Cancer Care Ontario

Enhancing the Delivery of Take-Home Cancer Drugs in Ontario

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ACRONYMS AND ABBREVIATIONS

AIMS	Assurance and Improvement in Medication Safety
BSA	Body Surface Area
CCO	Cancer Care Ontario
CMIRPS	Canadian Medication Incident Reporting and Prevention System
COI	Conflict of Interest
CPOE	Computerized Physician Order Entry
ISMP	Institute for Safe Medication Practices
ICP	Integrated Cancer Programs
IVCD	Intravenous Cancer Drugs
MASCC	Multinational Association of Supportive Care in Cancer
MOATT©	MASCC Oral Agent Teaching Tool
MOHLTC	Ministry of Health and Long-Term Care
NAPRA	National Association of Pharmacy Regulatory Authorities
OCP	Ontario College of Pharmacists
PPO	Pre-printed Order
RSTP	Regional Systemic Treatment Program
THCD	Take-Home Cancer Drugs

SYNOPSIS

Take-home cancer drugs (THCD) are medications used for the active treatment of cancer and are usually dispensed for administration in the home (e.g., oral chemotherapy). These drugs have become a standard treatment for many cancers and present opportunities and challenges for patients, providers, and the health system.

Robust guidelines with clear processes have been developed for intravenous cancer drugs (IVCD) and as a result, its delivery is viewed as more comprehensive, organized, safer and person-centred than THCD.

Currently, dispensing models for THCD remain variable across Ontario. To date, there has been no formal examination of delivery models for THCD nor have specific standards and expectations been established in the province. As such, in April 2017, CCO convened the Oncology Pharmacy Task Force. The mandate of this Task Force was to advise Cancer Care Ontario (CCO) on how to enhance the current system for THCD delivery to optimize quality and safety; subsequently, to deliver a report to the Ministry of Health and Long-Term Care (MOHLTC) based on the findings of the Task Force.

The objective of this report is to present consensus-based recommendations and alternate models of THCD delivery that optimize quality and safety. Our goal was not to create new knowledge but to make the best use of existing areas of evidence and lessons learned in other jurisdictions as well as to contribute to emerging practice to address the gaps.

A variety of approaches was used to inform the findings and achieve consensus:

- A systematic literature review
- A current state analysis of Ontario
- A scan of THCD delivery models in 12 jurisdictions in Canada and abroad
- Key informant interviews with cancer agencies and health services in Canada and abroad
- A three-step modified Delphi process with the Task Force to develop quality and safety recommendations
- An assessment of alternate models for Ontario with the Task Force
- Extensive consultation with subject matter experts, stakeholders and standard setting bodies at the local, regional and national levels

This document consists of the following:

- Methodology for all sections of the report
- Delivery models for THCD including an analysis of current state in Ontario and alternate approaches in other jurisdictions with a focus on Canadian provinces
- Guiding principles and consensus-based quality and safety recommendations for THCD
- A discussion on alternate models in the context of Ontario including discussions on implementation challenges, congruence with the recommendations, and key enablers for quality and safety.

BACKGROUND

Take-home cancer drugs (THCD), such as oral chemotherapy, are emerging as a standard treatment option for many cancers and causing a paradigm shift in the management of this disease.[1] Current delivery models, designed primarily around intravenous cancer drugs (IVCD) are safe, high quality and centralized; that is, they have defined administration standards and safety protocols as well as coordinated prescribing, dispensing, counseling and monitoring at the cancer centre/hospital. On the other hand, most Ontario cancer patients will experience a decentralized model of care for THCD; that is, certain components of care will be delivered by a range of providers outside of the cancer centre/hospital setting, including obtaining THCD through a specialty pharmacy (e.g., McKesson, Innomar, Bayshore) or other community pharmacy setting.[2–7] While robust guidelines have been developed to ensure the quality and safety of IVCD preparation and delivery,[8–13] there are few published for THCD with specific considerations for dispensing models, education for patients and providers, and processes for monitoring, adherence, and adverse events.[14] This has led to the drive for recommendations for THCD dispensing that embed high quality, safe practices while recognizing the unique aspects of THCD.

When clinically appropriate, THCD are an attractive option for patients as they offer convenience through fewer or shorter clinic visits, less disruption of daily activities, perceived control over treatment and minimal invasiveness. [15–19] There are also potential economic benefits to this approach, given the reduction in healthcare resource utilization (e.g., nursing and pharmacy time) compared to delivering IVCD in a cancer centre/hospital.[20]

While THCD may be the preferred option for many patients, some regimens are complex in terms of the administration schedule, high pill burden, frequent dosing and/or adherence.[16–18,21] This model of care is heavily reliant on the patient and/or caregiver to administer the treatment as well as to assess and manage the side effects as they arise.[16–18,21] Many safety checkpoints designed for IVCD in cancer centre/hospital settings including but not limited to independent double-checks at multiple points, ability to assess patient prior to treatment, ascertain dosing, triaging symptoms and adjusting therapy at the point of delivery, are bypassed when components of care are delivered in the home and community.[16–18,21] Directly observed therapy (as with IVCD) facilitated by education and supportive plans of care, is still the best strategy to ensure patient adherence.[21,22]

Given the complexities and risks involved with THCD, frontline counseling is essential to promoting medication adherence. At the point of dispensing, pharmacists have the opportunity to educate patients and/or caregivers about the treatment, support them in using them properly, discussing and monitoring adverse effects and adherence. Yet studies worldwide note that many pharmacists outside of the hospital setting have limited formal education and training to dispense, counsel and monitor for THCD and other medications for complex, chronic, rare, and difficult-to-manage conditions (e.g., rheumatology, hepatology).[23–25] [26] Known issues related to community dispensing of THCD include incorrect dosing and handling, limited monitoring and non-adherence (which can lead to under or overdosing), serious toxicity, morbidity, and mortality.[25,27,35,28,29,29–34]

Given the challenge and opportunity of THCD, Cancer Care Ontario (CCO) hosted a policy planning and consultation session in May 2014 with partners and stakeholders from across the healthcare spectrum. Through panel and facilitated small group discussions, participants gained a detailed understanding of the way Ontario delivers systemic treatment to patients.[4] It was noted that there is significant variation in the approach between IVCD and THCD demonstrating the need for greater standardization, and written policies to ensure safer practices across the medication management continuum.[4] Participants also gained an understanding of how other provinces approach the delivery of systemic treatment. Speakers emphasized the need for equivalent standards for IVCD and THCD.[4] Participants collaborated to generate ideas on how to bolster the current Ontario model and made a compelling case that the benefits to patients and to providers from system transformation deserve careful consideration.[4]

To catalyze further action, CCO established the Oncology Pharmacy Task Force in April 2017. The mandate of this Task Force was to advise CCO on how to enhance the current system for THCD delivery; subsequently, to deliver a report to Ministry of Health and Long-Term Care (MOHLTC) based on the findings of the Task Force. Appendix A outlines the Terms of Reference of the Task Force; Members are listed in the Acknowledgements. Members represented patient advocacy groups, pharmacy and pharmacist associations, regulatory bodies, health administrators, academics and subject matter experts.

METHODS

Task Force Member Selection

CCO leadership and partner organizations sought to identify representatives from patient advocacy groups, pharmacy and pharmacist associations, regulatory and standard setting organizations, and subject matter experts. The approach was to ensure that as many disciplines or organizations involved with the THCD delivery process, including patients and caregivers, had a voice focused on quality and safety of care at the table. Furthermore, ensuring representation of diverse perspectives ensures a comprehensive approach, builds support among the intended audience, and increases the chances of addressing challenges and barriers related to implementation.

Invitation letters and terms of reference were sent to available contacts and heads of patient advocacy groups, pharmacy and pharmacist associations, regulatory bodies, health administrators, and academics. They were asked to nominate one representative (and an alternate) who could provide subject matter expertise and commit to the objectives, parameters, and scope of the work. Senior health administrators, both pharmacists by training, were selected to represent the provincial Cancer Programs. A call for participation for patients and their caregivers was disseminated through CCO's Patient and Family Advisory Council. The Task Force also provided input to ensure comprehensive representation.

A Participation Agreement including a Conflict of Interest (COI) Declaration was required upon joining the Task Force. Measures to mitigate or eliminate a COI were dependent on what was appropriate to the severity of the situation. Actions required at each meeting included declaring the conflict to all concerned before discussion or asking the member to withdraw from discussion and/or final decision-making.

Literature Review

A literature review was conducted to understand optimal safety standards for THCD including evidence for strengths, gaps, enablers and implementation barriers. The search was done through a search in Ovid Embase, Ovid MEDLINE and Ovid Healthstar. The search strategies used a combination of key words and free text terms related to cancer drugs, community pharmacies/ pharmacists and dispensing. Searches were limited to the English-language and articles published within the past 10 years (2007-current). All titles and abstracts identified from the electronic database search were imported to Reference Manager Software (version 12).

After removal of duplicates the remaining citations were exported to an Excel database to screen title and abstracts and to manage findings. A single reviewer screened the search results by scanning titles and abstracts against the eligibility criteria.
To ensure accuracy and transparency, five percent of the citations were cross-screened by three reviewers. There were no discrepancies between the three reviewers.

In addition, a grey literature targeted review for guidelines and other relevant publications was conducted in Google Scholar followed by a review through subject matter experts. The first five pages of the web-based search results were scanned for potentially relevant articles. Furthermore, reference lists of included studies were scanned to identify additional relevant articles.

Current State Analysis and Jurisdictional Scan

In conjunction with the literature review, CCO completed current state analysis for Ontario and a scan of THCD service delivery models for thirteen jurisdictions in Canada and abroad (Appendix B). The information was used to inform the alternate models for Ontario, as discussed later in this report.

The current state analysis was informed by initiatives/research conducted by CCO Clinical Programs including Diagnosis and Treatment, Person-Centred Care and Provincial Drug Reimbursement. Information from the programs was collated, reviewed by the internal group, and subsequently presented to the Task Force for commentary and consensus.

The jurisdictional scan consisted of a review of government/cancer agency websites as well as key informant interviews with several program administrators to understand the delivery models and processes. The Canadian jurisdictions included Ontario, British Columbia, Alberta, Manitoba, Quebec, Saskatchewan, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and internationally, Australia, Netherlands, Ireland, United Kingdom and New Zealand. Jurisdictional scans and targeted interviews were synthesized and vetted by subject matter experts. A summary was provided to Task Force members.

Three-Step Modified Delphi

The modified Delphi method is a structured method to achieve consensus through a series of questionnaires and controlled feedback. The Delphi process does not create new knowledge; rather, it builds consensus for group decision-making. The technique is a widely used and accepted method for gathering data from respondents within their domain of expertise.[36,37]

From October 2017 to January 2018, a three-step modified Delphi method [36,37] was used to solicit expert opinion and gauge agreement on the definitions and recommendations for THCD.

QUESTIONNAIRE DEVELOPMENT

Thirty-five citations for articles, reports, standards, guidelines and/or recommendations on the provision of TCHD were identified through the literature review. Nine practice components emerged from a content analysis: education, training and qualifications for healthcare providers; drug access; prescribing; clinical verification; communication; dispensing; patient and/or caregiver education; monitoring for adherence and adverse effect identification; and incident reporting.

Members of the internal working group reviewed a summary of the information, streamlined the statements to ensure clarity, removed redundancies, discussed discrepancies, identified provincial priorities, and finalized a draft with 31 statements (29 recommendations and 1 definition) which was formatted as a questionnaire.

ROUND 1

The questionnaire was circulated by email to the Task Force members. Each participant was asked to give a response to a definition or recommendation on a five-point Likert scale, where 1 is strongly disagree and 5 is strongly agree. Members were also given the opportunity to provide comments and suggest additional items that may not have been included when developing the initial list of recommendations.

In Round 1, the intention was also to clarify issues regarding redundancies as well as the comprehension or composition of each recommendation. Comments regarding the following were set aside: challenges and barriers for implementation (e.g., shortage of human resources); region-specific considerations (e.g., rural and/or remote areas); and actionability (e.g., recommendation needs to go through a regulatory body). Response frequencies for each definition or recommendation were calculated and entered anonymously into a database. Seventy percent agreement was required to include a recommendation in the final list.

ROUND 2

There were 20 recommendations and two definitions presented at the Round 2 in-person meeting. The in-person meeting allowed for members to refine their views based on the knowledge of group results and comments. Participants were encouraged to discuss the list of recommendations that did not receive consensus until agreement was reached to retain, modify, or exclude from the final list.

Seventy percent agreement was still used to determine acceptance or rejection of a recommendation. Round 2 voting occurred using a show of hands and anonymity was not retained in this setting.

ROUND 3

The two definitions and 17 recommendations that were added, retained and/or modified in Rounds 1 and 2 were re-circulated to members in a second electronic survey. Members used the same voting method as described for Round 1 to gauge agreement on the recommendations that would be accepted in the final list.

Following Round 3, there was final editing by the internal working group on the recommendations for accuracy of content, development of ideas, organization and clarity of expression and opportunity for the Task Force to review the definitions (2) and draft recommendations (16) to be distributed for consultation.

Assessment of Alternate Models

Task Force members were individually, tasked with evaluating two alternate models identified through the jurisdictional scan, listing the top five strengths and top five limitations, and identifying enablers (training and change management) and assessing agreement (concordance) with the consensus-based recommendations.

Task Force Meetings

Members of the Task Force convened on a regular basis (every 4-6 weeks) from April 2017 to May 2018, in-person or by teleconference to ensure that input regarding the current state analysis, proposed definitions, recommendations, and alternate models, was as inclusive as possible.

Consultation Process

CCO conducted a two-step consultation process between February and March 2018 prior to finalizing the recommendations and model options. The review process was targeted to subject matter experts and key stakeholders at the local/regional level, health administrators/administration bodies, and regulatory bodies.

The 16 draft recommendations and two alternate models were initially shared with relevant CCO program teams, committees and communities of practice, followed by external stakeholders (Appendix C). Although question concepts were the same, formal feedback was obtained using mixed methods including but not limited to one-on-one interviews, online surveys, focus groups, interactive exercises, discussions and webinars.

Feedback was synthesized in a single document, categorized by recommendation and model, thematically related, and subsequently reviewed by the internal working group.

When warranted (e.g., multiple stakeholders identified a gap), the recommendations and/or model options were subject to additional discussion and review with Task Force Members, partner organizations and subject matter experts. Privacy and confidentiality was maintained throughout the consultation process.

The internal working group reviewed all of the feedback, both individually and collectively. The final standards were revised to eliminate redundancies, achieve clarity and conciseness. The Task Force reviewed and agreed upon the final 16 standards (Quality & Safety Recommendations for THCD) and 2 alternate models (Centralized and Partially Decentralized) in May 2018. The final draft of this report was circulated to the Task Force for review in January 2019.

CURRENT STATE & ALTERNATE MODELS

This section summarizes the findings from the Current State Analysis and Jurisdictional Scan with a focus on Canadian provinces. Key considerations for each model type were derived from Task Force feedback (Assessment of Alternate Models) and external consultations (Consultation Process).

The Current State in Ontario

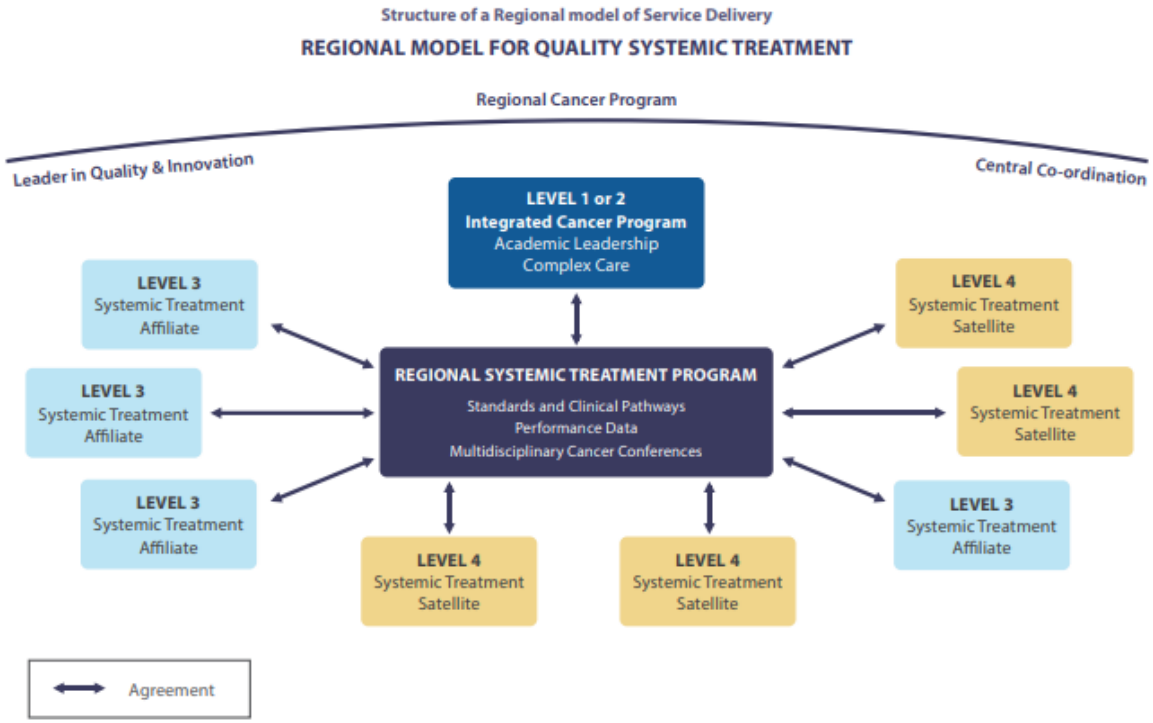
There are 74 systemic treatment facilities in Ontario. The Regional Model for Quality Systemic Treatment (Figure 1) in the province consists of a key set of fundamental elements and regional programs designed to implement, monitor, and evaluate quality indicators related to the delivery of safe, evidence-based, and person-centered care. The Model is an organizational framework for the delivery of systemic treatment within a Regional Systemic Treatment Program (RSTP). The main goal of the Model is to facilitate the provision of the appropriate care in the appropriate setting within the appropriate timeframe for all patients, regardless of where a patient receives systemic treatment. The Model is comprised of three integrated structures: Integrated Cancer Programs (ICPs), affiliate institutions, and satellite institutions, each with a defined scope of practice. The ICPs (Levels 1 and 2) are multidisciplinary organizations that provide complex cancer care. Affiliate institutions (Level 3) have their own systemic treatment programs, although they are linked through formal agreements with the RSTP. Satellite institutions (Level 4) have fewer oncology-related resources and have a formal linkage to the RSTP for support in delivering systemic treatment.

Community pharmacists are often a cancer patient's most accessible point of contact with the healthcare system and many have developed strong, trusting relationships with their patients. While some advantages have been identified for decentralized models (discussed further in the THCD Delivery Models in Canadian Provinces), there are persisting patient and provider safety challenges with respect to lack of oncology education and training, lack of facilities for safe dispensing, and lack of patient education, follow-up and monitoring in community pharmacies.

In Ontario, THCD can be dispensed through community pharmacies, which may have only a few patients on any specific cancer medication; hence, many community

pharmacy providers may lack regular exposure to, and experience with, the provision of THCD to cancer patients. For example, based on THCD claims (new and refills) from fiscal year 2016/17 (obtained from the Institute of Clinical Evaluative Sciences), 646,962 THCD were dispensed from 4448 different pharmacies.[38] Of the 4448 community pharmacies, 2463 dispensed no more than 1 THCD prescription per week and 4325 pharmacies dispensed less than ten THCD prescriptions per week.[38] In comparison, six pharmacies associated with cancer centres dispensed an average of 188 THCD prescriptions/week.[38]

Figure 1: Regional Model for Quality Systemic Treatment



In a low-volume setting, it would be challenging for community pharmacists to maintain the appropriate skills and knowledge required for dispensing oncology medications. Education, training, and assessment across all healthcare organizations/employers would be difficult to organize, standardize and enforce across the province without the oversight of regulatory bodies [e.g., Ontario College of Pharmacists (OCP)].[39]

Furthermore, in a pharmacy with low-volume THCD dispensing, many community pharmacies may not offer timely access to the actual drugs themselves, due to limited inventory and current purchasing patterns (e.g., only one dosage strength is stocked, or

the medication is only ordered from the wholesaler after the patient presents with a prescription, potentially necessitating a second, subsequent pharmacy visit.)

At this time, the level of compliance to National Association of Pharmacy Regulatory Authorities (NAPRA) standards for hazardous drugs in community pharmacies is unknown. While regulatory standards and provincial/national guidelines have been developed to ensure safe handling of hazardous drugs, it is unclear to what extent these have been adopted in the community; this exposes both patients and providers to undue risk.

In order to ensure continuity of care, community pharmacists must have relevant health information from the cancer care team (e.g., diagnosis, blood results) to support clinical/cognitive verification, to avoid duplication of effort and to make for a more person-centred experience.

Given the current state of information technology (IT) infrastructure/lack of system integration between most cancer centres and community pharmacies, patient information is not communicated easily or routinely between sites, and information sharing is often entirely reliant on the patient. As there is no formal communication protocol between cancer centre and community providers, with defined roles and responsibilities, there is a greater chance of duplication or gaps in care. Community pharmacy providers can face challenges in obtaining timely clarifications from the cancer care team on key information required for dispensing (e.g., patient's cancer diagnosis, treatment history or THCD regimen prescribed).

Gaps in care are more likely to occur if the patient does not bring prescriptions to their pharmacy right away, if a change needs to be made and/or if the protocol is unfamiliar. Furthermore, if community pharmacies are unfamiliar or unable to dispense all medications required for the systemic treatment regimen, this will result in patients having to visit more than one pharmacy. For example, some multiple myeloma regimens contain an IVCD in combination with an oral chemotherapy drug that require dispensing from a specialty pharmacy. In these cases, patients may need to visit/obtain their required medications for the regimen (including supportive care drugs) from up to three pharmacies with pharmacists who may not be communicating with one another.

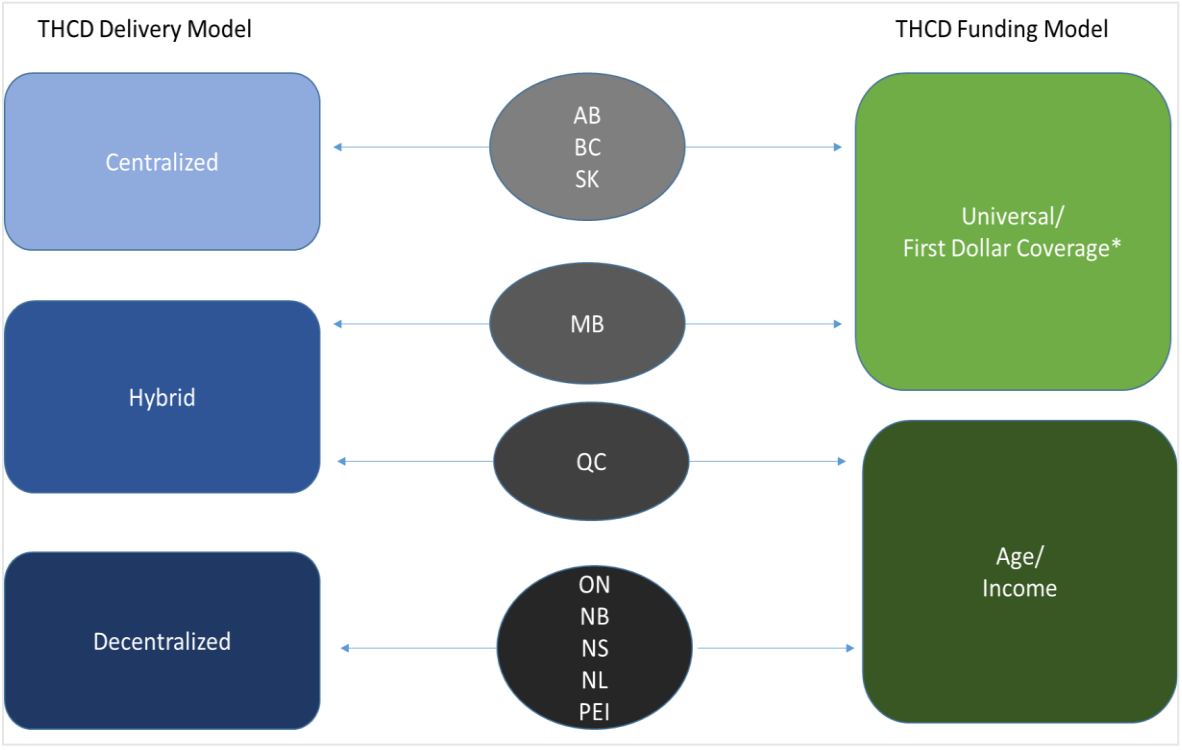
In addition, the current compensation model (e.g., lack of cognitive reimbursement for THCD) does not support employers or owners to commit to training, education and developing robust patient education and monitoring programs needed for oncology patients.

