approach for oral systemic therapy drugs

To begin the process, a comprehensive set of preprinted orders (PPOs) was developed. PPOs have been identified as important tools to improve patient safety and quality patient care in pharmacotherapy.⁹ In addition to improved legibility, the PPO can simplify the prescribing process and reduce the potential for prescribers to select incorrect doses or instructions, when compared with handwritten prescriptions on blank order forms. Unlike other PPOs, this set was designed to also act as outpatient prescriptions to assist the community pharmacist in dispensing any of these agents. Since the prescription is a communication from the prescriber to the dispenser, the PPO includes a set of additional pharmacist-specific instructions. The pharmacist is given the website address to access materials designed to assist with dispensing, patient counselling and follow-up encounters (telephone calls, return visits). Hospital approval processes for PPOs are very cumbersome, and only a few PPOs have been implemented to date, but work is ongoing.

Once presented with the drug-specific PPO, the community pharmacist is instructed to go to the CCNS website for the Pharmacy Toolkit (see Table 1 for instructions on how to access). The toolkit is designed to be a “just-in-time” document to give the pharmacist the necessary education and information to properly dispense the drug and provide guidance for patient care. Being a brief document (most are only 4 pages in length), the toolkit is an efficient resource

document for the pharmacist. Contents of the toolkits are listed in Table 1.

The Toolkit is intended to provide the pharmacist with all the key information about a systemic therapy drug in a very succinct package that allows review in approximately 5 to 10 min. Most community pharmacists have very busy practices that do not allow for much advance preparation, so brevity is important for the pharmacist to be able to use the Toolkit to its best advantage. There are some rules for dispensing oral systemic therapy drugs that the pharmacist should be aware of. Many drugs have significant drug-drug interactions, and several should be handled with caution by pharmacy staff (occupational safety concerns). A plan for patient follow-up is important, since these drugs have significant adverse effects (adverse drug reactions [ADRs]) that may not appear until several days or weeks into treatment. If the adverse effects do appear, the pharmacist may be able to handle some of these, but others require intervention by a family physician or oncologist and, in some cases, an urgent visit to the local emergency department. Within the toolkit, the ADRs are listed in a table with notations on who should manage them. If there is a concern about drug-drug interactions (e.g., a patient with a long list of medications to which this new drug is added), several online drug-drug interaction checking resources are listed for a quick double-check. With many of these newer drugs, the drug-drug interaction checking software available in most pharmacy IT systems is often incomplete or not current.

TABLE 2 Content components of the patient visit documentation forms**Initial Assessment and Patient Counselling Visit**

Checklist of questions designed for a brief, focused encounter

- Does the patient understand the treatment plan?
- Is the patient taking any other medications?
- Check for factors that could affect adherence; record Morisky score (see below)
- Counselling tips
- Has this assessment been communicated with the cancer care team?
- What is the follow-up plan?
- Morisky Medication Adherence Scale to assign numeric score for potential or actual adherence problem

First Follow-up Call/Visit

Open-ended questions; document as yes/no and/or written comments

- Does the patient understand treatment plan?
- Any initial problems with adherence?
- Foods and other drugs? Looking for interactions
- Has the patient used any medical services or visited the emergency department?
- Any adverse effects in the first few days?
- Other?

Continuing Follow-up Call/Visit

Short version: Checklist of questions (use at regular visits for prescription fills)

- Does the patient understand treatment plan?
- Any problems with adherence?
- Know which foods and other drugs to avoid? Looking for new medications or diet changes
- Has the patient used any medical services or visited the emergency department?
- Any adverse effects?
- Other?

Long version: Open-ended questions; use every 3 to 6 months (do not overuse)

- Same questions as the short version

Another key toolkit resource is the drug-specific Medication Info Sheet (MIS). The MIS is often used by clinic nurses or oncology pharmacists when they educate patients about their treatments. What makes the MIS different from the materials typically provided by the pharmacy IT system is the focus on what patients can do to either prevent or manage adverse effects. Other information, such as the risks to women who are pregnant (or who could become pregnant), includes practical suggestions to avoid these risks. The risks may not only be to patients but could also include partners and others who help with patient care (e.g., helpful daughters, of childbearing age, who give systemic therapy to their parent as part of their home support). In addition, the MIS is authored at a grade 8 comprehension level, with large print for older patients. Pharmacists can download and print the MIS for each drug and use these during patient counselling.

Patient counselling at the initial visit to receive cancer treatment agents can be challenging.