The current state presents significant safety challenges for both patients and providers. There is little doubt that moving treatments from hospital to home helps to fulfill the health system's commitment for patients to receive the right care, at the right place, at the right time; however, the goal is to ensure that THCD are delivered through a model that optimizes quality of care and patient safety. Exploring alternate approaches to service delivery is warranted.

THCD Delivery Models in Canadian Provinces

Each province administers its own program for systemic treatment. While provincial cancer agencies are generally fully responsible for the oversight of quality and safety of systemic treatment, the model of delivery can vary (Figure 2).

Figure 2: Summary of THCD Models in Canada



* Universal/First Dollar Coverage: refers to drug coverage where the patient does not incur any out-of-pocket costs (e.g., copayments or deductibles) for a funded drug

Decentralized Models

OVERVIEW

In a decentralized delivery model, there may be multiple administrators overseeing and monitoring the quality, safety, and access to all cancer services. In these models, the prescribing, dispensing and monitoring of cancer drugs is not confined within the cancer system. The funding mechanisms and/or processes to obtain public drug coverage for IVCD and THCD are different.

In Ontario, Nova Scotia, New Brunswick, Prince Edward Island, and Newfoundland and Labrador, THCD including restricted distribution and compassionate programs, are not delivered by the provincial cancer agency, but provided through community and/or specialty pharmacies. In these provinces, THCD coverage is dependent on patient eligibility factors (e.g., age and income) and may be associated with out-of-pocket costs. Private insurance has a larger role in these jurisdictions, as these public programs are not as comprehensive in terms of coverage. In Prince Edward Island, cancer specialists must write first cycle prescriptions. There are no official restrictions on prescribing in the other four provinces.

A majority of THCD prescriptions in Ontario and Newfoundland and Labrador are generated through Computerized Prescriber Order Entry (CPOE) and/or pre-printed order (PPO) while in Nova Scotia and New Brunswick, they are primarily hand-written. All five provinces reported that their dispensing pharmacies do follow provincial/national guidelines, policies or procedures on the safe handling of hazardous drugs. Newfoundland and Labrador is the only province among the five with a standardized clinical pharmacist-led counselling & monitoring program in all Cancer Centres and at six peripheral sites. The program involves patient education, medication reconciliation, adherence monitoring, toxicity monitoring and management as well as related supportive care issues. Although some provinces have legislated that critical incidents in hospitals must be reported, Nova Scotia and more recently, Ontario, are the only jurisdictions where the pharmacy regulator mandates that community pharmacies anonymously report incidents to an independent organization.

KEY CONSIDERATIONS FOR DECENTRALIZED MODELS

- Patients tend to have accessibility to a larger number of pharmacies; however, due to the high price point, restricted access (i.e. some are not certified to dispense THCD that are available through a controlled/restricted distribution program) and/or low dispensing volumes, community pharmacies may not stock/dispense these medications, increasing fragmentation, delays and complexity of access for patients.
- Greater likelihood that all non-IVCD drugs come from one pharmacy; although the existence of specialty pharmacies (in part because of non-restricted dispensing) increases fragmentation.
- Low dispensing volumes in many community pharmacies may result in pharmacists and pharmacies less familiar with knowledge and skills to dispense THCD in accordance with best practices. Training and assessment will be difficult to standardize and enforce without further assistance from regulatory bodies
- The compensation model does not support cognitive verification and monitoring programs needed in oncology

Centralized Models

OVERVIEW

In a centralized delivery model, a single administrator oversees and monitors the quality, safety, and access to all cancer services. Similar processes and policies are applied to the prescribing, dispensing and monitoring of THCD and IVCD. Prescribing and dispensing of cancer drugs are usually restricted to specific prescribers and pharmacies within the cancer system. Patients only follow one process to obtain public drug coverage for IVCD and THCD.

Currently, provinces with centralized delivery models offer universal and first dollar coverage for all cancer drugs. For many new and high cost drugs, patients may still need to meet specific clinical criteria to obtain coverage.British Columbia, Alberta, and Saskatchewan do not use retail pharmacies to distribute THCD, instead relying on cancer centre pharmacies with options for home delivery. In Alberta and British Columbia, restricted distribution and compassionate access programs are also available through cancer centre pharmacies. These provinces offer universal coverage for both THCD and IVCD with no associated out-of-pocket costs to the patient.

Prescribing THCD is restricted to named and authorized providers at Cancer Centres for all THCD in Saskatchewan and for first cycle prescriptions for a subset of THCD in Alberta. The majority of prescriptions for THCD in Alberta are prescribed using a CPOE system while Saskatchewan and British Columbia primarily use pre-printed orders (PPO). All three provinces reported that their dispensing pharmacies do follow provincial/national guidelines, policies or procedures on the safe-handling of hazardous drugs.

With respect to standardized monitoring programs for adherence and side-effect management, Alberta has developed a specific THCD multidisciplinary monitoring program, which is administered by the pharmacy team. In British Columbia, THCD monitoring programs are in place, and the need for standardization and tailoring of programs (to be therapy specific) have been identified as future enhancements. All three provinces reported that they routinely report medication incidents related to THCD. Voluntary and anonymous electronic reporting and learning systems are used to facilitate this activity.

KEY CONSIDERATIONS FOR CENTRALIZED MODELS

- Cancer centre may not be close to home and the model limits choice of patient pharmacy (as with IVCD)
- A multi-disciplinary team in one location; greater likelihood of streamlining processes, roles, tasks, communication, knowledge transfer and providing integrated care
- Training and education standards are established and provider competencies are acquired due to volumes and expertise
- CPOE systems may already be in place, which will facilitate best practices in prescribing
- Availability of patient data, hospital chart materials, and the treatment plan [e.g., electronic medical record (EMR)/integrated IT structure] in secure setting where confidentiality and privacy are ensured
- Clinical/cognitive verification and dispensing occurring at the same facility and the ability to implement independent double-checking processes to prevent errors from reaching patients
- If mail delivery options are required, there is potential for less face-to-face interaction with patients and/or caregivers, which may limit educational opportunities; however, consultations and patient counselling can be provided via phone or telehealth, where appropriate

Other Models

Some provinces deliver cancer services using a mix of centralized and decentralized processes. For example, in Manitoba and Quebec, cancer specialists prescribe the first cycle for active cancer treatments. These provinces rely on community/specialty pharmacies for dispensing THCD including restricted distribution and compassionate access programs. Manitoba offers universal coverage similar to British Columbia, Alberta, and Saskatchewan. Quebec determines a premium based on age and income in a mandatory insurance environment. Both reported that their dispensing pharmacies do have guidelines, policies or procedures on the safe handling of hazardous drugs. Similar to a majority of provinces, there are no established standardized monitoring programs and incident reporting is anonymous and voluntary.

KEY GUIDING PRINCIPLES

Key guiding principles informed the Task Force recommendations to enhance the delivery of THCD. These principles stem from extensive consultation and environmental scanning for CCO's strategic plans and programs (e.g., Ontario Cancer Plan, Cancer System Quality Index, and Systemic Treatment Provincial Plan).
40–44

Safe

- Avoiding, preventing and relieving negative outcomes or injuries caused by healthcare mangaement.

Effective

- Providing services based on scientific knowledge to all who could benefit.

Accessible

- Making care available in the most suitable setting in a reasonable time.

Responsive

- Providing care that is respectful of and receptive to a person's preferences, needs & values.

Equitable

- Care that is available to everyone regardless of personal characteristics or demographics.

Integrated

- Health services that have been coordinated across the system.

Efficient

- Optimally using resources to achieve desired outcomes.

DEFINITIONS & RECOMMENDATIONS: TASK FORCE CONSENSUS

In this section, the results of the Three-Step Modified Delphi process are presented first followed by the consensus-based definitions. Then the evidence for the quality and safety considerations for THCD followed by the linked recommendations that encompass these concepts. The definitions and recommendations were formulated using the accepted statements from the Three-Step Modified Delphi. The recommendations cover multiple practice components, meeting different patient needs and across practice settings. They align with existing areas of evidence to ensure quality and safety and contribute to emerging practice evidence to address the gaps (Literature Review).

Results of the Three-Step Modified Delphi

Table 1 describes the change in agreement from the statements proposed in round one to the final list of definitions and recommendations reviewed and endorsed by the Task Force.

Table 1: Change in Agreement from Delphi Round One to Final Version

	Initial List of Definitions & Recommendations (Delphi Round One)	Final List of Definitions & Recommendations Reviewed & Endorsed by The Task Force
Response rate	100%	100%
# of statements	29 (1 definition, 28 recommendations)	18 (2 definitions, 16 recommendations)
# of statements receiving >70% agreement without modification	10	16
# of statements receiving >70% agreement that required discussion/ modification	16	2
# of statements receiving <70% agreement	5	0
# of newly suggested statements	1	0
Agreement % range	32%-100%	83%-100%

Definitions

The following definitions were agreed upon by Task Force members:

Take-Home Cancer Drugs	Refers to cancer drugs used for active treatment that are typically administered orally or sometimes by injection (e.g., drugs injected into the skin or muscle). THCD includes cytotoxic chemotherapy (drugs that kill tumor cells), targeted therapies (drugs that target specific types of cancer cells with less harm to non-cancer cells), immunotherapy (drugs that help the immune system fight cancer) and some hormonal therapy† (drugs that slow or stop the growth of hormone-sensitive tumors).
Supportive Therapies	These prevent or treat the symptoms or problems associated with cancer treatment. Some examples of supportive therapies include anti-emetics (to prevent and treat nausea and vomiting) and colony-stimulating factors (medications that increase the number of certain blood cells).

Quality & Safety Recommendations for THCD

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. [25,27,35,28,29,29–34]
- ✓ The availability of a competent and skilled workforce is essential to ensure safe medication practices across the cancer care continuum.[2,6,13,45–49]
- ✓ Providers involved with THCD delivery should have appropriate skills and qualifications in the management and treatment of cancer. [2,6,13,45–49]
- ✓ The treatment of cancer and the modalities employed are continually evolving. Insufficient training and education on new protocols can compromise safe delivery of treatment. [2,6,13,45–49]
- ✓ 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. [2,6,13,45–48,50]

† Excludes hormone therapies that that do not require routine monitoring (e.g., tamoxifen, aromatase inhibitors, LHRH agonists)

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.[51–56]

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.[2,9,63–67,35,46,57–62]
- ✓ Handwritten prescriptions and verbal orders increase the potential for errors.[29,31,73,35,49,59,68–72]
- ✓ Standardization of the prescribing process and associated documentation reduces the likelihood of errors. [6,9,70–74,29,31,35,59,63,64,68,69]
- ✓ The use of computerized prescriber order entry (CPOE) to facilitate prescribing has demonstrated to improve safety.[64,75–82]
- ✓ 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. [2,3,9,47,83–85]

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

→ **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/m^2 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)

→ **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. → **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 → **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 → **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)

→ **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.[64,86–91]

✓ Patients and/or caregiver should have the knowledge and skills necessary to enable self-care and self-management safely outside the hospital environment.[62,92–95]

✓ 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.[96–99]

✓ 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.[92,95–101]

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.

Recommendation 9	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.[6,49,64,102–105]
- ✓ 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.[6,49,64,102–105]
- ✓ A plan improves safety in the delivery of treatment and ensures consistent communication to all providers that encounter the patient. [6,49,64,102–105]

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.[6,24,27,39,106–109]
- ✓ Standardized and thoughtful drug labeling practices need to be a part of an overall strategy to improve medication adherence and reduce inadvertent medication errors.[9,10,49,62,67,87,90,91,110]
- ✓ High pill burden can contribute to a patient's anxiety, confusion and subsequent non-adherence.[21,111,112]

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.

Recommendation 14	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 health-related quality of life, and unplanned health care service use.[113,114]
- ✓ Suboptimal adherence is associated with diminished therapeutic efficacy with lower exposure to drug, influencing risk for recurrence and mortality.[22,112,115,116]
- ✓ Proactive monitoring prevents escalation of symptoms and delayed contact with clinicians.[35,117–122]
- ✓ Proactive monitoring creates opportunities to answer questions and to reinforce key patient safety messages.[35,117–122]

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.[123–128]
- ✓ More effective organizational learning from potential and lower severity incidents could lead to system improvements that will reduce the risk of adverse events.[6,9,123,129,130]

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].

THCD DELIVERY MODELS TO ENHANCE QUALITY & SAFETY IN ONTARIO

This section discusses alternate models of THCD delivery that optimize quality and safety including implementation challenges and enablers as per synthesis of Task Force feedback (Assessment of Alternate Models).

A Centralized Model

Task Force members noted that a centralized model in Ontario (Figure 3) could offer patients a “one-stop shop” for services related to their cancer care. Potential benefits include:

- A multi-disciplinary team in one location (e.g., outpatient clinic in a hospital or cancer centre). With a multi-disciplinary team: roles cover all aspects of treatment (e.g., IVCD, THCD, surgery, radiation); specialists are available for consultation/clarification (i.e., through paging system, direct access to the prescriber’s clinic, or e-mail).; there is more likelihood for streamlining of roles; clinical/cognitive verification and dispensing occurring at the same facility and the ability to implement independent double-checking processes to prevent errors from reaching patients; allows for easier communication and knowledge transfer among providers; and better efficiency without compromising quality;
- Training and education standards are established and provider competencies are more easily acquired due to volumes and expertise;
- CPOE systems are already in place at all ICPs (Levels 1 and 2) and almost all Affiliate institutions (Level 3), which will facilitate safe prescribing;
- Availability of patient data, hospital chart materials (e.g., results of bloodwork, imaging, and laboratory tests) and the treatment plan (e.g., EMR/integrated IT structure) in a secure setting where confidentiality and privacy are assured. More specifically:
    - A patient’s height and weight are important for verifying the correct dose for many cancer agents that are dosed based on weight or BSA
    - Review of the patient’s blood work is required to ensure that parameters are adequate to proceed with their treatment.

- Many cancer drugs have a narrow therapeutic index, therefore it is important to review chemistry blood work and other laboratory tests to ensure that dose adjustments are made if required (e.g., for patients with reduced kidney or liver function).
- To confirm dosing is appropriate for the specific condition being treated. For example, the dose of lenalidomide is higher to treat multiple myeloma than it is to treat myelodysplastic syndromes.
- Pharmacists are able to access the EMR to review the physician and nursing notes to confirm treatment plan.
- The numbers of complex regimens including THCD combined with IVCD are increasing. Pharmacists would be able to view then entire regimen. Furthermore, obtaining all medications in one setting minimizes the errors related to timing i.e. if the THCD needs to be started the day after the IVCD for combination regimens.
- Many THCD require supportive therapies to be used as part of the treatment plan. For example, patients who are prescribed lenalidomide and dexamethasone must take an agent to prevent blood clots (i.e., aspirin) and the pharmacist would be able to review the supportive care plans for THCD.
- Cancer centres have adopted or have a plan in place to adopt NAPRA standards as per their commitment to OCP

Task Force members noted that a centralized model might be difficult or costly to implement depending on existing resources in cancer centres. As of December 2018, 31 (42%) systemic treatment facilities either own a community pharmacy or have a community pharmacy on-site. Cancer centres would need to assess the future capacity (e.g., space, human resources) of onsite retail pharmacies (if one currently exists) to handle the growth in prescription volume. Based on THCD claims, 87.5% of all THCD prescriptions are dispensed by community pharmacies in Ontario.[1] Cancer centre pharmacies would need to increase their staff to account for higher prescriptions volumes and to meet the quality and safety expectations outlined by the Task Force.

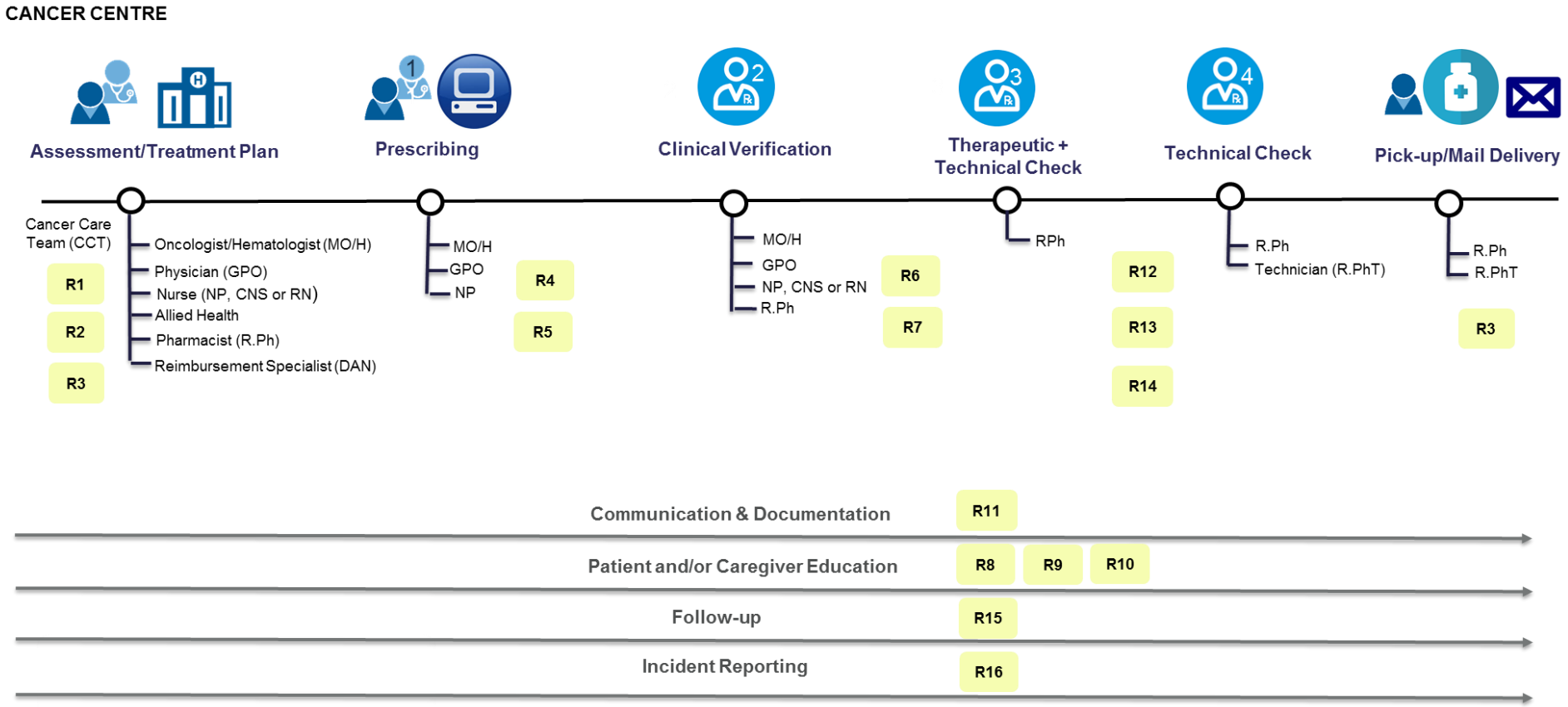
Members also noted that the implementation of a centralized model requires a significant amount of support by the regional cancer programs. At the very least (as with any model), ongoing training and professional development should be viewed as part of every provider’s role, and a certain amount of paid time should be devoted to maintaining competencies. Other types of organizational support can include: payment of some or all tuition for academic courses (usually limited to a specific amount of money or coursework per semester); registration fees and travel reimbursement for conferences up to a certain amount; and release time (paid release from one's job

during work hours) for specific training activities. However, as mentioned above, most systemic treatment facilities in Ontario have CPOE systems in place to support improved patient safety, decrease costs, and improve compliance with treatment guidelines. From 2006 to 2011, it is estimated that Ontario's CPOE system prevented 8,500 adverse drug events, 5,000 physician office visits, 750 hospitalizations, 57 deaths, and saved millions in annual healthcare costs; but only for patients receiving IVCD.[131] Implementing equivalent standards for THCD as IVCD could also result in significant cost saving for the health care system (e.g., physician office visits, unplanned emergency department visits).

Members also noted that pharmacies would require access to EMR/integrated IT infrastructure, point of sale/purchase systems and accounts set up with third-party payers (if not in place already). Fully integrated CPOE systems should theoretically allow for inclusion of the additional elements recommended for prescription content through auto-population where possible; however, resources would be required to enable IT changes in the CPOE system and to support documentation and training for providers. Cancer centres without outpatient pharmacies would need to consider whether dispensing could occur through the existing cancer centre pharmacy, or whether an outpatient satellite should be established. Members also noted that mail order programs would be required to ensure timely delivery [within 24-48 hours from the date the completed prescription (with approved drug coverage, where applicable, is received by the pharmacy) with signature upon receipt and to maintain the cold chain for refrigerated items. The model would need to be implemented in a way that ensures that patients receive their prescriptions as quickly as possible, acknowledging geographic barriers. Mail delivery may reduce face-to-face education opportunities with patients/or caregivers, but centres can conduct consultations or patient counselling over the phone or through telehealth, where appropriate.

With respect to the Quality and Safety Recommendations for THCD, the centralized model has the highest congruence in the current state. However, this model may not fully support access to care (R3) and further work will be required to engage affected stakeholders including consultation with regional cancer programs to provide advice/expertise on managing access to care issues.

Figure 3: Centralized Model Overlaid with Task Force Recommendations[§]



‡ The following diagram uses a *Models of Care* approach. A model of care is defined by its objectives, the patient pathway within the model, communication structures, the healthcare setting, and the staffing profile. The diagram highlights actions that are provider-specific, time-specific and/or required in the continuum of care for patients receiving take-home cancer drugs. Hence, task force recommendations are overlaid onto the model of care diagram numbered from R1 to R16.

A Partially Decentralized Model

Task Force members noted that although efforts could be made to centralize services at single sites, there are invariably context-specific circumstances where centralization is not possible owing to constraints and limitations at hospitals and cancer centres. Not all cancer centres currently have the infrastructure or capacity to dispense all THCD with existing resources and space. As of December 2018, 43 (58%) systemic treatment facilities do not own a community pharmacy or have an outpatient pharmacy on-site. Task Force members proposed a partially decentralized model (Figure 4) to accommodate these circumstances. This model would essentially have all of the benefits of the centralized model but would share the space and workload with select community/specialty pharmacies in the local area, referred to as *Affiliated Pharmacies* in the report**.** The model would be based around a memorandum of understanding between a cancer centre and the Affiliated Pharmacy to ensure quality and safety standards, joint accountability for practice components and allow for data sharing. The concept of Affiliated Pharmacies/select community partners in cancer care was identified in the Jurisdictional Scan [e.g. Community Cancer Network (CCN) in Alberta, Community Oncology Network (CON) in British Columbia]. Task Force members agreed upon the key characteristics of an Affiliated Pharmacy (Table 1) acknowledging that these proposed characteristics could differ somewhat based on the final model structure implemented locally owing to different assignment of responsibilities.

Members also noted that this model could be implemented at existing institutions, primarily at larger centres and with the support of existing specialty pharmacies. It could be more challenging to implement in a smaller practice setting and/or particular geographic areas. Some pharmacies may not want to apply (e.g., due to staff or budgetary concerns) or some pharmacies may not meet the key characteristics as outlined in Table 1; however, a shared model could be adopted across groups of institutions.

Affiliated Pharmacies could be selected through a competitive process, which would be fair to community establishments; however, there would need to be a discussion on the optimal number of Affiliated Pharmacies associated with each cancer centre to ensure quality and safety without compromise (e.g., feasibility for the cancer centre to provide oversight, adequate volumes to maintain competency).

With respect to the Quality and Safety Recommendations for THCD, the partially decentralized model (compared to the centralized model) largely supports access to care (R3). The model may also better enables monitoring (R15) and incident reporting (16) of THCD in the community as there would be a stipulation in the memorandum of understanding between the cancer centre and Affiliated Pharmacy.

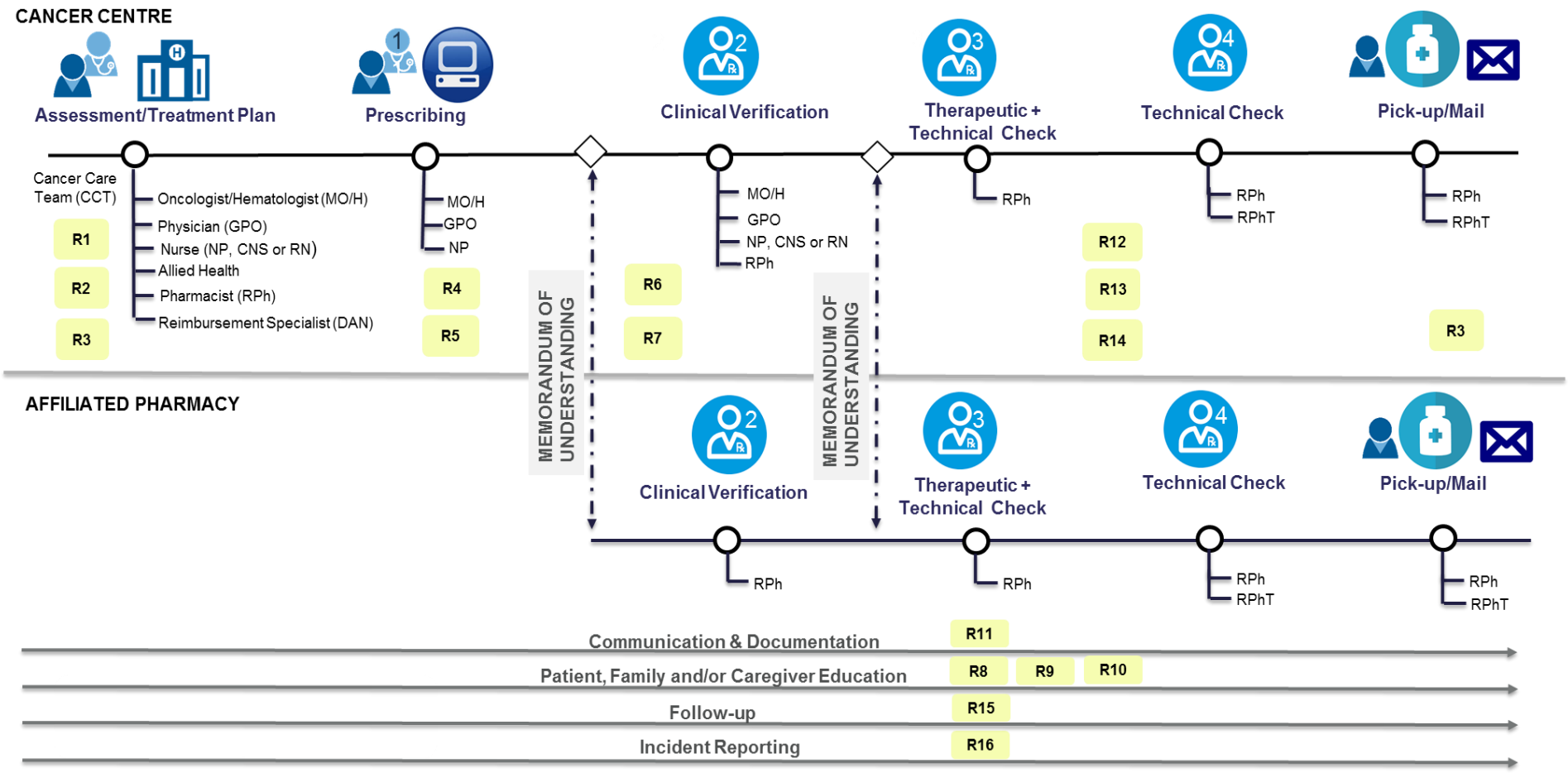
However, for patients requiring mixed regimens (IVCD and THCD) whether in combination or as sequential therapy, there may be duplication/inconsistency in patient and/or caregiver education (R8, R9, R10), communication (R11), monitoring (R15) and incident reporting (R16); hence, roles and responsibilities of each multidisciplinary team member should be defined and expectations should be clarified in the memorandum of understanding.

Table 1: Proposed Key Characteristics of an Affiliated Pharmacy *[§]

An affiliated pharmacy should have the following characteristics to ensure quality & safety:
• The capacity to serve large numbers of patients on THCD (e.g., staff, funding, storage, workflow). • Physical infrastructure and equipment that protects staff from exposure and a private space for patient counselling, education and monitoring. • Adoption of NAPRA standards • Joint accountability for practice components (e.g., patient education, monitoring) • An integrated IT infrastructure to view the full medication profile and to process any changes in the CPOE system resulting from dispensing or a standard process for communicating changes. If the IT infrastructure is not available, then a standard agreed-upon process to facilitate the above. • A team of pharmacists and pharmacy technicians that demonstrate competency in oncology care and have completed the appropriate training as defined by the CCO Regional Systemic Treatment Program Standards[13] • Dedicated time allocated for processing THCD to minimize safety risks. • A two-way, direct line of communication to address questions and concerns in a timely manner (e.g., prescribers to provide direct contacts, development of a portal for information sharing) • Take on the roles/responsibilities for oncology medications with a restricted distribution (e.g., data reporting to manufacturers)

[§] Adapted from CancerCare Manitoba

Figure 4: Partially Decentralized Model Overlaid with Task Force Recommendations**



** The following diagram uses a *Models of Care* approach. A model *of* care is defined by its objectives, the patient pathway within the model, communication structures, the healthcare setting, and the staffing profile. The diagram highlights actions that are provider-specific, time-specific and/or required in the continuum of care for patients receiving take-home cancer drugs. Hence, task force recommendations are overlaid onto the model of care diagram numbered from R1 to R16.

EXTERNAL CONSULTATION

Feedback submitted through the external consultation (Refer to Appendix C for a list of respondents) indicated strong support for the scope of the recommendations (100%) to enhance quality and safety for THCD delivery. Specific comments were minor and there were no substantive concerns from respondents regarding the clarity of the recommendations. Respondents agreed that the recommendations were very inclusive in terms of practice components and that all of the steps are valid and important in the treatment of the patient; however, they did note that the level of prescriptive requirements for some recommendations would result in additional administrative burden. The lack of funding, resources and personnel would be additional obstacles to overcome. Some respondents indicated that the language may need to be stronger (i.e. recommendations vs. requirements, should vs. must) and that the document, in its current format, allows for a great deal of variation in the application. Respondents recommended developing a supporting toolkit to standardize the interpretation and application. Suggestions included developing checklists and printed materials for cancer centres/hospitals and pharmacies as well as using webinars and educational materials for knowledge translation of all staff involved in THCD delivery, from senior management to frontline providers. Respondents also indicated that the full implementation of these recommendations in the current delivery model may be challenging because of their complexity, the novelty with respect to established practice, and the infrastructure needed to support their implementation. Respondents identified key enablers to facilitate implementation and change (discussed in Key Enablers for Quality and Safety) acknowledging that further work would be required to assess the readiness and capacity for change, costs and implementation timeframes.

KEY ENABLERS FOR QUALITY & SAFETY

This report presented discussions on the current state and alternate models for consideration in Ontario; however, there is an opportunity to enhance the quality and safety of THCD delivery within any model. Task Force members (Assessment of Alternate Models) and external reviewers (Consultation Process) identified key enablers for quality and safety in THCD delivery, regardless of the model in the province:

- Organization/employer support (e.g., financial, time-off) to provide oncology specific education and training to ensure that providers are appropriately trained and maintain the knowledge and skills required for their job function
- Integrated IT infrastructure and telehealth/virtual care/remote monitoring for better data sharing, communication and patient monitoring
- Standardized and widely disseminated educational materials for providers, patients and caregivers
- Dedicated time for providers to carry out specified tasks to minimize safety risks [e.g., CCO Resource Intensity Weight/Workload (RIW) for Pharmacists and Nurses]
- Availability of drug access navigators to provide much needed expertise and support to patients
- Reimbursement of cognitive services for pharmacists such as comprehensive review of the prescription (i.e. develop a cancer-specific MedsCheck program) and patient monitoring

NEXT STEPS

The following are the next steps required for advancing system change:

- CCO and OCP to work together to address training and education requirements for pharmacists and pharmacy technicians
- CCO to start to engage affected stakeholders including consultation with regional cancer programs to share the content of the report and discuss the safety recommendations for THCD
- CCO to conduct a readiness assessment/gap analysis for implementing recommendations at systemic treatment facilities to understand which regions may be able to change their THCD delivery model and what supports CCO can provide to enable change
- CCO to incorporate these recommendations in quality improvement work currently underway and planned in the next fiscal year
- CCO to work with the Ministry to understand how planned changes in health care delivery could enable a change in the THCD model (e.g. improvements in the electronic chart, developing in local networks of care, opportunities to use funding to increase safety of THCD delivery)
- CCO to support the MOHLTC with proposals including costing and timelines for potential system changes

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APPENDIX A: TERMS OF REFERENCE

(April 24, 2017)

1. MANDATE

Cancer Care Ontario has established this Task Force to examine Ontario's pharmacy service model for take-home cancer drugs (THCDs).

The mandate of this Task Force is to deliver recommendations and advice to Cancer Care Ontario on potential provincial pharmacy service models for THCDs in Ontario that optimize safe, high-quality, person-centred care.

The work of this Task Force will be informed by published evidence and key stakeholder opinions.

2. SCOPE AND RESPONSIBILIITES

Responsibilities of this Task Force will include:

- To evaluate the current Ontario pharmacy models for THCD, considering the perspectives of all stakeholders (e.g., patients, providers, administrators), and advise on the current challenges.

- To identify best practices that may be leveraged from other pharmacy THCD delivery models used in other jurisdictions, or other specialized pharmacy service models that are used for non-cancer specialty drugs.
- To develop principles and recommend provincial best practices for Ontario pharmacies dispensing THCD that promote safe, high-quality person-centred care.
- To advise on how the current system for THCD delivery could be enhanced, and identify options for potential future-state pharmacy models that support safe, high-quality, integrated, person-centred care, and the overall sustainability of Ontario's cancer drug programs.
- To advise on the content of a recommendations report.
- As required, to review literature & background information in advanced of scheduled meetings.

For the purpose of this work, this Task Force will not evaluate the following areas of Ontario's cancer drug delivery system:

- Ontario's cancer drug coverage model
- Ontario's submission and decision-making process for publicly funded cancer drugs
- The Exceptional Access Program's application and adjudication process
- Intravenous cancer drug delivery by private clinics

3. MEMBERSHIP

This Task Force will be co-chaired by the Provincial Head, Systemic Treatment, and Director, Provincial Drug Reimbursement Programs, Cancer Care Ontario.

This Task Force will include representation from:

- Ontario College of Pharmacists
- Ontario Pharmacists Association
- Canadian Pharmacists Association
- Neighborhood Pharmacy Association of Canada
- Canadian Cancer Society
- CanCertainty Coalition
- Canadian Society of Hospital Pharmacists
- Canadian Association of Pharmacy in Oncology
- Canadian Association of Pharmacy Technicians
- Institute for Safe Medication Practices Canada
- Oncology Drug Access Navigators of Ontario
- Oncologists/Hematologists
- Academic researcher
- Patients and caregivers
- Community pharmacists from retail and outpatient hospital/cancer centre settings in urban, rural and/or remote areas
- A CCO Regional Vice-President and a CCO Cancer Centre Director

4. SECRETARIAT

The Group Manager, Systemic Treatment Program, in consultation with the Chairs, will prepare and circulate meeting materials (e.g., agenda, minutes, background information, etc.) in advance of the meeting.

5. MEETING SCHEDULE

The group will meet on a regular basis via teleconference. Meetings will be 60-90 minutes in duration. It is anticipated that the group will meet every 4-6 weeks over a 12 month period. In-person meeting(s) may be required.

Additional work may be required between meetings to review literature and documents. All literature will be distributed to members of the working group for review.

6. DECISION-MAKING PROCESS

It is anticipated that decisions, advice, or recommendations put forth by the Task Force will be made by consensus. Chairs will be responsible for facilitating a discussion with equal representation from all members.

7. TIMELINES

It is anticipated that development of recommendations or advisory report on optimal pharmacy service models for Ontario will be completed by April 2018.

8. MEETING MINUTES

Minutes of all meetings will be kept and distributed to members of the working group.

9. TERM OF APPOINTMENT

Task force members will be asked to participate for a one-year period. Task-force members who are unable to participate for the entire duration of the Task Force should consult with the chairs in order to identify an appropriate replacement. The Terms of Reference will be reviewed after a 1-year period, as required.

10. CONFIDENTIALITY/CONFLICT OF INTEREST

Members of this Task Force will be required to sign Cancer Care Ontario's standard non-disclosure agreement and conflict of interest documents.

APPENDIX B: OUTPUTS FROM JURISDICTIONAL SCAN

Key Features of Ontario's Pharmacy Service Delivery Model for THCDs

Accessibility

- The population of Ontario is ~13.6 million (2014)
- There are 14 Regional Cancer Programs (RCPs) & 77 hospitals that deliver systemic treatment across the province
- The RCPS are the networks of stakeholders, healthcare professionals & organizations involved in cancer prevention & care within each of the province's 14 Local Health Integration Networks. Each is led by a Cancer Care Ontario (CCO) Regional Vice President
- For eligible clients, the Ministry of Health & Long-Term Care, through the Ontario Drug Benefit (ODB) Program pays for most of the cost of THCDs that are listed in the Ontario Drug Benefit Formulary
- Ontarians qualify under the ODB Program either when they turn 65, live in a long-term care or home for special care, or are enrolled under Home Care, Ontario Works, Ontario Disability Support Program, or the Trillium Drug Program.
- The Exceptional Access Program (EAP) facilitates patient access to drugs not funded on ODB Formulary, or where no listed alternative is available; however, in order to receive coverage, the patient must be eligible to receive benefits under ODB program. A funding request application must be signed by the authorized prescriber.
- The Case-by-Case Review Program (CBCRP) considers funding requests for oral & injectable cancer drugs for cancer patients who have rare clinical circumstances that are immediately life threatening, & who require treatment with an unfunded drug because there is no other satisfactory & funded treatment
- CCO's Systemic Treatment Quality Based (ST-QBP) provides funding based on bundled services, including consultation, evidence-informed treatment (oral & parenteral) & follow-up bundles, as well as a minimum number of unbundled services. List of funded regimens can be found on the ST-QBP webpage ((https://www.cancercare.on.ca/toolbox/drugformulary/stfmregimens/)

Prescribing

- Prescribing is not restricted to cancer specialists
- Subsequent prescriptions can be written nurse practitioners
- Pharmacists do not have prescribing authority but they can adapt/manage prescriptions (i.e., change drug dosage/formulation/ regimen, review/extend prescription for continuity of care)
- Approximately 95% of prescriptions for THCDs are generated either using CPOE or PPOs

Dispensing

- There are 4,150 community pharmacies
- THCDs can be dispensed from any pharmacy (i.e., cancer centre pharmacy, outpatient hospital pharmacy, community pharmacy)
- Controlled distribution available through specialty pharmacies (e.g. McKesson, Bayshore, SDM Specialty Network)
- Option for mail delivery
- In terms of safe dispensing, CCO has created clinical checklists for verification of THCDs in community pharmacies & cancer centre/specialty pharmacies (https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=362137, https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=362139)
- *Recommendations for the Safe Use & Handling of Oral Anti-Cancer Drugs (OACDs) in Community Pharmacy: A Pan-Canadian Consensus Guideline* have been released by CAPCA & CCO; however no assessments for uptake or concordance have been conducted

Incident Reporting

- Reporting critical incidents is a mandatory requirement for hospitals & they may voluntarily report incidents to CIHI's National System for Incident Reporting (NSIR)
- Incident reporting by community pharmacies is not mandatory
- There is no provincial tracking systems for incidents
- OCP is developing an mandatory medication incidents reporting framework for community pharmacies

Counselling & Monitoring

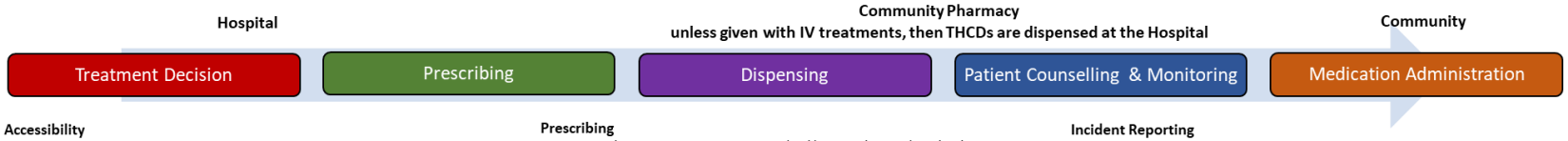
- Cancer Centres & specialty pharmacies are in a position to provide higher-quality patient education for THCDs due to frequency of patient interactions with their pharmacists
- Frequency & content of patient counselling is unknown & unlikely standardized across community pharmacies
- Call-back/monitoring programs for THCDs vary by site (likely occurring in cancer centres & specialty pharmacies)
- CCO's Drug Formulary provides evidence-informed information on cancer drugs used in Ontario for healthcare providers & patients; however utilization is unknown (https://www.cancercare.on.ca/toolbox/drugformulary/)

System Integration

- The Digital Health Drug Repository (DHDR) contains dispensed events for all publicly funded drugs & pharmacy services, as well as dispensed events for all monitored drugs. These records are submitted to DHDR through the Health Network System (HNS) via a near real-time feed to ensure most current data is available in the DHDR. DHDR contains over 1.4 billion records, including seven years of Ontario Drug Benefit (ODB) data & five years of Narcotics Monitoring System (NMS) data.
- DHDR provides clinically relevant information for health care providers to access quickly, securely, & efficiently, via two provincial Clinical Viewers (ClinicalConnect, ConnectingOntario). As of July 31, 2017, DHDR is available to 183 sites & over 76,000 health care providers across Ontario through these clinical viewers.
- With Digital Health Drug Repository (DHDR), authorized health care providers are able to securely view their patient's drug & pharmacy service information, at point of care, informing appropriate prescribing & supporting clinician's ability to prepare the Best Possible Medication History (BPMH) for the clinical drug assessment for their patient. DHDR is currently part of the province's Electronic Health Record (EHR) & shareable within the patient's health care team across multiple health care settings (e.g., hospitals, hospital in-patient pharmacies, family health teams, community health centres), significantly extending the reach of the Drug Profile Viewer (which has been available since 2008 to clinicians in over 200 sites across the province to view drug information).
- Drugs administered in a hospital setting are also available to the clinical viewers through the participating hospital sites.
- The clinical viewer organizations continue work related to further expansion of access to clinical viewers & DHDR at this time. Health care providers & health care organizations (including community pharmacies) can subscribe to the EHR through these clinical viewer organizations if they meet the privacy & security requirements to access the provincial assets.

Source: Personal Communication, Ontario Pharmacist Association, Ontario College of Pharmacists, Ministry of Health and Long Term Care (Ontario Public Drug Programs)

Key Features of Quebec's Pharmacy Service Delivery Model for THCDs



Accessibility

- The population of Quebec is ~8.2 million (2014)
- 74 hospitals deliver chemotherapy in the province
- There are 1,896 community pharmacies (http://napra.ca/pages/Practice_Resources/National_Statistics.aspx?id=2104).
- There are 9,313 licensed pharmacists (http://www.opq.org/doc/media/2686_38_fr-ca_0_odp_rapportannuel_vfinale_lr.pdf).
- Technicians are not regulated in Quebec & the number is unknown. There is a an education program at the Collège d'enseignement général et professionnel (CEGEP) de Drummondville; however, participation in the program is not mandatory for practice. Most technicians hold a diploma of professional education at the high school level. (http://www.opq.org/doc/media/1822_38_fr-ca_0_standards_atp_final_maj_18_fev_2014.pdf).
- Cancer patients may receive treatment at cancer centres or at their community hospitals. In either case, these institutions cover the cost of all medications delivered while someone is an inpatient & the cost of IV chemotherapy received at the institution. Each hospital has a formulary, which lists the medications they can use at that institution. This formulary varies from hospital to hospital.
- Medications that are taken at home are not paid for by the hospitals & may be covered by the provincial drug benefit plan & by private insurance plans.
- The Basic Prescription Drug Insurance Plan guarantees basic coverage for all Quebecers. Individuals not covered by a group insurance plan are eligible for the public plan, administered by the Régie de l'assurance maladie du Québec (RAMQ). The plan covers medications on the Liste de medicaments (http://www.ramq.gouv.qc.ca/en/publications/citizens/legal-publications/Pages/list-medications.aspx).
- Drugs not on this list may be covered by the RAMQ through the "mesure du patient d'exception". Physicians must complete the "Demande d'autorisation de paiement – Mesure du patient d'exception" & submit it to the RAMQ to obtain approval from the Régie before the prescription is dispensed.