Often patients are distressed, fatigued and/or overloaded with information given at the clinic visit. A follow-up visit or telephone call is recommended for many patients. The pharmacist is guided by the suggested plan in the Toolkit about what information is necessary to discuss at the initial visit and what information could be deferred to a follow-up call or even later visits to receive subsequent prescription fillings.

Documentation

Contemporary pharmacy practice standards require that patient interactions be documented by the pharmacist.¹⁰ Community pharmacists typically document drug-dispensing information, using pharmacy information systems designed for that purpose, but there is little or no documentation of communication with patient. Documentation is particularly important for hazardous drugs, such as cancer systemic therapy drugs, to enable continuity of care from one pharmacist to the next over the weeks, months, or years that patients receive

these drugs. A simple, standardized approach is needed for rapid but focused documentation that can fit into a busy pharmacy practice. To this end, single page, checklist-oriented documentation forms (Pharmacy Practice Guides) were designed to complement the pharmacy toolkits. Separate forms were developed for the Initial Assessment and Patient Counselling Visit, the First Follow-up Call/Visit and the Continuing Follow-up Call/Visits. Contents of the Practice Guides are listed in Table 2.

The intent is to keep the initial assessment and counselling visit fairly succinct and focused for patients who are distressed, fatigued and/or overloaded with information on their first day of treatment. This is followed by another pharmacy visit or telephone call a few days later, when patients are better able to focus more on learning about their drug therapy. Continuing visits or telephone calls are as important as the initial visits. Adverse effects may take weeks or months to emerge, and the pharmacist must remain vigilant over the full duration of drug therapy. Likewise, adherence to treatment has been shown to decline over time for many patients. Continuous patient assessments and reminders to continue taking full-dose therapy have been shown to improve patient medication adherence.¹¹ Often, the emergence of adverse effects will cause reduced medication adherence, so the pharmacist must be prepared to continue assessments and to continuously reinforce the adherence messages.

The Pharmacy Practice Guides are simple and may be scanned into the pharmacy IT system as ongoing documentation of patient care activities, beyond the dispensing of the medications. If any problems are identified, these guides should also be faxed to the contact person on the cancer care team. Note that the Continuing Follow-up Call/Visit forms are available in 2 formats. The long version has a series of open-ended questions to fully explore medication adherence, the presence of any drug adverse effects and other questions. These questions are based on the MASCC Oral Agent Teaching Tool tool¹² developed by the Multinational Association for Supportive Care in Cancer. The development team recognized that asking the same open-ended questions every 3 or 4 weeks could quickly become ineffective, so a short version was also developed for rapid use at most continuing visits, reserving the long version for use every 3 to

6 months or when problems with adverse effects or medication adherence are identified. The short version covers the same questions but with simple yes/no answers for rapid assessment and documentation.

Managing adverse effects and medication adherence

The pharmacist's role does not end with documentation of assessments and patient counselling. In the Pharmacy Toolkits, the table of ADRs identifies a number of ADRs that could be managed by the pharmacist. If the patient reports 1 (or more) of these ADRs during the assessment, the pharmacist should be prepared to offer management suggestions. This may or may not include the use of over-the-counter products.

But ADR management with many of the systemic therapy drugs used in cancer treatment is not always the same as for other drugs. To help the pharmacist manage these ADRs, another tool is available on the same CCNS website pages for each drug. The Adverse Drug Reaction Management Guide for each of these drugs provides more comprehensive discussion and recommendations, which the pharmacist may use to help the patient manage (and prevent, where appropriate) any ADRs. It is expected that, if the pharmacist helps the patient to manage an ADR, this will be documented along with the assessment information and that this documentation will be faxed to the cancer care team to ensure seamless care. More severe problems may require direct contact with the cancer care team.

Adherence management is critical to optimize the anticancer effect with oral systemic therapy agents. This is a key role for the community pharmacist, in collaboration with the rest of the cancer care team. Any score on the Morisky Medication Adherence Questionnaire (included in the Practice Guides used for assessment and documentation) that is greater than 0 is cause for concern, and a score of 2 or more suggests low adherence. This can best be assessed when there is a bond of trust between the patient and the pharmacist, built on a previous and current therapeutic relationship. To assist the pharmacist, a Practice Guide on Medication Adherence Management is also available on the website. This guide is not a documentation form; rather, it is a brief (2-page) summary of evidence and how this integrates into this process. Based on the most recent Cochrane review,¹¹ this guide

BOX 1 Reasons why the community pharmacist should handle cancer therapy prescriptions differently from most other prescriptions

Systemic therapy drugs used in treatment of cancer are hazardous medications^{5,6} for patients, families and staff.