Prescribing

- First cycle prescriptions are prescribed by oncologists (medical oncologists, oncology surgeons, dermato-oncologists, gyneco-oncologists, uro-oncologists, etc).
- Prescriptions can be written by some internal medicine physicians in hospitals that do not have an oncologist in-house
- Nurse practitioners do not have prescribing authority for THCDS
- Pharmacists do not have prescribing authority or the ability to change drug dosage, formulation or regimen or to renew or extend prescription for THCDs
- There is only one hospital that uses CPOE both for IV & THCDs
- Most of the other sites use PPOs for IV & handwritten prescriptions for THCDs

Dispensing

- Patients can fill their prescriptions for THCDs at a pharmacy of their choice unless the THCDS are given with an IV drug, then they are dispensed at an outpatient hospital pharmacy
- Specialty pharmacies and/or the option for mail delivery of THCDs are not part of the public system but they may be used for compassionate programs of industry.
- Commonly used guidelines include but are not limited to: Guidelines of the Ordre des pharmaciens du Québec (www.opq.org), Prevention Guide - safe Handling of Hazardous Drugs (https://asstsas.qc.ca/sites/default/files/publications/documents/Guides_Broch_Depl/GP65A_hazardous_drugs.pdf) & Recommendations for the Safe Use & Handling of Oral Anti-Cancer Drugs (OACDs) in Community Pharmacy: A Pan-Canadian Consensus Guideline (https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=372017)
- Pharmacists are not paid differently for their cognitive services when dispensing THCDs

Incident Reporting

- Reporting in community pharmacies is not mandatory & there is no provincial system for tracking incidents/accidents or near misses in these settings
- There is a separate system administered by the Ministry for reporting incidents/accidents & for declaring near misses that occur in hospitals
- Serious adverse effects would not be listed in hospital system but Health Canada would be informed of them

Counselling & Monitoring

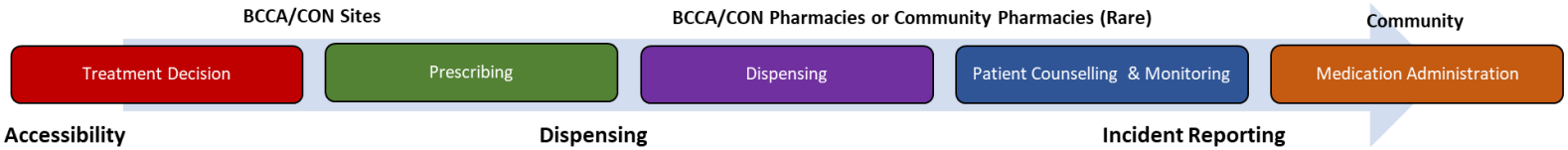
- Counselling & monitoring programs vary by practice setting
- At the hospital, for example, some teams make sure that patients being prescribed THCDs are seen by the pharmacist & receive all of the information necessary to directly contact the oncology nurse/pharmacist, if required
- Leaflets for community pharmacists are centrally available (www.geoq.info) & can also be used by the hospital teams
- The pamphlets are either handed to the patient or faxed to the community pharmacist
- These leaflets contain information about the counselling already provided at the hospital, contact information of the oncology nurse/pharmacist & main adverse effects to report and/or to act upon
- Many teams rely on the oncology nurse to manage toxicities through a phone-based program

System Integration

- There is a provincial prescription drug information system called dossier de santé du Québec (DSQ) that feeds into the electronic health records (EHR) at hospitals
- It works in near real time & captures all the prescriptions delivered at all the community pharmacies
- Authorized personnel in hospitals & community pharmacies can subscribe to the EHR; however different access permissions are associated to each approved role based on the users need-to-know to deliver care
- Community pharmacists are able to view imaging & lab work in the EHR

Source: Personal communication, Direction générale de cancérologie, Ministère de la Santé et des Services sociaux

Key Features of British Columbia's Pharmacy Service Delivery Model for THCDs



Accessibility

- The population of BC is ~4.6 million (2014)
- The BC Cancer Agency (BCCA) operates six regional cancer centres
- The BCCA also oversees the Communities Oncology Network (CON) which includes 19 community cancer centres, six community cancer services & 12 consultative clinics across the province
- The CON also partners with the regional cancer centres, systemic therapy & radiation programs, to deliver cancer patient care & support in 33 other community hospitals
- THCDs on the Benefit Drug List are funded by BCCA for all BC Medical Service Plan (MSP) patients for approved indications without an adjudication process
- For THCDs classified as Restricted, or not on the Benefit Drug List, a patient-specific application is submitted by the physician to the Compassionate Access Program (CAP) for case-by-case approval

Prescribing

- Prescribing is not restricted to cancer specialists
- Hormonal therapies often prescribed by family physicians
- Non-cancer specialists & nurse practitioners can prescribe certain medications for active cancer treatments if they have participated in the BCCA GPO Training Program
- Pharmacists do not have prescribing authority
- No CPOEs implemented but planned for next year
- Majority of prescriptions ordered through PPOs

Dispensing

- No charge to registered BC patients if THCDs are dispensed at the six BCCA or 34 CON hospital pharmacies
- The BCCA & CON locations are oncology dispensaries only including controlled distribution programs;
- There are 1,301 community pharmacies
- Patients are asked to fill supportive care at retail pharmacies
- Unfunded THCDs can be dispensed at community or specialty pharmacies (<1%)
- Option for mail delivery
- BCCA has Pharmacy Practice Standards for Hazardous Drugs
- The BCCA Oncology Pharmacy Education Program is a non-accredited, self-directed, online continuing professional education program & is freely available to anyone however, pharmacists practicing at BCCA/CON must be enrolled
- Pharmacists are not paid differently for cognitive services

Counselling & Monitoring

- No standardized monitoring program but the BCCA offers call back programs by nurses or pharmacists for certain THCDs (e.g. capecitabine) 7-10 days after the prescription is filled & touchpoints on every refill
- Short staffing limits the ability to implement call back programs for all THCDs
- The BCCA staffs a nursing telephone service line during business hours to answer general questions about treatment & symptoms
- For emergencies relating to on-going treatment, patients can call the main cancer agency line operating 24/7 & they will be triaged to an on-call physician or the ED

Incident Reporting

- The web-based BC Patient Safety & Learning System (PSLS) holds information about patient safety events, including adverse events, near misses, safety hazards, patient complaints & claims
- It is available to providers in all BC health care settings
- Reporting is voluntary & can be done anonymously
- Data sharing agreements in place with external agencies (e.g. CIHI)

System Integration

- PharmaNet is a real-time, province-wide network that links all BC pharmacies to a central set of data systems
- Every take-home prescription dispensed in BC is entered into PharmaNet to prevent accidental duplication, fraud, drug interactions & dosage errors
- PharmaNet can be viewed by authorized users from community & hospital pharmacies, EDs, clinics, the College of Pharmacists of BC, the College of Physicians & Surgeons of BC
- Patients cannot opt out of PharmaNet but they can set a password so that practitioners can access their information only if the password is shared with them
- The BCCA Information System (CAIS) is an EMR
- The BCCA uploads take-home & IV cancer drugs dispensed at BCCA/CON sites into the medication profile
- Only BCCA/CON staff have access to CAIS but other authorized users may have access to the entire EMR
- CAIS & PharmaNet have no interface & no information is transferred between the two systems

Source: Personal Communication, Pharmacy Director, BC Cancer Agency

Key Features of Alberta's Pharmacy Service Delivery Model for THCDs

Cancer Centre/CCN Designated Sites

Treatment Decision | Prescribing

Cancer Centre/CCN Designated Hospital Pharmacies

Dispensing | Patient Counselling & Monitoring

Community

Medication Administration

Accessibility

- The population of Alberta is ~4.1 million (2014)
- The Community Cancer Network (CCN) is the multidisciplinary team that connects all Alberta Health Services (AHS) cancer care sites
- The CCN is comprised of two tertiary, four associate & 11 community cancer centres
- There are also four hematology centres (two are pediatric centres) in Calgary & Edmonton
- To join the CCN, a site must be accredited through Accreditation Canada, submit a Cancer Centre Designation Request to AHS, & recertify annually to ensure the site is following standard procedures & processes
- THCDs on the AHS Cancer Drug Benefit Program are funded by AHS for Alberta patients registered in the Cancer Registry with a disease classified in the International Classification of Diseases for Oncology, with no application or prior approval required

Prescribing

- Prescribing is not restricted to cancer specialists
- All pharmacists registered on the clinical register may prescribe by adapting a prescription or may prescribe in an emergency however pharmacists who have been granted an additional prescribing authorization may also prescribe to initiate drug therapy and/or manage ongoing drug therapy (except for narcotics)
- Additional prescribing authorization from the College of Pharmacists of Alberta can be obtained by having at least one year of full-time experience & submitting three cases to the College or by completing the AHS Pharmacy Practice Residency Program
- THCDs listed in Group 1 can be prescribed by a non-cancer specialists
- The initial prescription of THCDS listed in Group 2 must be written by authorized & named Cancer Centre medical staff member but subsequent prescriptions can be written by a non-cancer specialist
- THCDs listed in Group 3 must be prescribed as part of a research or clinical drug trial approved by AHS & written by the principal/ co-investigator in charge of the trial
- THCDS approved for special access by Health Canada are also listed under Group 3 & must be prescribed by authorized & named Cancer Centre medical staff member

Prescribing (continued)

- All Cancer Centre/CCN sites use CPOE systems
- Community-based providers order THCDs through PPOs available on the internal AHS web-based portal

Dispensing

- The AHS provides THCDs specified in the Outpatient Cancer Drug Benefit Program, at no charge, to eligible residents as long as they are dispensed at the Cancer Centre/CCN Designated Hospital Pharmacies; retail or specialty pharmacies are not involved in dispensing THCDs
- Initial prescriptions are reviewed & dispensed at the Cancer Centre but subsequent prescriptions can be dispensed at CCN designated hospital pharmacies
- The inventory for subsequent prescriptions are shipped from the Cancer Centre to the CCN designated hospital pharmacy closest to the patient's home
- There are 1,223 community pharmacies
- Patients are asked to fill supportive care at retail pharmacies
- Controlled distribution programs available through RevAid
- There is an option for mail delivery
- Pharmacists at Cancer Centre/CCN Designated Hospital are not paid differently for cognitive services as they are salaried & unionized
- Provincial guidelines for safe use & handling of drugs are available through the internal AHS web-based portal & AHS training manuals are sold externally
- The oncology medication safety self assessment tool developed by ISMP & ISOPP (2012) is also used at sites

Incident Reporting

- The web-based Reporting & Learning System (RLS) holds information about adverse events, near misses, hazards & provides training & resources to manage & discuss quality & safety issues
- It is available to providers in all health care settings in Alberta
- Reporting is voluntary & can be done anonymously
- Data sharing agreements in place with external agencies (e.g. CIHI)

Counselling & Monitoring

- Standardized counselling & monitoring programs are in place
- Patient handouts & education sheets (reviewed by multi-disciplinary teams) are available for pharmacists to through the internal AHS web-based portal
- There is a pharmacist-initiated telephone callback service for new patients or patients on new medications; elderly patients; & patients with specific disease-drug combinations
- The initial call back is within first two weeks of dispensing
- If patient request additional call backs (usually one or two following the initial call works for a majority of patients), they would be enrolled in the THCD monitoring program at the pharmacy

System Integration

- The Pharmaceutical Information Network (PIN) is a single sign on, web-enabled application within the Alberta Netcare Electronic Health Record (EHR) that provides access to a patient's active & previous medications
- The PIN is a central repository of the patient's Medication Profile
- The ultimate goal of PIN is to facilitate improved quality of care by providing authorized health care providers with the information & tools needed to make optimal drug therapy decisions
- The PIN not only provides access to a patient's medications, but also includes allergy & intolerance information, pharmacy care plans, access to drug monographs, drug decision support, dispense information & the ability to create prescriptions & manage warnings
- The majority of records on the EHR Medication Profile are dispenses submitted by community pharmacies through daily submissions via Pharmacy Batch
- Standard Alberta Netcare Portal (ANP) security measures are in place to protect this information

Source: Personal Communication, Pharmacy Director, Cancer Services, Alberta Health Services

Key Features of Saskatchewan's Pharmacy Service Delivery Model for THCDs

Accessibility

- The population of Saskatchewan is ~1.1 million (2014)
- The Saskatchewan Cancer Agency (SCA) operates two treatment facilities attached to tertiary hospitals: the Allan Blair Cancer Centre in Regina & the Saskatoon Cancer Centre
- There are 16 Community Oncology Program of Saskatchewan (COPS) centres located in regional hospitals throughout Saskatchewan
- The SCA drug formulary provides a listing of the anti-cancer drugs & some supportive drugs funded by the Agency with no pre-qualification or approvals required as the prescription is adjudicated at the time of dispensing
- Formulary drugs are provided free of charge to SK residents that are registered with SCA when used according to the funding eligibility guidelines
- Coverage for special formulary listings for new &emerging drug treatments must be approved through the SCA Treatment Evaluation Program (STEP)
- Case-by-case requests must be approved by the Exceptional Drug Coverage (EDC) program

Prescribing

- Prescribing is restricted to authorized & named cancer specialists at the Cancer Centres only
- For adjuvant hormonal therapies, the cancer specialist may transition care to a GP within three to six months after the initiation of such therapy at the Cancer Centre
- No CPOE systems are implemented in the province
- PPOs available for all oral prescriptions or protocols (e.g. combination IV/oral protocols, concurrent chemo/RT)

Dispensing

- Nearly 100% of THCDs & supportive care (formulary) are dispensed at the two cancer centre pharmacies
- There are 352 community pharmacies
- Other supportive care must be filled at community pharmacies
- If a patient chooses to obtain THCDs or supportive care (formulary) from a community pharmacy, they are responsible for 100% of cost upfront, with reimbursement only at SCA net drug cost
- Controlled distribution programs available through Cancer Centre pharmacies
- Option for mail delivery & telehealth
- Provincial guidelines for safe use & handling of cytotoxic drugs are used at the Cancer Centre pharmacies
- Unknown whether other provincial or national guidelines are being used in community pharmacies
- Pharmacists are not paid differently for their cognitive services

Incident Reporting

- Incident reporting is voluntary & can be done anonymously through a web-based portal
- When an incident is reported, professionals in the Regional Health Authority (RHA) & SCA report information (excluding the identity of the patient) to Provincial Quality of Care Coordinators in the Ministry of Health.
- An investigation is conducted on each critical incident. Following the investigation, RHAs & the SCA generate recommendations for improvement that they are then responsible for implementing in their region
- Patient safety alerts are issued when the result from an investigation may benefit the province more broadly

Counselling & Monitoring

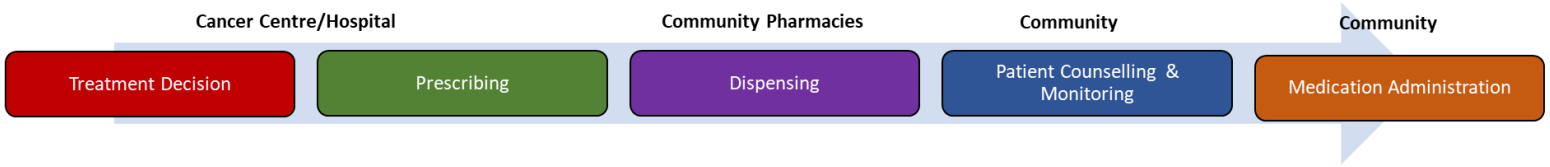
- There is no formalized monitoring program but standard work for oncology pharmacists at the Cancer Centres includes monitoring lab work, toxicity & adherence
- There is also a call back program for initial prescription & an in-person follow-up at subsequent clinic visits
- Patients/caregivers are also provided with a number to call for side-effect & toxicity management

System Integration

- The Pharmaceutical Information Program (PIP) is a secure computer system that contains information about a resident's prescribed & dispensed medications
- Oncology & other medications administered in the hospital will not be included in a patient's PIP profile as currently an older pharmacy system (Rx3000) that is not integrated with PIP is being used at sites; however, system upgrades are planned for next summer
- The PIP provides authorized health care professionals like pharmacists & physicians with confidential access to patient medication records
- The PIP feeds into eHealth Saskatchewan (EHR)
- A Joint Services Access Policy (JSAP) exists for all eHealth Saskatchewan integrated services including PIP, electronic labs & imaging
- Community pharmacists & other providers in health care settings can subscribe to the EHR
- The Health Information Protection Act (HIPA) provides the rules for the collection, use, & disclosure of personal health information & safeguards to ensure patient confidentiality

Source: Personal Communication, Pharmacy Director, Saskatchewan Cancer Agency

Key Features of Manitoba's Pharmacy Service Delivery Model for THCDs



Accessibility

- The population of Manitoba is 1.3 million (2014)
- Cancer Care Manitoba (CCMB) has two tertiary locations in Winnipeg
- Through partnerships with the Winnipeg Regional Health Authority (WRHA), CCMB specialists work at six sites in Winnipeg
- Outside of Winnipeg, through partnerships with four regional health authorities, CCMB provides community based cancer services through the Community Cancer Program (CCP) Network at 17 locations
- The Home Cancer Drug (HCD) Program covers eligible outpatient oral cancer & specific supportive drugs that support outpatient cancer treatment as listed in the HCD Program Formulary at no cost to patients who are registered in the Pharmacare Program
- Pharmacare is an income-based program that provides drug cost assistance to eligible Manitobans who do not have coverage under a federal or other provincial program

Prescribing

- First cycle prescriptions or change in therapies for active cancer treatments are prescribed by cancer specialists
- Hormonal therapies may be written by non-cancer specialists
- Subsequent prescriptions for THCDs can be written by non-cancer specialists including nurse practitioners
- Pharmacists have no prescribing authority
- Where possible, CPOE systems are used & orders are generated through ARIA (VMO) system but some physicians still use handwritten prescriptions

Dispensing

- Patients can fill prescriptions at a pharmacy of their choice
- There are 385 community pharmacies
- There is an option for mail delivery
- For surveillance & monitoring purposes, oral fludarabine, oral ponatinib & oral vismodegib must be dispensed from CCMB
- Pharmacists dispensing the THCDS listed above, must be certified & recertified annually
- Controlled distribution programs available through Revaid
- Winnipeg Regional Health Authority safe use & handling guidelines are available but compliance outside CCMB is unknown

Incident Reporting

- Reporting is voluntary
- There is no provincial system for tracking incidents
- Information remains at the local level unless reported to CCMB

Counselling & Monitoring

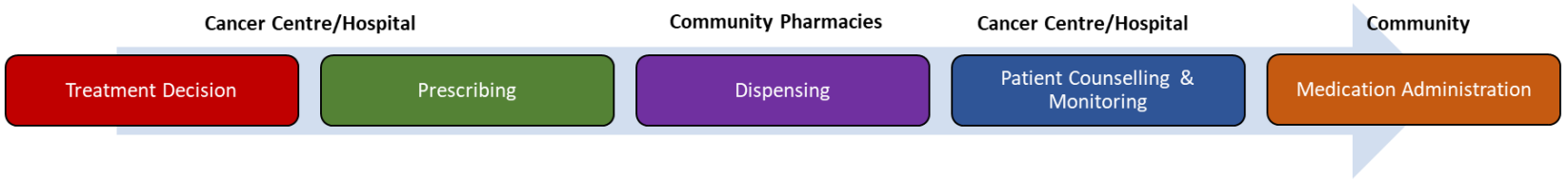
- No standardized counselling or monitoring programs in community pharmacies
- In some cases. patients may receive reminder aids or counseling from clinical pharmacists to enhance adherence

System Integration

- The Drug Information Program Network (DPIN) is an electronic, on-line, point-of-sale prescription drug database that connects Manitoba Health & pharmacies in the province
- DPIN generates complete drug profiles for each client in real time for all residents regardless of the payer
- The prescription's indication is not collected & must be inferred from other data
- Services not captured in the DPIN include hospital pharmacies, nursing stations, ward stock, & outpatient visits at CCMB

Source: Personal Communication, Director, Provincial Oncology Drug Program, CancerCare Manitoba

Key Features of New Brunswick's Pharmacy Service Delivery Model for THCDs



Accessibility

- The population of New Brunswick is ~754,000 (2014)
- Four primary cancer treatment centres & a few satellite sites across two health authorities
- Coverage for THCDs provided through private insurance, the New Brunswick Prescription Drug Program (NBPDP) or federally run drug plans
- Only ~10% of residents are members of the NBPDP

Prescribing

- No official restriction on prescribing (apart from drug formulary criteria)
- Generally prescribed by cancer specialist but can include GPOs (site dependent)
- Does not include pharmacists or nurse practitioners
- Only one site has CPOE but no built-in protocols
- A majority of prescriptions are handwritten with some use of PPOs

Dispensing

- Generally, dispensing occurs in community pharmacies as there are no outpatient hospital pharmacies
- There are 222 community pharmacies
- Controlled distribution programs at specialty pharmacies
- Option for mail delivery
- No preferred provider network
- Pharmacists are not paid differently for their cognitive services for dispensing THCDs
- No provincial safe use & handling guidelines
- Unknown whether other provincial or national guidelines are being used in community pharmacies

Incident Reporting

- Reporting is voluntary
- There is no provincial system for tracking incidents
- Information remains at the local level

Counselling & Monitoring

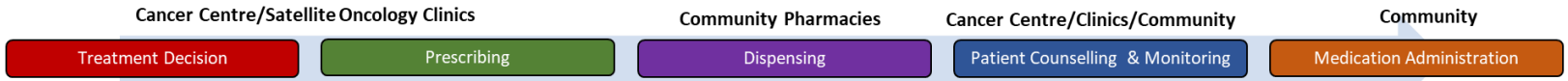
- Patients are asked to fill their prescriptions & then return to the treatment centre for 1:1 counselling & adverse effects monitoring
- Generally, patients have not expressed concerns about the logistics of the program but phone calls can be arranged if patients are unable to return to the site
- One major pharmacy site is in the initial stages of implementing a pharmacist monitoring program

System Integration

- As of Dec 2016, the Drug Information System (DIS) in NB was live for 100% of pharmacies
- Prior to Dec 2016, only members of NBPDP were captured in DIS
- Every resident filling a prescription must present a health card which allows for data capture
- The DIS feeds into the EHR (contains lab work, diagnostic imaging etc.)
- EHR access is open to all users who qualify based on their role (includes pharmacists)
- A role based access control matrix is used & different access permissions are associated to each approved role based on the users need-to-know to deliver care

Source: Personal Communication, Provincial Pharmacy Director, New Brunswick Cancer Network

Key Features of Nova Scotia's Pharmacy Service Delivery Model for THCDs



Accessibility

- The population of Nova Scotia is ~942,900
- There are two cancer treatment centres: the Nova Scotia Cancer Centre & the Cape Breton Cancer Centre
- The IWK Health Centre for Women & Children also provides services for women & pediatric cancer patients
- There are seven satellite oncology clinics located in hospitals throughout the province o patients can receive their cancer treatment closer to home
- Nova Scotia Pharmacare Programs (e.g. Senior's Pharmacare Program, Drug Assistance for Cancer Patients) provides outpatient prescription drug benefits for medications listed on the Nova Scotia Formulary to eligible residents
- Drugs not listed in the formulary may be covered through the Exception Drug Status Process

Prescribing

- Prescribing is not restricted to cancer specialists
- First cycle prescriptions are generally written by cancer specialists however non-cancer specialists (e.g. GPO, nurse practitioners) can write subsequent prescriptions
- Pharmacists do not have prescribing authority
- There are some PPOs available for THCDs however prescriptions are primarily hand-written

Dispensing

- No outpatient hospital pharmacies
- There are 303 community pharmacies
- Most THCDs can be dispensed at community pharmacies
- Drugs that are part of controlled distribution programs are ordered & coordinated in clinic, & dispensed to the patients directly via mail through specialty pharmacies
- Pharmacists are encouraged by the Health Authority to use the *Recommendations for the Safe Use & Handling of Oral Anti-Cancer Drugs (OACDs) in Community Pharmacy: A Pan-Canadian Consensus Guideline* have been released by CAPCA & CCO
- The information from the national guidelines have been summarized in CCNS's practice guide, *Safe Handling—Cancer Medications in the Community Pharmacy*. The guide adapts these guidelines to the community setting, including practical approaches for cleaning, decontamination, spill management & personnel issues

Incident Reporting

- Nova Scotia is the only province with a mandatory requirement by the College for its pharmacies to anonymously report errors to an independent organization
- 100% of pharmacies in Nova Scotia have the Community Pharmacy Incident Reporting (CPhIR) which has been designed by ISMP Canada contributes to the Canadian Medication Incident Reporting & Prevention System (CMIRPS)
- Hospitals have a different reporting system called Nova Scotia Safety Improvement & Management System (SIMS)
- No information is transferred between CPhIR & SIMS

Counselling & Monitoring

- Counselling & monitoring is primarily provided at the clinic under the direction of the cancer specialist; however the content & frequency will vary by site as it is at the discretion of the cancer specialist
- There was a pilot project for six months where an oncology pharmacist was assigned to a 1 FTE at the Cape Breton Cancer Centre to develop & operationalize a proposed Oral Systemic Therapy Case Manager (OSTCM) position in order to facilitate congruence to recent provincial standards. Physician & nursing staff provided overall positive feedback & the results were presented to local & provincial senior leadership with a business plan & budget for the OSTCM role & is currently awaiting a funding decision
- A set of drug-specific tools has also been developed to support community pharmacists is available on the public website supported by Cancer Care Nova Scotia (CCNS); however the uptake is unknown

System Integration

- The Nova Scotia Drug Information System (DIS) is a province-wide system that will, over time, contain a comprehensive medication profile for everyone who gets a prescription filled in a community pharmacy in Nova Scotia
- All drugs that are dispensed in community pharmacies are entered into the DIS including THCDs
- Note that IV cancer drugs are not entered in the DIS as prescription information for IV cancer drugs remains with the Cancer Centres
- The DIS is a secure & private system - only authorized healthcare providers can access your medication profile & their access is subject to the provisions set out in the province's Personal Health Information Act (PHIA)
- The DIS is a component of Nova Scotia's EHR system called SHARE (Secure Health Access Record) which in its very early stages of implementation
- Healthcare providers including community pharmacists can subscribe to the EHR; however different access permissions are associated to each approved role based on the users need-to-know to deliver care

Source: Personal Communication, Oncology Pharmacist, Nova Scotia Cancer Care Program

Key Features of Newfoundland & Labrador's Pharmacy Service Delivery Model for THCDs

Accessibility

- The population of Newfoundland & Labrador is ~528,500 (2014)
- Newfoundland & Labrador has one main cancer centre located in St. John's & six peripheral clinics
- There is also a pharmacy-led oral chemotherapy clinic in St. John's
- The Cancer Centre also offers video conferencing for patients to reduce the travel time for follow up appointments
- The Newfoundland & Labrador Prescription Drug Program (NLPDP) provides outpatient prescription drug coverage for medications listed in the Newfoundland & Labrador Interchangeable Drug Products Formulary to eligible residents
- There are five main plans under the NLPDP: The Foundation Plan, The 65 Plus Plan, the Access Plan, the Assurance Plan & the Select Needs Plan
- The NLPDP will pay prescription costs & other related benefits, for which a person is eligible, only where those services are not, or are no longer, reimbursable by a third party
- A request for coverage of medications not on the formulary may be submitted using the Special Authorization process

Prescribing

- Prescribing not restricted to cancer specialists
- Initial prescription is usually generated by cancer specialists at the Cancer Centre but subsequent prescriptions may be written by non-cancer specialists (e.g. urologists, GPO, GP, NP)
- Pharmacists do not have prescribing authority
- CPOE systems are used at the Cancer Centre & five peripheral clinics & orders are generated through ARIA (VMO) system; only one clinic uses handwritten prescriptions

Dispensing

- No outpatient hospital pharmacies
- There are 195 community pharmacies
- Most THCDs can be filled at any community pharmacy
- Controlled distribution programs available through specialty pharmacies (e.g. McKesson)
- Option for mail delivery
- No provincial guidelines for safe use & handling
- Unknown whether other provincial or national guidelines are being used in community pharmacies

Incident Reporting

- Reporting is voluntary & can be anonymous
- There is no provincial system for tracking incidents

Counselling & Monitoring

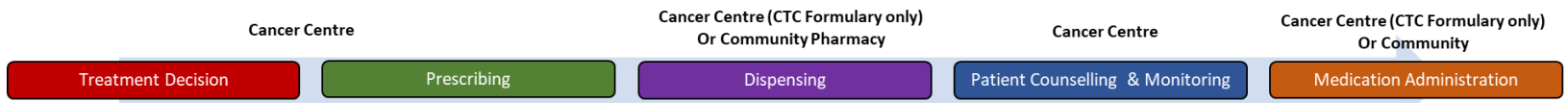
- There is standardized clinical pharmacist-led counselling & monitoring program at the Cancer Centre & six peripheral clinics
- The program involves patient education, medication reconciliation, adherence monitoring, toxicity monitoring & management, & related supportive care issues
- Patients are followed for two cycles of their treatment either collaboratively with the cancer specialist during scheduled clinic visits, through clinic visits with the oncology pharmacist alone, & through the call back program (timing & frequency of calls are drug-specific)

System Integration

- There is a province-wide Health Information Network (HIN) that supports a person-specific EHR & facilitates sharing of data between providers in all health care settings
- The Pharmacy Network is a component of the EHR
- The Pharmacy Network is a Drug Information System (DIS) that connects all retail pharmacies & provides tools & processes to support prescribing, dispensing & compliance monitoring
- Note that information on any cancer drugs dispensed by the cancer program (e.g. IV) are not captured in DIS however community pharmacists can subscribe to the EHR to see clinical notes & lab work
- Authorized personnel working in community pharmacies will have access to the Pharmacy Network through Kroll, an authorized Pharmacy Practice Management System (PPMS)
- Updates to Kroll have been made to accommodate communication & synchronization with the Pharmacy Network
- The Access to Information & Protection of Privacy Act (ATIPPA) & the Personal Health Information Act (PHIA) provides the rules for the collection, use, & disclosure of personal health information & safeguards to ensure patient confidentiality
- Patients cannot opt out of the system but they can apply a consent directive to their profile which will require health care professionals to enter a password, chosen by the patient, in order to access their health information

Source: Personal Communication, Clinical Oncology Pharmacy Specialist, Eastern Health Cancer Care

Key Features of PEI's Pharmacy Service Delivery Model for THCDs



Accessibility

- The population of PEI is ~146,300 (2014)
- There are two cancer treatment centres: the Queen Elizabeth Hospital (QEH) in Charlottetown or the medical oncology satellite clinic at the Prince County Hospital (PCH) in Summerside
- There are two funding channels for medications listed on the Health PEI Formulary Drugs for Oncology: Pharmacare & the CTC Formulary
- Pharmacare - eligible patients must be enrolled in the applicable Pharmacare drug program for which coverage is required. Specific medications may be covered under different Pharmacare drug programs
- CTC Formulary - patients do not need to enroll in this program. All patients with a valid PEI Health Card are automatically eligible to receive medications listed under this program at no cost to the patient.
- THCDs are either classified as open-benefit or restricted
- Open Benefit – medications that have "open benefit" listed as their funded eligibility criteria are available to beneficiaries without any restrictions
- CTC Formulary with Restrictions– the adherence to the funded eligibility criteria for these medications will be confirmed by staff at PEI oncology sites.
- Pharmacare Special Authorization (manual paper-based process)–the listed Funded Eligibility Criteria for each medication corresponds to the special authorization (SA) criteria required by the prescriber under Pharmacare. Physicians must ensure patients meet the corresponding criteria. If a SA submission is required, it must be submitted by the prescriber. If a prescription is written by oncologist, select medications do not require the submission of a SA form

Prescribing

- First cycle prescriptions are prescribed by a cancer specialist
- Subsequent prescriptions can be written by a clinical associates or nurse practitioners at the Cancer Centre under direction of a cancer specialist
- Pharmacists do not have prescribing authority
- CPOE systems are in place are used for IV drugs however a majority of THCDs are ordered through handwritten prescriptions
- A pilot project was implemented for capecitabine prescriptions
- A PPO is used for capecitabine orders. Once prescribed by the oncologist, it is reviewed by a nurse or clinical pharmacist at the Cancer Centre. The prescription is faxed to the patient's preferred community pharmacy followed by a phone call from the Cancer Centre to inform the pharmacist in advance that the patient will be filling the prescription at their site & also flagging any of allergies, potential interactions & medical conditions. Phone calls for first cycle prescriptions take about 20-30 minutes whereas subsequent prescriptions require 10-15 minutes
- PPOs have been created for other THCDs & will be rolled out in the near future

Dispensing

- No outpatient hospital pharmacies & 51 community pharmacies
- THCDs under Pharmacare programs are routinely dispensed from community pharmacies
- THCDs under the CTC Formulary must be dispensed & administered at PEI oncology sites (QEH or PCH) or other approved hospital
- Controlled distribution programs available through RevAid
- There are no provincial safe use & handling guidelines
- Within the Cancer Centre, the BCCA Pharmacy Practice Standards for Hazardous Drugs are used for safe use & handling of THCDs
- Unknown whether other provincial or national guidelines are being used in community pharmacies
- Pharmacists are not paid differently for their cognitive services

Incident Reporting

- Reporting is voluntary
- There is no provincial system for tracking incidents
- Information remains at the local level

Counselling & Monitoring

- Nursing-based counselling & education sheets for THCDs are provided to patients at the Cancer Centre

System Integration

- The Drug Information System (DIS) is an electronic record of all outpatient prescription medications (except for IV drugs) dispensed in PEI
- The medication profile captures information about the prescription as well allergies, adverse reactions & medical conditions
- The medication profile on DIS is linked to health care sites such as pharmacies, physicians' offices, health centres & hospitals
- The DIS feeds into an EHR (Cerner) at hospitals
- Only physicians, nurses, pharmacists & other authorized health care professionals can access the medication profile
- Privacy is protected under Pharmaceutical Information Act
- Authorized user must sign a confidentiality agreement & access the profile only for reasons specified under the Act
- There are serious penalties for unauthorized or inappropriate use of profile information
- Patients cannot opt out of DIS as all PEI pharmacists are required by law to record prescriptions in the DIS via the patient's health card number; however patients can set a password so that practitioners can access their information only if the password is shared with them

Source: Personal Communication, Oncology Pharmacist, PEI Cancer Treatment Centre

Key Features of Australia's Pharmacy Service Delivery Model for THCDs

Accessibility

- The population of Australia is ~23.78 million (2015)
- There are 698 public hospitals & 624 private hospitals[1]
- Majority of public & private hospitals treat cancer patients & have cancer clinics
- There are 5,270 community pharmacies: New South Wales (33.4%), Victoria (23.4%), Queensland (20.4%), Western Australia (10.2%), South Australia (8.1%), Tasmania (2.1%), Australian Capital Territory (1.2%) & Northern Territory (0.6%)[2]
- There are 27,452 pharmacists with general registration (can work unsupervised) & 1,784 with provisional or limited registration (postgraduate training/supervised practice[3])
- Technicians are not regulated in Australia & the number is unknown
- The Australian Government's Pharmaceutical Benefits Scheme (PBS) subsidizes the cost of many different prescription medicines listed in the formulary (including chemotherapy drugs) for people with a current Medicare card
- Eligibility criteria for a Medicare card: Australian or New Zealand citizen, Australian permanent resident, covered by a Ministerial order or visiting from a Reciprocal Health Care Agreement country
- Some PBS medicines are cheaper for people with the following cards: Pensioner Concession Card, Commonwealth Seniors Health Card, Health Care Card & Department of Veterans' Affairs Health Card.
- The PBS Safety Net further reduces the cost of PBS medicines once a patient/family have spent a certain amount; however, payments for non-PBS medicines do not count towards the PBS Safety Net
- If a medicine is prescribed but not subsidized under the PBS, a hospital will usually still charge the patient the co-payment price; however, in a community pharmacy, the patient and/or private insurer would be responsible for the full cost

Prescribing

- No official restriction on prescribing apart from PBS criteria (listed medicines can only be prescribed by doctors, dentists, optometrists, midwives & nurse practitioners who are approved to prescribe PBS medicines under the *National Health Act 1953);* however, cancer drugs are generally prescribed by cancer specialists[4]

Prescribing (continued)

- In some cases, a cancer specialist may transition care to a non-cancer specialist after therapy has been initiated for a patient
- Pharmacists do not have prescribing authority or the ability to adapt or manage prescriptions (i.e., change drug dosage/formulation/ regimen, review/extend prescription for continuity of care)
- Electronic prescribing is not mandated. Most hospitals have some form of electronic chemotherapy prescribing for IV drugs using various software; however, oral agents & supportive care treatments are generally hand written prescriptions

Dispensing

- THCDS can be dispensed from cancer centre/hospital, community & specialty pharmacies
- A pharmacy can dispense any cancer therapies so long as comply with PBS requirements
- Some community pharmacies have contracts with private hospitals to supply cancer medications for hospital use
- There is an option for mail delivery
- Pharmacists are not reimbursed for any specialized services relating to provision of cancer or other high risk/complex medicines
- There is a standard dispensing fee built into the PBS price listing which covers general pharmacy services
- Commonly used guidelines include but are not limited to: *Guidelines for the Safe Prescribing, Dispensing & Administration of Cancer*[5], *Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel*[6], *Standards of Practice for Clinical Pharmacy Services*[7], *Guidelines for Compounding of Medicines*[8], *Safety & Quality Improvement Guide Standard 4: Medication Safety*[9] *& ISOPP standards of practice. Safe handling of cytotoxics*[10]
- All institutions have their own medications management guidelines, which include some provisions around their accepted practices. These are usually taken from the guidelines listed above & are adapted for site specific use

Incident Reporting

- Incident reporting is voluntary & anonymous
- There are state-based hospital reporting systems [e.g. RiskMan, formerly Victorian Health Incident Management System (VHIMS)[11]] but these are not linked nationally

Counselling & Monitoring

- There are no standardized patient education protocols, adherence & toxicity monitoring programs across pharmacies but many sites follow EviQ recommendations & adapt these for site specific use[12]

System Integration

- There is no single repository for all drug information for a patient
- All prescribed medications (both IV & THCDs) dispensed at the cancer centre/ hospital are entered in a computer-based medical record accessible to cancer centre/hospital staff only
- Most hospitals encourage patients to have all medications for specialized services dispensed at the hospital pharmacy to assist with complete medical record, medication reconciliation, pharmacist monitoring & intervention, as required
- There is a relatively new national initiative program called *My Health Record*[13] - a secure online summary of a patients' health information including medications dispensed at community pharmacies. Patients can control what goes into it & who is allowed to access it. Currently, there are ~5milliion participants, mostly from Queensland & New South Wales

References (Accessed June 8, 2017)

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13 https://myhealthrecord.gov.au/internet/mhr/publishing.nsf/content/home

Source: Personal Communication, Pharmacy Research Manager, Melbourne, Australia

Key Features of Netherland's Pharmacy Service Delivery Model for THCDs

Accessibility

- The population of Netherlands is ~16.94 million (2015)
- There are 80 hospitals that provide cancer services
- There are ~1800 community pharmacies
- There are ~4000 licensed pharmacists
- There are ~20,000 technicians; however, they are not regulated in the Netherlands
- There are two types of health insurance: basic insurance & optional additional insurance
- The basic package in the Netherlands is compulsory & provides the same basic health coverage across all insurers, as it is set by the government
- Basic health insurance costs around 100 euros per month & covers: appointments with your doctor; hospital stays, surgery & emergency treatment; ambulance services & patient transport; medicine prescriptions; blood tests; dental care for children under 18 years; limited dental care for adults over 18, restricted to dental surgery, dental x-rays & removable dentures; & mental health care
- Health insurers reimburse only registered drugs prescribed for licensed indications, from the Drug Reimbursement System (GVS) (https:// www.medicijnkosten.nl/)

Prescribing

- Only medical specialists (oncologists, hematologists, pulmonologists, urologists & some gastroenterologists) can prescribed THCDs
- Nurse practitioners & family physicians are not considered medical specialists in the Netherlands so they are not allowed to prescribe THCDs
- There are no general practitioners in oncology

Prescribing (continued)

- There are doctors who are in training to become medical specialists. They can only prescribed when the prescription is co-signed by a supervising medical specialist
- Pharmacists do not have prescribing authority or the ability to adapt or manage prescriptions
- Electronic prescribing through computerized prescriber order entry (CPOE) systems is mandated by the government

Dispensing

- By regulation (implemented four years ago), the dispensing of all cancer drugs has been centralized to hospital pharmacies. Although the primary objective of this regulation was financially driven (i.e. to reduce spillage), the general opinion is that this centralization improves the quality of pharmaceutical care, because knowledge is also centralized
- In the past, each community pharmacy would see a handful of patients undergoing a variety of oncological treatments, & thus the knowledge on optimizing patient adherence, side-effects, drug-drug interactions & patient counselling remained limited there.
- There are no specialty pharmacies
- Home delivery is possible by courier
- Pharmacists are reimbursed for their cognitive services for each dispensing; however, additional reimbursement is given for first cycle prescriptions because more comprehensive counseling takes place at that time

Incident Reporting

- Incident reporting is not mandated by law but it is the professional standard
- There is a centralized database where all hospitals report medication errors
- There is also centralized database where doctors, pharmacists & patients can report side effects

Counselling & Monitoring

- There are no standardized patient education, adherence & toxicity monitoring programs at the national level; however, all hospitals have a site-specific protocol

System Integration

- There are several drug information systems
- Dispensing data from ~80% of community pharmacies feeds into an electronic health record that is accessible to hospital staff who are involved in in treating the patient
- Community pharmacies can access the dispensing data if the patient has given permission through a national switchboard
- The hospital pharmacy can use the same switchboard to see the dispensing data of the community pharmacy, but also only when the patient has given permission

Source: Personal Communication, Hospital Pharmacist, OLVG Amsterdam

OUTPUT: PHARMACY REFORM DISPENSING MODELS BY CCO EVIDENCE SEARCH AND REVIEW SERVICE

Introduction and Background

Take home cancer drugs (THCD) have emerged as a standard treatment option and preference for many cancer patients. An increasing number of effective cancer treatments can now be taken at home by pill or injection. In Ontario, patients can fill their THCD prescriptions at a pharmacy of their choice including specialized oncology pharmacies in cancer centres or hospitals (cancer pharmacies), retail pharmacies in hospitals also known as hospital pharmacies, or community pharmacies. Community pharmacies also known as "retail pharmacy –community" refers to a drugstore usually located in the community that fills prescriptions for cancer and non-cancer medications. They serve all members of the public. Figure 1 below shows the recommended approach for community pharmacists to ensure safe and appropriate drug dispensing in Ontario.[1]

Figure 1. Checklist Tool for Community Practice in Ontario[1]

Clinical Verification of Cancer Drug Prescriptions	
Patient	❑ Verify patient using two identifiers present on Rx ❑ Confirm height and weight on Rx with patient ❑ Check for allergies ❑ Confirm diagnosis/indication with patient ❑ Identify if new or continuing treatment ❑ Check for toxicity or intolerance from previous cycle (if applicable) ❑ Identify barriers to adherence
Regimen	For the regimen, verify correct: ❑ Indication ❑ Drugs & route ❑ Scheduling & interval ❑ Start date correct interval from previous treatment (if applicable)
Dose	❑ Verify correct dose for indication ❑ Verify correct calculated dose for patient using BSA and/or weight (if applicable) ❑ Check for modified dose (if applicable) ❑ Check for drug interactions
Patient Care	❑ Verify supportive care provided ❑ Identify what education has been provided and reinforce – how and when to administer – cycle schedule – importance of adherence – proper handling, storage and disposal – side effects and management strategies ❑ Identify toxicities to monitor & plan follow-up

For cancer patients, THCD can be more convenient: no need for regular cancer clinic visits, minimally invasive and less disruptive of daily activities for patients. For hospitals, THCD may result in substantial reductions in healthcare resource utilization and health care costs compared to delivering IV chemotherapy in a hospital. Previous data showed that 0.34% of Ontario drug benefit (ODB) claims processed by pharmacies in 2013-14 fiscal year were THCD prescriptions; and a total of 132, 10 and 2 THCD were dispensed per week by cancer pharmacies, hospital pharmacies and community pharmacies, respectively.[2] However, shifting cancer treatment from the hospital to the home introduces new challenges to providing safe, accessible and high quality treatment. Approximately 65% of Ontario

oncologists are concerned with the safety associated with patients, caregivers and family members administering, storing and handling oncology drugs in the home environment.[3] Providers and patients must find new ways to maximize benefit while minimizing risk by modifying current approaches to patient education, prescribing and handling chemotherapy, monitoring adherence and managing toxicity. THCD moves the responsibility for the management and monitoring of drugs to patients, family members and local community pharmacists, who may not have the appropriate training in this area.[4] Pharmacists working in community pharmacies typically dispense very few cancer drug therapies. As a result, they often have limited knowledge, experience and comfort dispensing THCD.[5] It is important to gather information to create a THCD model for community pharmacies that will ensure safety, high quality and an integrated approach to care.

PURPOSE OF THE REVIEW

The purpose of this review is to identify dispensing models for THCD across four international jurisdictions (Australia, New Zealand, United Kingdom, and The Netherlands).

More specifically, our review seeks to address the following questions:

1. Where can patients fill their prescriptions for THCD?
    a. What dispensing models exist? Are there any options for mail delivery?
    b. What requirements, accreditations, certifications are needed to dispense THCD at community pharmacies?
    c. What qualification/training is required of community pharmacists dispensing THCD at community pharmacies?
    d. Are there information management/information technology (IM/IT) solutions used for tracking dispensing data for analysis and reporting requirements?
    e. How are pharmacists / pharmacies reimbursed for their cognitive services when dispensing anticancer drugs?
    f. Are there regional or national guidelines for safe use and handling of THCD?
    g. Are there patient education, adherence & toxicity monitoring programs? What do these entail? When and how often? Are these standardized?
2. What are the barriers, limitations of THCD provided by community pharmacies?

METHODS

Three databases including Ovid Embase, Ovid MEDLINE and Ovid Healthstar were searched. The search strategies used a combination of key words and free text terms related to cancer drugs, community pharmacies/pharmacists and dispensing. Searches were limited to the English-language and articles published within the past 10 years (2007-current). For detailed search strategies see Appendix A. All titles and abstracts identified from the electronic database search were imported to Reference Manager Software (version 12). After removal of duplicates the remaining citations were exported to an Excel database to screen title and abstracts and to manage findings.

A single reviewer screened the search results by scanning titles and abstracts against the eligibility criteria presented in Table 1. To ensure accuracy and transparency, 5% of the citations were cross screened by 2 reviewers. There were no discrepancies between the two reviewers. In addition, key organizational websites and a web-based search was conducted as listed in Table 2. The first five pages of the web-based search results were scanned for potentially relevant articles. Also, reference lists of included studies were scanned to identify additional relevant articles.

Table 1. Eligibility Criteria Check List for Title and Abstract Screening

Eligibility Checklist		
Inclusion Criteria:		
Item	Response Options	Notes
1. Language: The article is written in the English-language?	☐ Yes ☐ No	
2. Intervention/Population: Is the article related to cancer drugs?	☐ Yes ☐ Can't Tell ☐ No	
3. Is the article related to community pharmacies? (e.g. pharmacists, pharmacy technicians, pharmacy assistants)	☐ Yes ☐ Can't Tell ☐ No	
4. Is the article describing topics related to drug dispensing? (e.g. dispensing models, qualifications/training of community pharmacists, limitations/barriers, Reimbursement of pharmacists for providing cognitive services, IM/IT tracking systems, guidelines for safe use and handling , patient education, adherence & toxicity monitoring programs, mailing)	☐ Yes ☐ Can't Tell ☐ No	
Final Eligibility:		
***Moves to Full Text eligibility screening**	☐ Yes* ☐ Maybe* ☐ No	

Table 2. Web-based Search and Key Organizations

Sources of Research Evidence	Source
Jurisdictional Scan/ Web-based Search	Google search engine
Organizations/Websites	1. Clinical Oncological Society of Australia (COSA) 2. Australia Government Department of Health 3. Cancer Drug Alliance Australia 4. Pharmaceutical Defense LTD Australia 5. Society of Hospital Pharmacists of Australia (SHPA) 6. Cancer Australia 7. National Pharmacy Association (UK) 8. Cancer Research UK 9. North of England Cancer Network 10. Royal Pharmaceutical Society (UK) 11. Royal Corwall Hospital (UK) 12. Nice Evidence Search in Health and Social Care (NHS)

	13. Cancer Care New Zealand 14. New Zealand Government (Pharmacy Management Agency) 15. The Royal Dutch Pharmacists Association
Key jurisdictions of interest	1. Australia 2. United Kingdom 3. New Zealand 4. The Netherlands Note 1: These countries have been highlighted by the Systemic Treatment Program (STP) as key jurisdictions of interest and thus will be searched independently. Note 2: 1 article identified from Ireland was included in this study

Our evidence review was limited to four jurisdictions of interest (Australia, New Zealand, United Kingdom, and The Netherlands). However, during our evidence search a relevant article describing barriers and challenges associated with dispensing THCD representing Ireland was located. Upon discussion with the ST team the article was included within the review.