- There are many new systemic therapy drugs on the market; pharmacists cannot keep current with the new and emerging drug information.
- Most cancer systemic therapy drugs are seen rarely in the typical community pharmacy.
- Most pharmacists are unfamiliar with systemic therapy drugs for cancer and not prepared to provide appropriate patient care.
- Community pharmacists may incorrectly assume that all patient care will be managed by the hospital-based clinicians.
- Community pharmacists have an established therapeutic relationship with their patients, which should include patients receiving systemic therapy drugs for cancer.
- Most patients want care “close to home,” not long distance or over the telephone by a health care professional unknown to them.

FIGURE 1 Process map for initial oral systemic therapy prescription

PG = practice guide.

may provide helpful tips to the pharmacist as he or she continues to assess and counsel the patient regularly through the treatment journey. Problems with adherence, and the steps taken to resolve these problems, must also be communicated with the cancer care team, either by telephone conversation or as written notes on the documentation forms that are faxed to the team contact. In more difficult circumstances, the community pharmacist may wish to consult with the team directly to determine a collaborative approach to help the patient achieve optimal adherence.

Other practice guides and patient education materials

There are additional materials available on the CCNS website that may be useful in some circumstances. Some oral systemic therapy drugs are ordered based on body surface area. An optional Practice Guide on Dose Verification for Cancer Medications can help the pharmacist to recalculate the final dose when checking the prescription. For pharmacies with Microsoft Office products on their computer desktop, the guide also comes in an automated version that performs the calculations once all parameters are

FIGURE 2 Process map for continuing oral systemic therapy prescription

PG = practice guide.

entered. The pharmacist may need to measure the patient's height and weight to perform the necessary dose calculations.

Another challenging aspect of working with oral systemic therapy drugs for cancer is the potential occupational risk to pharmacy staff. There are, at present, no guidelines for safe handling of these drugs in the community pharmacy setting, but there are national guidelines aimed at hospital settings.¹³⁻¹⁵ The information from these guidelines is briefly summarized in CCNS's practice guide, "Safe Handling—Cancer Medications in the Community Pharmacy."¹⁶ The recommendations from the guidelines are adapted to the community setting, including practical approaches for cleaning, decontamination, spill management and personnel issues. This guide may be useful for pharmacies in which staff are concerned for their personal safety while handling these drugs.

There are additional patient education materials on the website to assist the pharmacist in patient counselling. These materials are more often used by the clinic nurses when they teach patients, but the resources are available for use by any health professional. The materials are downloaded in the same way as all other materials discussed in this article (Table 1). These include the following:

- Oral Systemic Therapy: A Guide for Cancer Patients and Families
- Cytotoxic Precautions at Home: A Guide for Cancer Patients and Families
- Oral Systemic Therapy Patient Education: A Guide for Health Professionals

Summary

A number of factors (Box 1) would suggest that community pharmacists manage patients on oral systemic therapy for cancer differently than those patients receiving more "usual" medications. The rarity of prescriptions for these oral drugs in most community pharmacies and the high-risk nature of the medications are compounded with a general lack of pharmacist knowledge or readiness to provide appropriate levels of patient care. To address these factors, CCNS has introduced a battery of tools to assist the pharmacist at each step. An optimal process flow, using these new tools, is illustrated in Figures 1 (initial prescriptions) and 2 (continuing prescriptions). The tools provide the pharmacist with drug information, practice guidance and patient interaction documentation forms. Continuous communication with the hospital-based cancer care team is facilitated by standardized documentation for routine care and telephone contact when an actual or potential problem is identified. Coordination of

effort and interventions is essential to the care of these patients. Although the clinical services are not currently reimbursed separately from traditional dispensing fees, the potential for cost savings as well as the positive effect on quality patient care provide a strong argument for

future reimbursement negotiations. As pharmacists adopt these practice changes, they should become more effective in their role as a member of the oncology care team and provide seamless and effective pharmaceutical care to these cancer patients. ■

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Lead author Larry Broadfield passed away a few months before the publication of this article. Over his 30+-year career as an oncology pharmacist, he was operational and clinical manager of a major cancer centre pharmacy, an active researcher, undergraduate educator and leader of oncology pharmacy both nationally and internationally. He was honored by several cancer and pharmacy organizations both during and after his passing for his lifelong contributions to care. He will be missed.

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