ORGANIZATION OF THE REPORT

The report is presented by country and by the following 12 themes:

1. Availability of community pharmacy dispensing THCD
2. Dispensing model(s)
3. Number of community pharmacy, pharmacy technicians and professional bodies
4. Pharmacist's qualification or education or training needed to dispense THCD by community pharmacists
5. Requirements, accreditations, certifications needed to dispense THCD at a community pharmacy
6. Patient education program
7. Cognitive services reimbursement program
8. Adherence monitoring program
9. Incident reporting program
10. Toxicity monitoring program
11. System integration
12. Challenges and barriers associated with dispensing THCD
13. Regional or national guidelines for safe use and handling of THCD

Table 3. Abbreviation List

Abbreviations	Definition
ADR	Adverse Drug Reaction
BOPA	British Oncology Pharmacy Association
CAM	Complementary and alternative medicines
CARM	Centre for Adverse Reactions Monitoring
CDF	Cancer Drug Fund
CIM	Clinical Incident Management
CMI	Consumer Medicines Information
CMR	*"Centrale Medicatiefouten Registratie"*
COSA	Clinical Oncological Society of Australia
COSHH	Control of Substances Hazardous to Health
CP(s)	Community Pharmacy/Pharmacists
CPG	Cancer Pharmacists Group

CPOE	Computerized Physician Order Entry
DAA	Dose Administration Aids
EHR	Electronic Health Record “het Electronisch Patiëntendossier”
EMR	Electronic Medical Record
EPR	Electronic Patient Record
EPS	Electronic Prescribing System
ETP	Electronic Transfer of Prescriptions
GPhC	General Pharmaceutical Council
HI	Healthcare Identifiers
HIS	Health System Integrator
IM	Information Management
IT	Information Technology
LCA	London Cancer Alliance
MCQ	Multiple Choices Questions
MTX	Methotrexate
NRLS	National Reporting and Learning Service
OAM	Oral Anticancer Medicines
OTC	Over-The-Counter
PES	Prescription Exchange Service
PhwSI	Pharmacists with Special Interests
SACT	Systemic Anti-Cancer Therapies
SCR	Summary Care Record
SELCN	South East London Cancer Network
SHPA	Society of Hospital Pharmacists of Australia’s
SNOMED-CT	Systematized Nomenclature of Medicine- Clinical terms
THCD	Take Home Cancer Drug

RESULTS

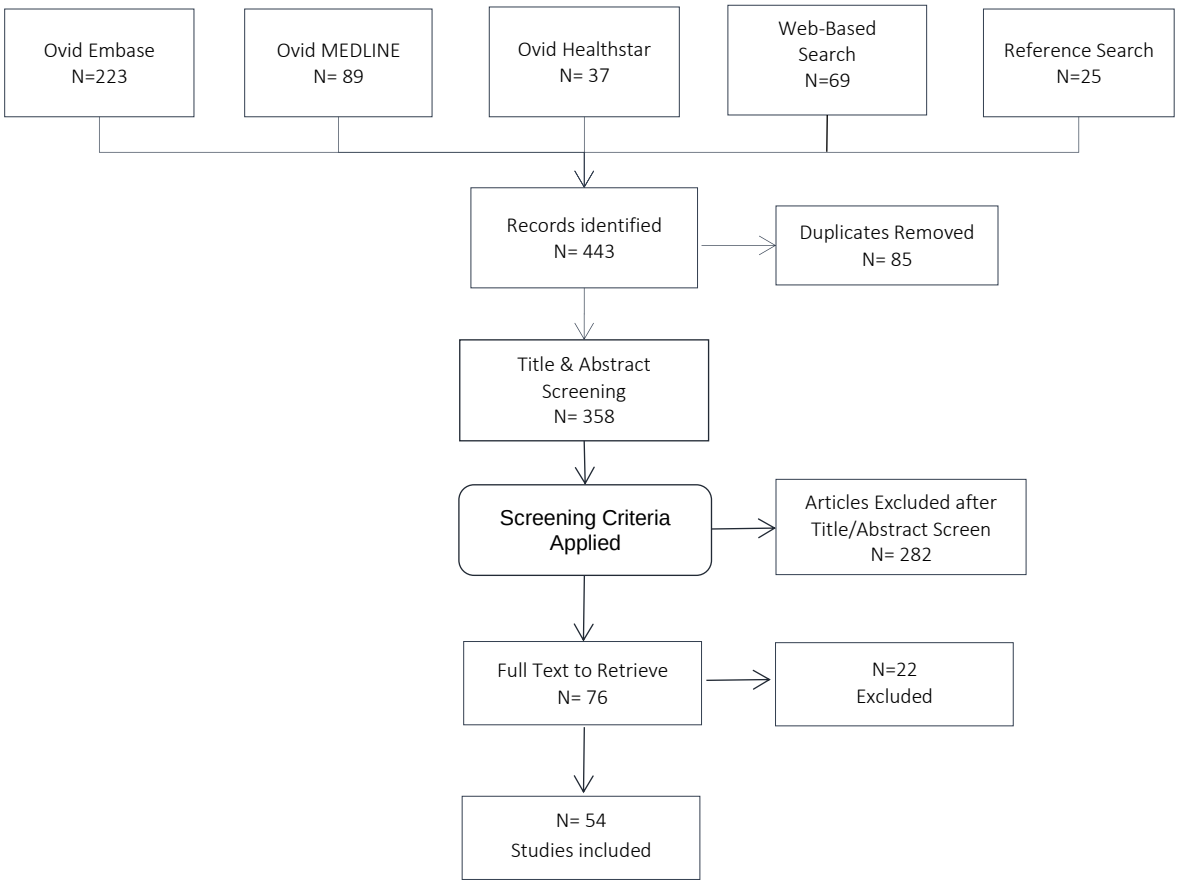
- Our review identified literature from 4 jurisdictions (Australia, The Netherlands, New Zealand and United Kingdom).

- Our search strategy identified a total of 443 unique articles (see Figure below). After reviewing titles and abstracts, we identified a total of 74 potentially relevant articles. After reviewing the full text, 54 articles were included.
- Across the included articles, 16 were from Australia, 8 were from The Netherlands, 7 were from New Zealand and 22 were from United Kingdom and 1 from Ireland.

- Across the included articles, 4 articles were identified from the database search, 6 articles were identified from the reference lists of included studies and 44 articles were identified from web – based search.

- We identified 9 primary research articles and the remaining literature (n=45) includes a fact sheet, report, position statement, briefing note and guidelines.

Figure 2. Study Selection Process (PRISMA Diagram)



- Most included articles reported cancer drug dispensing for all clinical settings including both hospital and community settings (n=28).
- We identified 12 articles that specifically discussed drug dispensing in community settings.
- The remaining 14 articles discussed other themes such as system integration, incident reporting, and number of community pharmacies.
- No article reported the mail delivery option.

Australia

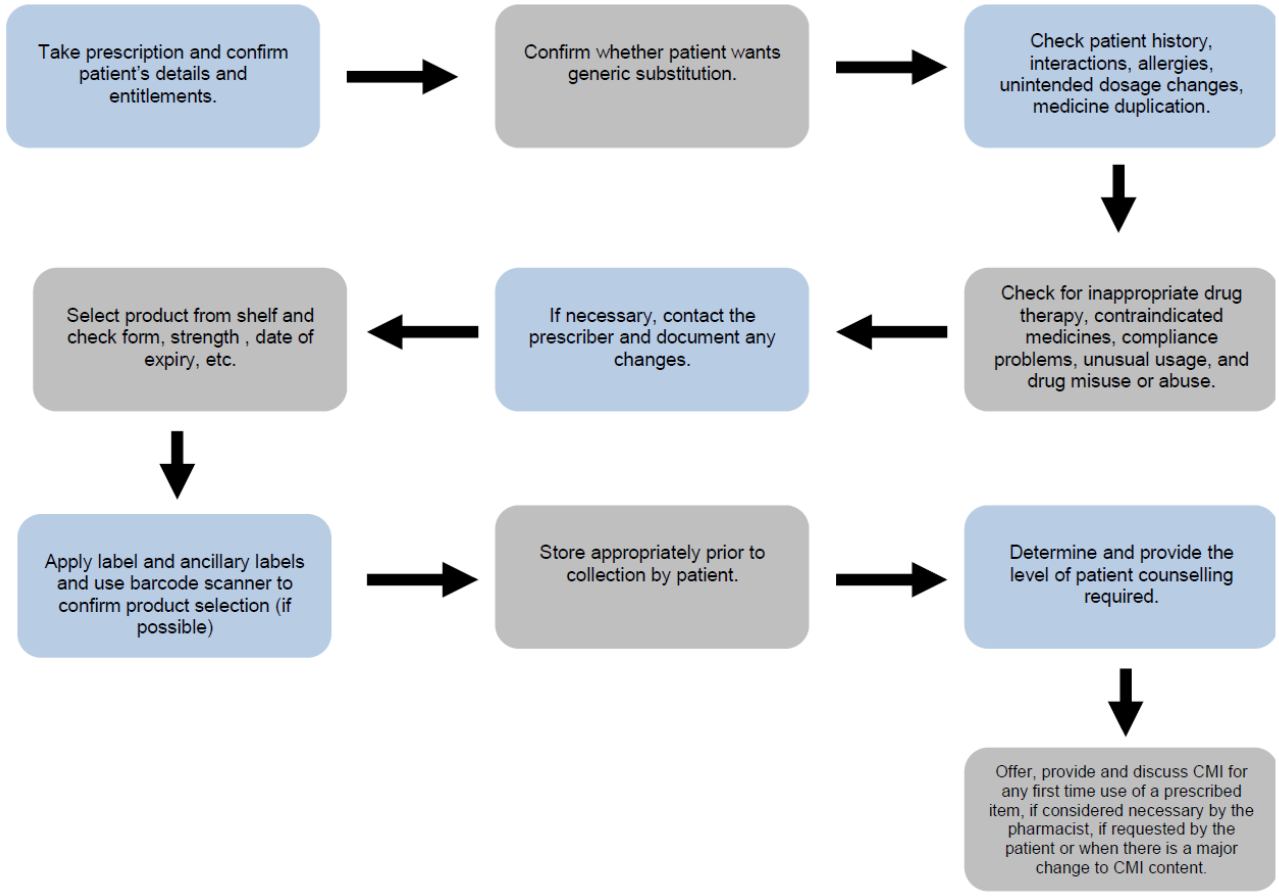
AVAILABILITY OF COMMUNITY PHARMACY DISPENSING THCD

- In Australia, patients can fill their THCD from hospital and community pharmacies.
- Twelve articles reported dispensing of THCD at a community pharmacy.[6-17]

DISPENSING MODEL

- One article reported THCD dispensing model at a community pharmacy.[12]
- Community pharmacists check prescription from physicians, confirm patient information, select and label the product and store the product and counsel patients. [12]

Below is a snapshot of a community pharmacist's dispensing role[12]



NUMBER OF COMMUNITY PHARMACY, PHARMACY TECHNICIANS AND PROFESSIONAL BODIES

- By June 30, 2015 there was 5,510 community pharmacies in Australia.[18]
- The Clinical Oncology Society of Australia (COSA) is the national body representing health professionals from all disciplines whose work involves the care of cancer patients; and the Cancer Pharmacists Group (CPG) is the only national multidisciplinary forum for pharmacists working in cancer services in Australia.[19]
- No publication reported the number of pharmacy technicians nor information regarding their respective regulatory bodies.

PHARMACIST'S QUALIFICATION OR EDUCATION OR TRAINING NEEDED TO DISPENSE THCD BY COMMUNITY PHARMACISTS

- Seven articles reported the education and/or training needed by pharmacists in both hospital and community settings to dispense THCD [6;7;10;14;15;17;19] of which 3 articles were specific to community pharmacists.[6;14;17]
- CPG of COSA offers 2 courses in clinical skills and advanced clinical practice on COSA Chemotherapy Guidelines application in clinical practice with a focus on development and improvement of skills of junior pharmacists; leadership development for senior pharmacists. [6;19]
- Summary of the recommendations for pharmacist's education and training is provided in Table 4.

Table 4. Recommendations for Pharmacist's Education and Training

Recommendations
Pharmacist should have the appropriate training, knowledge and skills in cancer chemotherapy verification as defined by the Society of Hospital Pharmacists of Australia (SHPA) Standards of Practice for Clinical Oncology Pharmacy.[7;10;15] • **All pharmacy staff should have competency testing for the verification and dispensing of chemotherapy.[7;10;15]** • **Pharmacist should have appropriate knowledge of oral antineoplastic drugs, doses, frequencies, indications and supportive therapies.[14]** • **The learning activities of pharmacists should address the issues encountered in the community pharmacy setting[14;17], such as:** ✓ **General principles in cancer treatment.** ✓ **Handling oral antineoplastic drugs and related wastes.** ✓ **Oral antineoplastic prescriptions and protocols.** ✓ **Adverse effects and supportive therapies.** ✓ **Drug interactions.** ✓ **Patient education.**

REQUIREMENTS, ACCREDITATIONS, CERTIFICATIONS NEEDED TO DISPENSE THCD AT COMMUNITY PHARMACY

- No article reported the accreditation, certification needed by community pharmacies to dispense THCD.

PATIENT EDUCATION PROGRAM

- Three articles reported that pharmacists should provide written and oral medication plans, diaries, medication calendars, expected side-effects and explain how to take supportive medication to patients.[6;9;11] **Cognitive Services Reimbursement Program**
- No article reported on cognitive services reimbursement program.

ADHERENCE MONITORING PROGRAM

- According to one article, patients should be provided with details of accessible 24-hour contact information with medical, nursing and pharmacy staff to whom they can direct queries. This information must be given on the first visit and reinforced on subsequent visits.[15]

INCIDENT REPORTING PROGRAM

- One article reported the Australian Adverse Drug Reaction Reporting System, an online reporting tool for health professionals described in Table 5.[20]

Table 5. Description of the Australian Adverse Drug Reaction Reporting System[20]

Australian Adverse Drug Reaction Reporting System
• **Providers can report a case of a suspected adverse reaction in association with a medicine (including complementary, OTC or prescription) or a vaccine.** • **Information in the report is collected to assist in the post market monitoring of the safety of therapeutic goods under the *Therapeutic Goods Act 1989* (the Act).** • **All reports are assessed and entered into the Therapeutic Goods Administration's (TGA's) Australian Adverse Drug Reactions System (the ADRS).** • **The report is completed online at https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase** **The TGA collects personal information in this report to:** • **Assess the safety of medicines and vaccines under the Act.** • **Contact the reporter of the adverse event if further information is required.** • **Contact representatives of entities that supply therapeutic goods, to discuss reported adverse events.** • **Check that the same information has not been received multiple times for the same adverse event.**

TOXICITY MONITORING PROGRAM

- Four articles reported toxicity monitoring program for THCD dispensed in both hospital and community settings.[6;9;11;15]
- Pharmacist can monitor cancer drug toxicity by:
  - ✓ Reviewing drug information.
  - ✓ Prescription and provision of anti-emetics.
  - ✓ Checking blood
  - ✓ Communicating with patients and other providers.
- Recommendations for toxicity monitoring are provided in Table 6.

Table 6. Recommendations for Toxicity Monitoring

Recommendations
• **Pharmacists should have access to the treatment plan, the chemotherapy protocol and relevant patient parameters.[6]** • **Guidelines should exist for prescribing antiemetic's with cancer chemotherapy.[9]** • **Blood counts need to be frequently checked.[9]** • **Patient monitoring, including laboratory tests and the parameters for initiating the next cycle of chemotherapy, should be clearly defined in the protocol or treatment plan. For example, a neutrophil count of greater than 1 x 10^9 is usually required for a cycle of cancer chemotherapy to proceed.[9]** • **Patients should be given both information about who to contact in the event of an emergency or severe adverse events.[9]** • **Before discharging, the patient should receive discharge medicines including those to control nausea and vomiting, and pre-medications to be taken prior to the next cycle of chemotherapy.[11]** • **Questions on compliance, treatment tolerability, and adverse events must always be addressed at each visit to the pharmacy.[15]**

SYSTEM INTEGRATION

- According to one article, My Health Record is the system integration solution for patient information management.[21]
- My Health Record is a secure online summary of health information that allows health care providers to access up-to-date information about the patient's medical history, medication prescription and dispensing.
- Pharmacists use the eMedication Management system which consists of:
  - ✓ Electronic Transfer of Prescriptions (ETP)
  - ✓ Prescription Exchange Service (PES)
  - ✓ Prescription and dispense view in My Health Record system
- The description of the system integration is provided in Table 6.

Table 6. Description of the System Integration

My Health Record [21]

• **My Health Record is a secure online summary of health information.**
• **Registered healthcare providers, the System Operator and other system participants are permitted to collect, use and disclose information in My Health Record.**
• **Registered pharmacists can access the prescription, dispense records, patient's discharge summary and shared health summary and up-to-date information about the patient's medical history, medication profile, events summaries, allergies, adverse reactions and immunizations.**
• **My Health Record is designed to help pharmacies deliver safer, quality healthcare.**
• **Pharmacists can apply for eMedication Management registration at https://www.digitalhealth.gov.au/using-the-my-health-record-system/for-pharmacists.**
• **The following are the three steps required to register for and access the My Health Record system for pharmacists/health care providers:**
  ✓ **Register with the Healthcare Identifiers (HI) Service to obtain a HPI-O.**
  ✓ **Register with the My Health Record system.**
  ✓ **Request a NASH PKI Certificate to access the My Health Record system.**

My Health Record [21]

Components of My Health Record: eMedication Management – for Pharmacists:

- ***Electronic Transfer of Prescriptions (ETP)***
  - ✓ **A desktop software that creates and sends electronic prescription information (ePrescriptions).**
  - ✓ **These scripts are sent to a Prescription Exchange Service (PES) where they are stored and can be retrieved during dispensing.**
  - ✓ **A unique barcode is generated and printed on the paper prescription.**
  - ✓ **The patient takes the paper prescription to the participating pharmacy where the pharmacist will scan the barcode to retrieve the prescription details from the PES.**
- ***The Prescription Exchange Service (PES)***
  - ✓ **There are two PES systems operating in Australia – eRx Script Exchange and MediSecure.**
  - ✓ **Each PES system is required to meet specific standards set by the Commonwealth Government.**
  - ✓ **A prescriber or dispenser may be connected to one, or both PES systems.**
- ***Prescription and Dispense View***
  - ✓ **A copy of the prescription information will flow through to the My Health Record system via the PES and be visible in the Prescription and Dispense View.**
  - ✓ **Dispensers will be able to send dispense information to the PES and onto the My Health Record system where it will be visible in the Prescription and Dispense View.**

The main benefits of My Health Record system is improvements in continuity of care and patient outcomes:

- ✓ **Improved medication chart accuracy.**
- ✓ **Improved hospital discharge summary.**
- ✓ **Easier to collect medical information.**
- ✓ **Improved decision making.**
- ✓ **Improved communication between providers.**

CHALLENGES AND BARRIERS ASSOCIATED WITH DISPENSING THCD

- Nine articles reported challenges and barriers associated with THCD dispensed at both hospital and community settings.

Potential challenges and barriers include: complex chemotherapy regimen, origin of prescription and safe handling of chemotherapy drugs (Table 7).

Table 7. Description of challenges and barriers associated with to dispensing THCD

Challenges and barriers	Description
Chemotherapy regimen	**The chemotherapy regimen is very complex:** • Cancer drugs have a narrow therapeutic index: a small increase in dose can result in toxic effects, life-threatening side-effects;[6;7] while under-dosing can lead to failure of therapy.[9;16] • Scheduling of oral chemotherapy is difficult to follow when doses are required to be taken as an 'on-off' regimen or on a weekly basis.[6] • Nomenclature, and the complexity of calculations are not fully understood by the staff.[8] • The intermittent treatment of cancer may be hard for some patients to understand leading to misinterpretation of dosing and risk of serious harm.[15]
Origin of prescription	• Dosages are not always expressed consistently leading to incorrect interpretation and risks of over dosage.[8] • Developments and changes in drug delivery can lead to over dosage.[10] • Incorrect prescribing, dispensing errors and patient misinterpretation have led to serious toxicities and fatal outcomes.[14]
Safe handling	• Oral chemotherapy drugs present a health and safety risk to staff, carers and patients handling them.[15]

REGIONAL OR NATIONAL GUIDELINES FOR SAFE USE AND HANDLING OF THCD

- Eight articles reported 6 guidelines for safe use and handling in both hospital and community pharmacy settings.
- The reported guidelines include:
    1. The Clinical Oncological Society of Australia (COSA) guidelines for the safe prescribing, dispensing and administration of cancer chemotherapy.[7;8;10]
    2. Safe use of oral cytotoxic medicines.[9]
    3. Requirements for clinical pharmacy services for every cycle of chemotherapy.[11]
    4. Seven steps in the verification process for oral antineoplastic prescriptions.[14]
    5. SHPA Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer.[15]
    6. Recommendations to be followed before prescribing, dispensing or administering oral chemotherapy for cancer.[16]
- The description of these guidelines are provided in Appendix B, Table 1.

The Netherlands

AVAILABILITY OF COMMUNITY PHARMACY DISPENSING THCD

- Since 2013, community pharmacies no longer dispense THCD.
- Patients can fill their THCD from public pharmacies located in hospital.[22]

DISPENSING MODEL

- No article reported on dispensing model.

NUMBER OF COMMUNITY PHARMACY, PHARMACY TECHNICIANS AND PROFESSIONAL BODIES

- At the end of 2013, there were 1,974 community pharmacies in The Netherlands.[22]
- No article reported on pharmacists' professional body.
- No publication reported the number of pharmacy technicians nor information regarding their respective regulatory bodies.

PHARMACIST'S QUALIFICATION OR EDUCATION OR TRAINING NEEDED TO DISPENSE THCD BY COMMUNITY PHARMACY

- According to one article, pharmacists and pharmacy technicians should be trained in the application of:
  - ✓ The *"Centrale Medicatiefouten Registratie" (*CMR)'s recommendations for safe handling of methotrexate (MTX).
  - ✓ The standard operating procedure, entitled 'Methotrexate: prescription order entry, medication surveillance and logistics'.[23]

REQUIREMENTS, ACCREDITATIONS, CERTIFICATIONS NEEDED TO DISPENSE THCD AT COMMUNITY PHARMACY

- No article reported on requirements, accreditations, certifications needed to dispense THCD at the community pharmacy.

PATIENT EDUCATION PROGRAM

- No article reported on patient education program.

COGNITIVE SERVICES REIMBURSEMENT PROGRAM

- No article reported on cognitive services reimbursement program.
-

ADHERENCE MONITORING PROGRAM

- No article reported on adherence monitoring program.**Incident Reporting Program**
- According to 3 articles, the CMR described above is the nationwide medication incidents reporting system.[23-25]
- Drug incidences are reported to CMR which sends email alerts including recommendations to follow to health care providers.
- A description of the incidence reporting program is presented in Table 8.

Table 8. Description of the Incidence Reporting Program

Centrale Medicatiefouten Registratie[25]
CMR is a multicenter reporting system for medication incidents. **CMR supports risk management of medication processes by:** • **Sending out alerts and newsletters to prevent the reoccurrence of specific high-risk medication incidents.** • **Generally informing healthcare providers and policymakers about risks.** **The CMR system consists of:** • **A website (http://www.medicatieveiligheid.info)** • **A database** • **A web-based reporting form** • **An application to import reports generated in other reporting systems** • **An application to generate an overview of reported education incidents** • **A national warning system for healthcare providers** ***Web-based reporting form*** **The reporting form consists of four sections:** • **Administrative information** • **Patient data** • **Information about the medication incident** • **Questions concerning the need to issue an alert**

Centrale Medicatiefouten Registratie[25]

Classifications in reporting form

The CMR reporting form has three important classifications:

- **A medication error classification**
- **A classification of causes**
- **A classification of harm to the patient.**

Reporting routes

- **One of the routes for reporting a medication incident is the web-based reporting form.**
- **Most Dutch hospitals have their own internal system to register all kinds of reported events including medication incidents.**
- **If the hospital does not use the web-based reporting form then the hospital can use one of the two computerized ways to send these reports to the CMR database: The first way is to extract these reports manually from the internal reporting system and the hospital manually uploads these reports to the CMR database through the CMR website. The second way is to use a direct real-time interface between their internal reporting systems and the CMR database for submitting their internal reports about medication incidents directly.**
- **Some community pharmacy chains are now also using internal reporting systems with a direct interface to the CMR.**
- **Besides these formal ways healthcare providers may also contact the CMR team informally by telephone or email.**

Analysis and feedback

- **The CMR team screens the submitted reports to sort out which medication incidents are potentially interesting. This is primarily done on the basis of three predefined general criteria: (1) risk of recurrence; (2) educational potential for other healthcare providers; and (3) actual or potential risk of serious harm to the patient.**
- **Reports may also be selected for further scrutiny when they concern a predefined topic of special interest (such as an accidental interchange of patients or of sound-alike and look-alike medicines).**
- **The CMR team decides which reports potentially qualify for an alert or as an item for the CMR newsletter, and which ones should be marked for further analysis of a special interest topic.**
- **The CMR team can also perform additional analyses of the entire database to track and define similar earlier cases.**
- **Users can analyze their own reports and compare these with all the reported medication incidents within a sector (hospitals, community pharmacies, mental care institutions).**

National warning system

- **Alerts consist of reported medication incidents with a high risk of recurrence, high educational potential for other healthcare providers, and/or actual or potential risk of serious harm to the patient.**
- **The healthcare providers can notify on the report form whether the medication incident meets the requirements of an alert, but the CMR organization forms its own opinion during the screening process.**
- **All practising pharmacists in The Netherlands receive (for free) the alerts and newsletters.**

Security and confidentiality

Centrale Medicatiefouten Registratie[25]
• **The hosting and IT security comply with the latest Dutch ICT standard (NEN 7510), which is based on the international standard ISO/IEC 17799.** • **Healthcare providers always submit their report over a secure Internet connection.** • **Each member of the CMR team has signed a contract of confidentiality.** • **The CMR cannot publish any report without formal approval of the healthcare provider, even when the publication does not contain retraceable information.** • **The database only records the ID number of the reporting healthcare practice.** ***Database structure*** • **The CMR database is maintained in a Microsoft SQL server.** • **The applications use ColdFusion for data driving and the operating system is a Microsoft Windows server. The applications and data storage communicate using XML.** • **The CMR database and the applications have been developed and are maintained by a software development firm (Ritense BV, Amsterdam http://www.ritense.com).** **A cross-country comparison of other nationwide reporting systems (Canada, Denmark, United Kingdom and United States of America) is provided in Appendix D, Table 1.**

TOXICITY MONITORING PROGRAM

- One article reported a cancer drug interaction monitoring program which is described in table 9.

Table 9. Description of the Toxicity Monitoring Program

Monitoring cancer drug interactions[26]
• **For an interaction between intravenous oncolytic drugs and acenocoumarol, the International Normalised Ratio (INR) is monitored more frequently.** • **The interaction between the intravenous oncolytic drug(s) and an antiepileptic drug is monitored during the oncolytic regimen using a blood sample. The hospital pharmacists discuss the results of the blood tests with the physicians.** • **The interaction between furosemide and cisplatin reported by CPs of an ambulatory cancer patient is monitored during the oncolytic regimen.** • **If an interaction between metronidazole and fluorouracil occurs, the local pharmacist will contact the prescriber of metronidazole.**

SYSTEM INTEGRATION

- Two articles reported the following two system integrations (Table 10).[26;27]
- Electronic health record "*het Electronisch Patiëntendossier"*, a national controlled exchange platform for summaries of healthcare records.
- The medication prescribe system that includes 2 computer systems: the electronic prescribing system (EPS) and the electronic patient record (EPR).

Table 10: Description of the System Integrations

Electronic health record and the computer systems
Electronic health record (EHR), "*het Electronisch Patiëntendossier* [27]. • **EHR is an obligatory national electronic health record.** • **EHR is controlled exchange platform for summaries of healthcare records.** • **The EHR is provided by the Dutch government and exclusively accessible for general practitioners, pharmacists and medical specialists.** • **EHR contains a list of physical and psychological health problems, prescribed medication and possible allergies for a specific patient.** • **EHR is composed and controlled by the treating healthcare professionals.** • **The regional EHR is linked to the national EHR.** • **Authorization is required to consult the EHR.** • **The EHR only allows the healthcare provider treating a patient to consult his or her medical information.** • **Patients can check the EHR file for incorrect usage.** • **The three issues concerning the privacy of patients in the EHR: autonomy, confidentiality and security.** **There are several expected advantages of the EHR.** • **The most important advantage is a smaller chance of making treatment errors because medical staff sees what medicines have been prescribed or which treatment has been chosen, and can adapt to it.** • **The EHR checks chosen treatment plans for possible contraindications or allergies and, if so, a notification appears.** • **It is more difficult to make errors through miscommunication because of unreadable handwriting.**
There are 2 computer systems used to prescribe medication[26]: 1. **The electronic prescribing system (EPS)** ✓ **Through EPS, all medications (except oncolytics) are prescribed by physicians, both for ambulatory and hospitalised patients.** ✓ **EPS provides an overview of all prescribed medication. In addition, it is possible to collect all medication records prescribed outside the hospital by using an open care information system (OZIS, Open Zorg Informatie Systeem).** ✓ **OZIS allows exchanging of prescription data electronically between pharmacists and primary care providers working in the same region.** 2. **The electronic patient record (EPR) or hospital information system is used in the daily monitoring of hospitalised patients and also contains a module to prescribe predefined oncolytic regimens.**

CHALLENGES AND BARRIERS ASSCOCIATED WITH DISPENSING THCD

- Three articles reported potential challenges and barriers asscociated with dispening THCD including drug interaction and complex chemotherapy regimen (Table 11).[23;28;29]

Table 11: Description of challenges and barriers associated with to dispensing THCD

Challenges and barriers	Description
Chemotherapy regimen	• MTX is a drug with different indications and different dosage regimens.[29] • Fatal incidents can occur when MTX is taken daily instead of weekly.[23]
Drug interactions	• Paroxetine and fluoxetine are both antidepressant drugs that inhibit CYP2D6 and the efficacy of tamoxifen. • In community pharmacies, this drug–drug interaction is easily ignored. • Generally the two drugs are most often prescribed by different physicians and the two may be dispensed by two different community pharmacies.[28]

REGIONAL OR NATIONAL GUIDELINES FOR SAFE USE AND HANDLING OF THCD

- One article described the clinical rule and standard operating procedure for safe prescribing and dispensing of MTX.[23]
- A description of these guidelines are provided in Appendix B, Table 2.

New Zealand

AVAILABILITY OF COMMUNITY PHARMACY DISPENSING THCD

- In New Zealand, patients can fill their THCD prescription from hospital and community pharmacies.
- Two articles reported that New Zealand has community pharmacies dispensing THCD.[30;31]

DISPENSING MODEL

- No article reported on the dispensing model

NUMBER OF COMMUNITY PHARMACY, PHARMACY TECHNICIANS AND PROFESSIONAL BODIES

- There are about 1,000 community pharmacies in New Zealand.[32]
- The pharmacy workforce includes more than 3,500 pharmacists. Approximately 75% of these pharmacists work in a community pharmacy.[32]
- The Pharmaceutical Society of New Zealand (PSNZ) represents the pharmacy profession.[31]
- No publication reported the number of pharmacy technicians nor information regarding their respective regulatory bodies.

PHARMACIST'S QUALIFICATION OR EDUCATION OR TRAINING NEEDED TO DISPENSE THCD BY COMMUNITY PHARMACISTS

- One article reported a training offered by the Pharmaceutical Society of New Zealand (PSNZ) to community pharmacists in chemotherapy dispensing which is described in Table 12.[31]

Table 12. Description of Pharmacist's Training

Training offered PSNZ
PSNZ offers training to community pharmacists in chemotherapy dispensing in community pharmacy. Upon completion of the course, community pharmacists should be able to: • **Identify different chemotherapy agents, how they are used and which cancers they treat.** • **Identify medication that can be used to protect patients receiving cancer treatment.** • **Explain the safe handling and dispensing of oral chemotherapy in the pharmacy and by patients/ caregivers.** • **Explain what all pharmacists should know to be able to safely dispense an oral chemotherapy prescription.[31]**

REQUIREMENTS, ACCREDITATIONS, CERTIFICATIONS NEEDED TO DISPENSE THCD AT COMMUNITY PHARMACY

- No article reported on requirements, accreditations, certifications needed to dispense THCD at a community pharmacy.

PATIENT EDUCATION PROGRAM

- One article reported patient counseling on chemotherapy regimens.[30]
- Recommendations about patient education is provided in Table 13.

Table 13. Recommendations for Patient Education Program

Recommendations
• **When dispensing chemotherapy medicines ensure that patients understand all the information that is on the medicine.** • **If a medicine is not to be taken every day patients need to be told this; it should be clearly stated what the interval between each dose should be and that a dose should not be repeated until that interval has passed.** • **Particular care should be taken when consulting with patients with English as a second language and all information should be appropriate to the patient's stage of health literacy.[30]**

COGNITIVE SERVICES REIMBURSEMENT PROGRAM

- Before, pharmacists were reimbursed based on a fixed fee per item dispensed which covered the costs of dispensing and brief counselling.
- Now, pharmacies are reimbursed for the cost of the medicines they dispense from one funding pool and remunerated for professional services from another.
- The payment mechanism for the extended services such as Medicines Use Review or Medication Therapy Assessment is part of a specific contract arrangement between the pharmacy and their District Health Board.[33]

ADHERENCE MONITORING PROGRAM

- No article reported on adherence monitoring program.

INCIDENCE MONITORING PROGRAM

- Two articles reported two incidence monitoring programs (Table 14).[34;35]
- The bpac^{nz} Patient Safety Incident Reporting System, an online reporting system for health care professionals.
- The Centre for Adverse Reactions Monitoring (CARM) in Dunedin is New Zealand's national monitoring centre for adverse reactions.

Table 14. Description of the Incidence Monitoring Programs

The bpac^{nz} Patient Safety Incident Reporting System and the Centre for Adverse Reactions Monitoring
The bpac^{nz} Patient Safety Incident Reporting System[35] • **From the online tool, users can comment on reports and view comments and observations made by peers on an incident.** **The bpac^{nz} Patient Safety Incident Reporting system reports on:** • **Clinical process or procedure** • **Medications** • **Medical devices and equipment** **The system is:** • **Completely anonymous,** • **No identifying information is collected or recorded,** • **Focused on systems or processes rather than individuals,** • **Independent and non-punitive.** • **The report is submitted online in the www.bpac.org.nz/safety.** • **The health provider submits the incidence through a customized online form http://www.patientsafety.org.nz/report.aspx.**
The Centre for Adverse Reactions Monitoring (CARM) in Dunedin is New Zealand's national monitoring centre for adverse reactions.[34] • **It collects, evaluates and analyses spontaneous reports of adverse reactions to medicines, vaccines, herbal products and dietary supplements used in New Zealand.** • **Pharmaceutical companies are also important contributors to the CARM database.** • **Reports received by CARM are submitted voluntarily.** • **The CARM database is the source for regular report outputs that support New Zealand pharmacovigilance.** • **Each report received by CARM is evaluated by a medical assessor.** • **After each report has been assessed by one of CARM's Medical Assessors, letters providing relevant information about the adverse drug reaction (ADR) are sent in response to each report that may include information about causality, similar reactions and prescribing advice to assist with risk-benefit assessment of future treatment for the patient involved.** • **The database also serves to support enquiries from health professionals regarding clinical decision making when unusual symptoms are thought to be therapy related.**

TOXICITY MONITORING PROGRAM

- One article reported that pharmacists should discuss drug history and the chemotherapy regimen with the patient and prescriber, respectively.[30]
- Summary of recommendations for toxicity monitoring is provided in Table 15.

Table 15. Recommendations for Toxicity Monitoring Program

Recommendations
• **Before a patient begins treatment pharmacists should discuss all the medicines they are currently taking including any over-the-counter (OTC) or complementary and alternative medicines (CAM).[30]** • **Discussions between prescribers and pharmacists about the chemotherapy regimen should be undertaken to reduce the risk of errors, particularly before a patient begins chemotherapy and whenever the treatment regimen is changed.[30]**

11. System Integration

- One article reported the use a shared electronic medical record (EMR) system that includes a health system integrator (HIS) to manage patient information across the health system.[36]
- EMR contains all patient information and medical history; HIS is a communication platform (Table 16).

Table 16. Description of the System Integration

Electronic medical record[36]
• **Health care providers used EMRs to manage the patient's problem list, electronically enter clinical progress notes, perform electronic prescribing, manage medication lists, order laboratory tests and x-rays, manage diagnostic test results, automatically issue preventive reminders, and access external clinical decision support programs.** • **HIS integrates and supports electronic clinical messaging, online communications, and security systems to facilitate and support communications with other parts of the health sector.** • **Primary care providers, hospitals, radiology providers, and pathology laboratories, as well as most specialists and midwives use HL7 messaging to communicate with each other.** • **Each public and private hospital has a well-developed patient management system linked to a range of specialized hospital clinical systems, via a patient portal.** • **Efforts to automate the flow and management of prescriptions are at an early stage.** • **The creation of the National Health Index (NHI), provides patients with a unique health identifier. The number is used and it is required on all claims, referrals, pathology requests, and prescriptions. The NHI is used to access all data no matter where it is stored, it is accurately linked to a patient.** • **GPs are given secure online access to their local hospitals and nursing homes, enabling them to track and observe their own patients' care.** **All GPs have the capacity to:** • **Print medication prescriptions** • **Manage medication lists** • **Issue automatic preventive reminders** • **Access external decision support programs** • **Access patients' medical records from outside the office** • **Perform clinical messaging** • **Enter clinical progress notes** • **Receive rapid automated status messages and electronic discharge summaries for each patient** • **Communicate with national registries and report quality indicators <u>electronically</u>**

CHALLENGES AND BARRIERS ASSOCIATED WITH DISPENSING THCD

- One article reported the main challenges and barriers associated with dispensing THCD including the complexity of the treatment regimen and drug interactions (Table 17).[30]

Table 17. Description of the main Challenges and Barriers associated with dispensing THCD

Challenges and barriers	Description
Chemotherapy regimen	The main challenges of dispensing THCD from community pharmacies include: • Chemotherapy has a narrow therapeutic window • The complex and cyclical nature of some chemotherapy treatment regimens increases the potential for error during prescribing and dispensing • The likelihood of errors such as incorrect doses, incorrect medicine, incorrect supply and missed doses[30]
Drug interactions	• Potential interaction of chemotherapy with OTC or CAM[30]

REGIONAL OR NATIONAL GUIDELINES FOR SAFE USE AND HANDLING OF THCD

- No article reported on regional or national guidelines for safe use and handling of THCD.

United Kingdom

AVAILABILITY OF COMMUNITY PHARMACY DISPENSING THCD

- In United Kingdom, THCD are dispensed in primary, secondary and tertiary care Eleven articles reported that United Kingdom has community pharmacies dispensing THCD.[37-47f]

DISPENSING MODEL

- The dispensing model was described in two articles.[38;43]
- There are three potential levels of services provided by a community pharmacy dispensing THCD: Level 1, Level 2 and Level 3. The description of the dispensing model is provided in Table 18 below.

Table 18. Description of THCD Dispensing Model

Dispensing Model
Three levels of oral chemotherapy services by community pharmacists:[38;43] • **Level 1 (Baseline service): Community pharmacists (CPs) supply patients' oral anticancer medicines (OAMs) while complying with recommendations of the 2008 National Patient Safety Agency alert on OAMs. Pharmacists dispensing OAMs confirm that the prescribed dose is appropriate for the patient by having access to the OAM protocol and treatment plan.** • **Level 2 (Specialized service): CPs check prescribed OAMs by referencing to the treatment protocols and verifying the prescribed chemotherapy as defined by the British Oncology Pharmacy Association(BOPA) Verification Standards 2010 before supplying OAMs.** • **Level 3 (Advanced service): CPs undertake all the level 1 and level 2 checks as part of the verification protocol of the prescription but also assess the patients clinically to ensure that it is safe to proceed with OAM.**

[f] The NHS is divided into primary care, secondary care, and tertiary care. Primary care is often the first point of contact for people in need of healthcare, and may be provided by professionals such as GPs, dentists and pharmacists. Secondary care, which is sometimes referred to as 'hospital and community care', can either be planned (elective) care such as a cataract operation, or urgent and emergency care such as treatment for a fracture. Tertiary care refers to highly specialized treatment such as neurosurgery, transplants and secure forensic mental health services.

- **For all levels, the patients would have been seen in secondary care or by a GP in a shared care arrangement.**

NUMBER OF COMMUNITY PHARMACY, PHARMACY TECHNICIANS AND PROFESSIONAL BODIES

- The number of community pharmacies increased from 9,756 in 2001 to 11,236 in 2012.[48]
- BOPA consists of the following members: hospital, community and academic pharmacists. pharmacy technicians, those in the pharmaceutical industry and other healthcare professionals.[49]
- No article reported on the number of pharmacy technicians.
- Also, BOPA's members include pharmacy technicians.

PHARMACIST'S QUALIFICATION, EDUCATION OR TRAINING NEEDED TO DISPENSE THCD BY COMMUNITY PHARMACISTS

- The qualification, education or training needed to dispense THCD at a community pharmacy was reported in 5 articles.[41;50-53]
- Pharmacists need:
  - ✓ Local competency training programs for oncology drug verification
  - ✓ Training in the care of cancer patients using the service framework for Pharmacists with Special Interests (PhwSI)
  - ✓ Broad knowledge of cancer and OAMs, organization and coordination of cancer care; patient information and support needs and advanced communication skills
  - ✓ Accreditation for safe prescription verification of systemic anti-cancer therapies (SACT)
  - ✓ Accreditation programme for oral SACT counselling by pharmacy staff
- Detailed recommendations for staff education and training are presented in Table 19.

Table 19. Recommendations for Pharmacist's Qualification, Education and Training

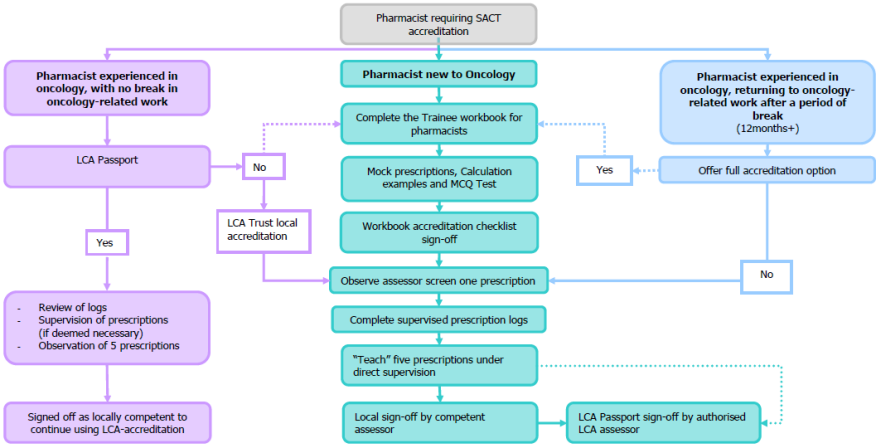
Qualification Education Training	Recommmendations
Training for oncology prescription verification	**BOPA training [50]** • Oncology pharmacists who verify oncology prescription should complete a specialist training program. • All members of staff undertaking the verification of prescription must have demonstrated suitable competence and be locally accredited for the task. It is recommended that local competency training programmes for verification of oncology pharmacy staff include as a minimum: ✓ A documented training programme listing the areas of competency and knowledge required. ✓ A list of specific competencies that must be obtained. *BOPA competencies and the Skills for Health PHARM56 standard provide a template of suitable competencies. ✓ A period of supervised verification of chemotherapy prescriptions. During this period all prescriptions should be double checked by trained and competent pharmacist(s) and a log sheet recording each prescription/ item should be maintained. *A suitable minimum number of items for the log sheet should be agreed locally. It is suggested that 50 items should be the minimum and must include a variety of different prescriptions that reflect local case mix.

Qualification Education Training	Recommmendations
	✓ A signature of pharmacist clinical lead responsible for cancer services confirming that the individual is competent to verify cancer medicine prescriptions. • It is recognised that in some organisations it may not be possible to always ensure that all oral prescriptions are verified by a trained oncology pharmacist (e.g., when oral prescriptions are presented to dispensary staff). • Trusts[g] must therefore ensure that appropriate training and accreditation on the safety aspects of oral anticancer medicines is provided to any pharmacy staff involved in dispensing and supply of these medicines. Oral SACT poses the same as risks as IV SACT. • Trusts should work towards only having trained oncology pharmacists checking all prescriptions for SACT. • A trained oncology pharmacist must always be available to provide advice to dispensary staff to dispense and supply oral anticancer medicines • Further work is ongoing in defining specific educational competencies outlining the knowledge and understanding that an appropriately trained pharmacist verifying a prescription must have. The BOPA committee's work plan for 2010 includes a commitment to develop e-based learning to support oncology pharmacists. In future BOPA will seek to work with the new Professional Leadership Body (PLB) in setting standards for cancer pharmacy. • The Centre for Pharmacy Postgraduate Education (CPPE) has produced a distance learning package Cancer in relation to pharmacy practice' which provides 10 hours of training. ✓ It is suggested completion of this package could be used as part of the background knowledge that underpins the competency training. • A detailed description about the 12 competencies for clinical pharmacy verification of oncology prescriptions is provided in The BOPA Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines March, 2010. The 12 competencies include: 1. Check Prescribers Details 2. Check Patient and Prescription Details 3. Check Chemotherapy Protocol 4. Check and update Pharmaceutical Care Plans 5. Check Body Surface Area is Correctly Calculated 6. Check Doses Are Calculated Appropriately 7. Check Drug Administration Details 8. Check Laboratory Values: Full Blood Counts (FBC)

[g] Trust Pharmacy is Hospital Pharmacy that provides healthcare and pharmaceutical services to patients, staff and the local community.

Qualification Education Training	Recommmendations
	9. Check Laboratory Values: Renal and Hepatic Function 10. Check Laboratory Values: Other Clinical Tests 11. Monitor Renal Function for Carboplatin and Cisplatin 12. Provide Medication Counselling/ Information Care
Training for Pharmacists with Special Interests	**Community pharmacists in the care of cancer patients should be trained using the service framework for Pharmacists with Special Interests (PhwSI)[41]** • PhwSI are pharmacists who work primarily in the community and deliver clinical services beyond the scope of their core professional role or may undertake advanced interventions not normally undertaken by their peers. • The community pharmacist will have demonstrated appropriate skills and competencies to deliver those services without direct supervision.
Training for Safe prescription verification of SACT	**Passport Accreditation Programme Guidance: Safe prescription verification of Systemic Anti-Cancer Therapies (SACT) by pharmacists[53]** • This document is designed for use by all General Pharmaceutical Council (GPhC)registered pharmacists (AfC Band 6 and above) working within a Trust that is part of LCA, who require accreditation and training to be added to the register for competency of verification of systemic anti-cancer therapies (SACT); this includes any temporary/locum staff. • Pharmacists new to oncology should complete the full local and London Cancer Alliance (LCA) accreditation. • For oncology-experienced pharmacists that do not have a LCA passport, but have local LCA accreditation, they should continue with the LCA accreditation and/or new Trust's local accreditation in order to be added to the local SACT verification register. *Suggested local accreditation* • All LCA Trusts must cover as a minimum the local accreditation outlined below in order to qualify for the LCA Passport accreditation. • Each Trust should ensure their local accreditation covers the required induction for their respective areas. ✓ Read relevant clinical policies (e.g. *febrile neutropenia guidelines, tumor lysis guidelines, extravasation policy*). ✓ Read local SACT prescription verification procedure. • Familiarization with local and national chemotherapy protocols/algorithms and guidelines and how to access/use these. • Access to electronic prescribing system(s) with associated training (as required). • Knowledge of funding streams/mechanisms for funding (e.g. Cancer Drugs Fund (CDF)) for certain chemotherapy drugs and the local processes for approving/re-ordering and invoicing, where appropriate. *Supervised prescription logs* The required number of prescriptions to qualify for LCA Passport is detailed below.

Qualification Education Training	Recommmendations
	• *Stage I* (Watch one): Supervisor "walks through" screening process for one prescription. • *Stage II:* Do a minimum of 50 supervised prescriptions logs, which must include a variety of different prescriptions: ✓ At least 4 different regimens and including at least 3 different clinical trials. ✓ A minimum suggested guide of 10 prescriptions per area of competence is recommended. ✓ It is recommended wherever possible that these logs are reviewed by the specialist pharmacist in that field. ✓ The supervisor should refer to the LCA competency framework for details of the minimum requirements to cover in each verification episode. ✓ If any of the minimum requirements for each verification episode are missed, a 20% increase in total number of logs is recommended. • *Stage III (*Teach 5 : Pharmacist in training will "walk through" their screening process with the supervisor ✓ The supervisor will directly supervise the screening of the prescriptions without prompting ✓ Supervisor should refer to the LCA competency framework for details of the minimum requirements to cover in each screening episode. *Re-accreditation and retraining* • Re-accreditation should be completed after a period of twelve months from the date of addition to the Register. • Self-declaration ✓ I wish my name to remain on the local register for verification of SACT prescriptions. ✓ I have screened a minimum of ten SACT prescriptions in the last twelve months. ✓ I declare that I remain competent to screen SACT prescriptions. ✓ I have read the local chemotherapy policies and am familiar with the SACT protocols currently in use. • Read the local SACT prescription verification SOP and be familiar with the BOPA Standards for clinical pharmacy verification of prescriptions for cancer medicines. • Retraining should be considered if it is identified through the error reporting system that an accredited pharmacist has made a clinical error during a verification session. The suggested criteria for re-training include: ✓ One error that has caused severe patient harm. ✓ Two clinically significant dosing errors resulting in potential patient harm.

Qualification Education Training	Recommmendations
	✓ An error that has financial implications to the Trust. "*Grandparent clause"* • Under this grandparent clause, exemption from further accreditation is open to pharmacists who have already completed a local SACT prescription verification training program and have been deemed competent by a local competency assessor. Below details what needs to be completed in order to be signed off for the LCA SACT prescription verification Passport 
Training for SACT counselling	Accreditation programme for SACT counselling by pharmacy staff[52] • This document is designed for use by all registered pharmacists and pharmacy technicians working within a Trust that is part of LCA, who require accreditation to be added to the register for competency of counselling of oral SACT. *Trainee responsibilities* Trainee must: • Undergo local induction • Read LCA accreditation program • Familiarize themselves with the oral SACT counselling handbook and how to access/use this document. • Complete Multiple Choices Questions (MCQ) (questions will be available in advance but must be answered in a test setting) • Complete local supervision with an authorized assessor *Assessor responsibilities* Authorized assessor must: • Facilitate local supervision of the trainee • Review MCQ and supervised counselling record of the trainee *Accreditation checklist* • The checklist below details the requirements for both local and LCA accreditation/sign-off.

Qualification Education Training	Recommmendations

- A pharmacist or pharmacy technician can be deemed competent to counsel patients on oral SACT by designated assessors, identified by the Chief Pharmacist of each Trust.
- LCA will hold a central list of accredited assessors for each Trust, for reference.

Trainee name: Job title:		Date:
KNOWLEDGE		
Familiar with oral SACT counselling handbook and how to access/use this document Completed the MCQ test (Pass mark 80%)	Assessor's details: Name: Signature: Job Title:	
COUNSELLING RECORD		
Record of supervised oral SACT counselling completed to LCA criteria (see supervised counselling record)	Assessor's details: Name: Signature: Job Title:	
LOCAL REGISTER		
Pharmacist or pharmacy technician's name added to the local register for counselling of oral SACT	Assessor's details: Name: Signature: Job Title:	

Training

MCQ test

- The test provides pharmacy staff with the essential theoretical knowledge required to underpin practice.
- The test must be completed before undertaking supervised practice.
- A minimum score of 80% is required to pass. Any less than the minimum score will constitute a fail and the trainee is expected to re-take the test. If a maximum of three attempts are made, the trainee will be referred to their line manager for an action plan. Detailed information about MCQ Test is provided in Appendix E, Table. 1

Supervised counselling record

The required number of supervised counselling to qualify for LCA accreditation is detailed below.

- *Stage 1: Watch one* – Trainee should observe their assessor undertake one patient counselling before attempting themselves

Qualification Education Training	Recommmendations

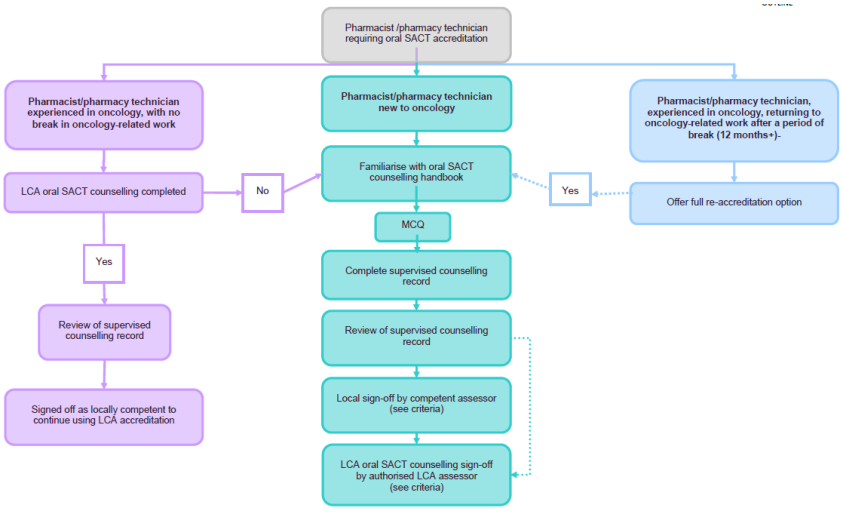
- *Stage 2*: *Do three* – Trainee should counsel three patients under direct supervision of an accredited
  pharmacist or pharmacy technician
- *Stage 3*: *Teach one* – to your assessor, counsel one patient still under direct supervision and without any prompting
- A minimum of three supervised assessments will take place against the counselling record with the trainee using the checklist.
- Both theoretical and practical assessments need to be completed in order pass the competency training.

Re-accreditation

Re-accreditation needs to be completed after a period of 12 months from the date of registration by the pharmacist or pharmacy technician. The re-accreditation procedure includes:

- The pharmacist/pharmacy technician should be familiarized with the oral SACT counselling handbook and the training slides for essential counselling elements, and are required to indicate they complete it.
- Complete one supervised record – Teach one – to your assessor, counsel one patient still under direct supervision and without any prompting.

Below is a detailed schematic of the counselling accreditation program process.



- Detailed information about LCA Oral SACT Counseling Checklist is provided in Appendix E, Table 2.
- Detailed information about LCA Oral SACT Supervised Counselling record for Pharmacy Staff, Appendix E, Table 3.
- Detailed information about LCA Accreditation Certificate for oral SACT counseling, Appendix E, Table 4.

Qualification Education Training	Recommmendations
	• Detailed information about LCA Re-Accreditation Certificate for oral SACT counseling, Appendix E, Table 5.
Education	Four broad areas in which community pharmacists need education and training to deliver THCD[38]: 1. Knowledge of cancer and OAMs 2. Organization and coordination of cancer care 3. Patient-specific information and support needs 4. Advanced communication skills

REQUIREMENTS, ACCREDITATIONS, CERTIFICATIONS NEEDED TO DISPENSE THCD AT A COMMUNITY PHARMACY

- Three articles reported requirements, accreditations and certifications needed to dispense THCD at community pharmacies (Table 19).[41;43;50]
- Detailed recommendations for Requirements, Accreditations, and Certifications are presented in Table 20.

Table 20. Recommendations for Requirements, Accreditations, and Certifications

Recommandations
• **For pharmacy dispensing cancer drugs, SACT are verified by a trained oncology pharmacist. In the absence of a trained oncology pharmacist, Trusts must ensure that appropriate training and accreditation on the safety aspects of oral anticancer medicines is provided to any pharmacy staff involved in dispensing and supplying of these medicines.** • **In order to support dispensary staff involved in the dispensing and supplying of OAMs a trained oncology pharmacist must always be available who is able to provide oncology pharmacy advice to dispensary staff.[50]** • **The PhwSI qualification is considered to be obligatory for CPs to dispense THCD. A chemotherapy cannot be dispensed at the premises when the specialist pharmacist is unavailable; alternative arrangements, possibly involving similar pharmacies could be made. The alternative would be to take the prescriptions back to secondary care.[41]** • **Commissioners and secondary care Trusts should discuss potential opportunities for OAMs o be dispensed in primary care, including a baseline assessment of the potential demand, and that only those who have undertaken additional training and can comply with the service models should be accredited to provide the service.[43]**

PATIENT EDUCATION PROGRAM

- Three references reported patient education programs provided by a community pharmacy (Table 21).[40;44;45]
- Such education programs include:
  - ✓ Side effect and strategy to minimize
  - ✓ Safe handling of chemotherapy
  - ✓ Counselling might be provided by nurse or community pharmacists

Table 21. Recommendations for Patient Education program

Recommendations
• **Community pharmacist has to advise on both cancer medication dispensed and OTC.** • **Pharmacists should help patients understand the importance of self-care to minimize side effects and should know how to manage them. [40]** **Additional resources provided by the authors:** **Cancer Research UK (CRUK) website provides scientific information and statistics, training materials and patient resources (including leaflets and posters)** • **The *National Patient Safety Agency* (NPSA) alert requires all patients to be issued with a copy of their treatment plan, which should contain details of drug doses and frequencies.** • **Pharmacists should counsel patients on the safe handling and storage of anticancer medicines and on common side effects of chemotherapy such as sickness and diarrhea, mouth problems, hair loss, skin side-effects and bone marrow suppression.** • **Pharmacists should counsel patients receiving anticancer medicines to be particularly aware of symptoms of infection such as sore throat, raised temperature, pain passing urine, cough or breathlessness.[45]** **Pharmacy staff dispensing drugs to patients must also ensure that patients understand the following[44]:** • **Principles of safe handling, storage and disposal.** • **That if used, medicine spoons or measures should be used only for the purpose of administering the specific anticancer medicine, washed with warm soapy water after use and disposed of safely when no longer required.** • **Any drug specific advice regarding safely crushing of tablets or opening of capsules.** • **How to safely store their oral anticancer medicines and told where and how to return unused medicines for disposal.**

COGNITIVE SERVICES REIMBURSEMENT PROGRAM.

- No article reported on cognitive services reimbursement programs.

ADHERENCE MONITORING PROGRAM

- No article reported on adherence monitoring programs.

INCIDENT REPORTING PROGRAM

- One article reported an incidence reporting program.[54]
- The National Reporting and Learning System (NRLS) allows community pharmacist to report patient safety incidents (Table 22).[54]

Table 22. Description of the Incidence Reporting Program

The National Reporting and Learning System (NRLS)
• **Community pharmacies record patient safety incidents in an incident log and report these to the National Reporting and Learning Service (NRLS).** • **The easiest way to make these reports is via the NRLS website.** • **To facilitate the collection and recording of the information needed to report an incident to the NRLS a form has been produced which community pharmacies may choose to use.** **How to submit a report of a patient safety incident** 1. **Go to www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/healthcare-staff-reporting/** 2. **Click on the link 'Healthcare staff |report here'.** 3. **The first question asks 'In which service did the Patient Safety Incident occur.** 4. **An ID number will appear on the bottom of the screen that is unique to the report.**

TOXICITY MONITORING PROGRAM

- Three articles reported toxicity monitoring programs. [37;40;45]
- Such programs includes:
  - ✓ Chemotherapy cycle monitoring
  - ✓ Traffic light symptom tools
  - ✓ Collaboration between community pharmacists and secondary care professionals
- Recommendations for toxicity monitoring programs are provided in Table 23 below

Table 23. Recommendations for the toxicity monitoring program

Recommendations
The 2009 report of the National Chemotherapy Advisory Group, "Chemotherapy services in England: ensuring quality and safety" recommends: • **Cancer Networks should consider whether there are further opportunities to devolve chemotherapy delivery from cancer centres to cancer units (or closer to home) while still maintaining safety and quality.** • **Service commissioners monitor the proportion of treatment cycles given at a cancer centre, cancer unit or closer to home, and the introduction and expansion of nurse-led and pharmacist-led chemotherapy.[37]** • **The use of traffic-light-symptom reporting tools is encouraged because these provide recommended actions to patients when they are experiencing side effects.[40]** • **It is essential that CPs taking on dispensing of anticancer medicines are supported by their colleagues in secondary care and by their local Cancer Network.[45]** ***Additional resources provided by the authors*** **Macmillan website provides comprehensive information on all tumor types, treatments and individual chemotherapy drugs. They have a nurse-led support line and also employ GPs and pharmacists who work locally on a range of projects (safety monitoring).**

SYSTEM INTEGRATION

- One article reported the electronic health record which is described in Table 24.[55]

Table 24. Description of the system integration

The electronic health record[55]
• **The EHR is managed by NHS England, the National Information Board (NIB) and the Health and Social Care Information Centre.** • **The EHR is accessible to primary, secondary and social care providers and to patients.** • **The EHR are stored by GPs, hospitals, mental health providers and in some community care settings.** • **Scotland, Wales and Northern Ireland have their own local electronic health records.** • **The record includes information about medical history, care preferences and lifestyle.** • **Patients can book appointments and order repeat prescriptions online.** • **At present, only a few electronic records are shared between providers.** • **In England Summary Care Record (SCRs) were rolled out on an 'opt-out' basis, with ~1.4% of patients opting-out. 94% of England's population had an SCR by March 2015.** • **The Connecting Care program created by Clinical commissioning groups and NHS Trusts in Bristol, Somerset and Gloucestershire shares electronic records between primary, secondary and social care.** **National standards for electronic health records:** • ***The NHS Number* should be used as a single unique identifier for patients when sharing information.** • ***Open Application Program Interfaces* should be provided by all electronic health record suppliers. The interfaces can be viewed by suppliers, who can then create programs that work together to exchange patient information.** • ***Systematized Nomenclature of Medicine –Clinical terms (SNOMED CT),* a common terminology, should be used by all clinicians when writing clinical terms into electronic records.** ***The Transfer of Care Initiative* will create common standards for how medical records are transferred when a patient is admitted, discharged or referred. The Professional Record Standards Body has also been established to develop further standards for the structure and content of electronic health records.** **Funding for electronic health records:** **NHS England has several schemes to support electronic records:** • **The Integrated Digital Care Fund awards money to NHS Trusts to facilitate the adoption of modern, safe standards of electronic record-keeping.** • **The Nursing Technology Fund provides grants to Trusts to buy digital services for nurses.** • **The NHS Innovation Accelerator scheme that funds fellows who have worked with industry and the third sector to develop health technology.** • **Vanguard sites are partnerships between health and care organizations that will provide new care models.** • **Issues with the electronic health record include:** ✓ **Inconsistency of data collection.** ✓ **Limited access to patient information** ✓ **Loss of functionality**

The electronic health record[55]
✓ **Hardware issues**

12. Challenges and barriers associated with dispensing THCD

- Twelve articles described the challenges and barriers associated with dispensing THCD at a community pharmacy. [37-42;44-47;52;56]
- There are at least 10 issues that should be addressed by community pharmacists dispensing THCD.[37]
  1. Patient numbers per locality
  2. The pharmacist's competence in chemotherapy regimens
  3. Availability of the drug
  4. Origin of the prescription: Only 8% of GPs specialize or have a particular interest in cancer
  5. Requirement for shared care documentation
  6. Training
  7. Continuity of community pharmacy workforce
  8. Handling and disposal of cytotoxic drugs and associated waste.
  9. Out-of-hours support
  10. Remuneration of pharmacists
- Detailed description of challenges and barriers associated with dispensing THCD at community pharmacies are provided in Table 25 below.

Table 25. Challenges and Barriers associated with dispensing THCD

Challenges and barriers	Description
Treatment outcomes	• Cancer treatments carry side effects.[40;42] • There are risks of fatal outcomes if incorrect doses of oral anticancer are used.[44;46;47]
Patient numbers per locality	• Sometimes it is difficult to know the number of patients willing to use CP services.[41]
Chemotherapy regimen	Potential errors associated with interpreting the chemotherapy regimen: • Incorrect verification of dose. • Pulsed dosing misinterpreted as continuous. • Inability to recognize variations in pulsed dosing for same drug, but used for different disease. • Wrong strength tablet/capsule dispensed. • Drugs continued where cessation of treatment was intended; inaccurate numbers of tablets dispensed (potential for over or under dose). • Where more than one drug is prescribed, schedules swapped-due to (i) poor labelling or (ii) poor patient understanding. • It is difficult to follow a chemotherapy regimen when it consists of both parenteral and oral cytotoxic components.[41] • Inaccurate drug frequency, quantity or duration of treatment.[42;56]
Availability of the drug	• Cancer drug is not always available.[38] • In community pharmacy, only small volume of OAM prescriptions are dispensed.[38] • Community pharmacies are unlikely to be able to keep stocks of these drugs.[41]

Challenges and barriers	Description
Drug interactions	• Cancer treatments carry potential interactions.[40]
Origin of the prescription	• Electronic prescription format not appropriate.[38] • Inaccurate prescriptions.[41]
Documentation	• Inability to access protocols and patient's clinical information.[38] • Issue with data security.[38] • There is currently no system in place for CPs to know what treatments patients are taking outside of the medication that the particular pharmacy supplies.[40] • Lack of appropriate documentation.[41] • Unreported numbers of unreported incidents.[42]
Training and education Related	• Pharmacists' lack of clinical knowledge in oncology drugs and patients' needs.[38;39] • Lack of advanced communication skills, competency training locums and other staff, no published national standards to guide CPs in dispensing and supplying OAMs for cancer treatment, none that define safe practice for CPs, no nationally recognized training and accreditation programs for CPs.[38] • Lack of adequate training.[41] • CPs may lack appropriate training for dispensing and counselling chemotherapy patients.[45]
Lack of knowledge regarding treatment plan	• CPs are kept in the dark regarding treatment regimen. • Missing information in the prescriptions.
Continuity of community pharmacy workforce	• Unavailability of an appropriately trained covering pharmacist.[41]
Inter-professional issues	• Difficulties in communication/feedback of information between primary and secondary care providers[38;39]
Remuneration	• More financial support is needed due to the degree of expertise and extra time required for CPs.[41]
Handling and disposal of cytotoxic drugs and associated waste	• CPs are obliged to follow control of substances hazardous to health (COSHH regulations).[41] • There are concerns about safe management of anticancer medicines in secondary care.[45]
Out-of-hours support	• There are queries relating to the chemotherapy or disease that are urgent.[41]
The service environment	• Business versus clinical Service. • Depth of work involved. • Lack of space within pharmacy to store OAM. • Toxic drugs.[38]

Challenges and barriers	Description
Resource related	• Lack of time to deliver service. • Time-consuming nature of service. • Lack of reimbursement. • Expensive drugs to dispense.[38]

REGIONAL OR NATIONAL GUIDELINES FOR SAFE USE AND HANDLING OF THCD

- Nine articles reported nine guidelines for safe use and handling of THCD:
    1. The BOPA Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines.[57]
    2. Guidance to Support BOPA Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines (March 2010, Expired 2012).[50]
    3. BOPA Standards for Pharmacy Verification of Prescriptions for Cancer Medicines.[58]
    4. Guidance to Support the Prescribing, Dispensing and Administration of Oral Anti-Cancer Medicines in Primary Care.[42]
    5. NPSA Guidance intended to promote the safe use of the medicines listed to treat cancer.[56]
    6. The Safe Handling and Administration of cytotoxic Products for the Treatment of Cancer.[59]
    7. Standards For Dispensing And Supply Of Oral Anticancer Medicines.[44]
    8. Standards for the safe use of oral anticancer medicine.[46]
    9. Systemic Anti-Cancer Therapy Care Pathway – Guidelines on the Safe Use of Oral Anti-cancer Medicines.[47]
- Detailed recommendation for safe use and handling of THCD are provided in Appendix 2, Table 3.

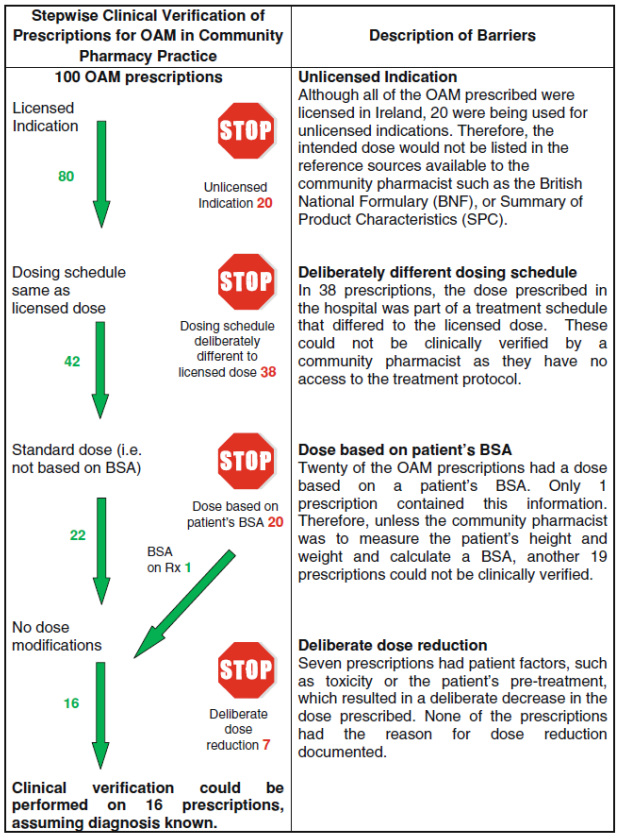
Ireland

- One article from reported challenges and barriers associated with dispensing THCD at community pharmacies[39].
- Detailed description of challenges and barriers is provided in Table 26 below

Table 26. Challenges and Barriers associated with dispensing THCD

Challenges and barriers	Description
Origin of the prescription	• Prescription incomplete, impossible to check dose if height, weight or BSA not included. • Badly written prescriptions and contact details of doctor are illegible.
Training and education Related	• Pharmacists' lack of clinical knowledge in oncology drugs and patients' needs. • No experience.
Lack of knowledge regarding treatment plan	• CPs are kept in the dark regarding treatment regimen. • Missing information in the prescriptions. • CPs assume that patients have been informed about treatment regimens from the hospital which is not always the case.
Inter-professional issues	• Difficulties in communication/feedback of information between primary and secondary care providers.

Challenges and barriers	Description
Verification Related	• Unlicensed Indication. • Deliberately different dosing schedule. • Dose based on patient's BSA. • Deliberate dose reduction. Detailed description for these barriers is provided in the figure below



Discussion/Limitations

- This report shows that in Australia, The Netherlands and New Zealand, patients can fill their prescription for cancer drugs from a community pharmacy.
- Only 2 jurisdictions (Australia and United Kingdom) reported their dispensing model.
- In Australia, community pharmacists check prescriptions from physicians, confirm patient information, select and label the product and store the product and counsel patients.
- In United Kingdom, there are three potential levels of services provided by a community pharmacy dispensing THCD:

  - ✓ Level 1 (baseline service): service providers undertake supply of the oral anticancer medicine.
  - ✓ Level 2 (specialized service): service providers check the oral anticancer medicine prescription.
  - ✓ Level 3 (advanced service): service providers assess the patients clinically to ensure that it is safe to proceed with chemotherapy.

- Although many articles reported information for both hospital and community settings this report provides a comprehensive understanding of dispensing THCD at community pharmacies.
- Our findings did not provide an answer as to whether there are any options for mail delivery.

APPENDICES FOR OUTPUT FROM ESRS

APPENDIX A. SEARCH STRATEGIES

Table 1, 2 and 3 present the search strategies developed for Ovid Embase, Ovid MEDLINE and Ovid Healthstar respectively.

TABLE 1. OVID EMBASE SEARCH STRATEGY

	Search Term(s)	# of Hits
1	Antineoplastic Agents.mp. or exp antineoplastic agent/	1874231
2	exp consolidation chemotherapy/ or exp cancer chemotherapy/ or exp adjuvant chemotherapy/ or exp chemotherapy/ or exp induction chemotherapy/ or exp cancer combination chemotherapy/ or exp combination chemotherapy/	562425
3	(Anticancer drug* or anticancer agent*).mp.	46452
4	(cancer drug* or cancer medecine*).mp.	14052
5	1 or 2 or 3 or 4	2063109
6	dispensing.mp.	11923
7	filling.mp.	71721
8	labelling.mp. or exp drug labeling/	56305
9	disposal.mp.	41877
10	handling.mp.	93964
11	exp drug storage/	10973
12	exp counseling/	137531
13	Drug Information.mp. or exp drug information/	24638
14	tracking.mp.	83470
15	reporting.mp.	185291
16	selection.mp.	508002
17	preparation.mp.	362014
18	(training or education).mp.	1333399
19	(certification* or accreditation*).mp.	67574
20	(toxicity or adherence).mp.	1148192
21	6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20	3830247

22	(pharmac* adj2 (outpatient or community)).mp.	12437
23	Community Pharmacy Services.mp.	432
24	Community-based pharmacy.mp.	29
25	drug store*.mp.	437
26	(retail pharmacy or retail pharmacist*).mp.	510
27	(Outpatient* pharmacy or Out-patient* pharmacy or Outpatient* pharmacist* or Out-patient* pharmacist*).mp.	806
28	(Community-based pharmacist* or community pharmacist*).mp.	4635
29	(community adj (pharmacy or pharmacies)).mp.	7958
30	(speciality adj2 (pharmacy or pharmacies or pharmacist*)).mp.	8
31	22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30	13319
32	5 and 21 and 31	301
33	limit 32 to (english language and last 10 years)	223

Table 2. Ovid MEDLINE Search Strategy

	Search Term(s)	# of Hits
1	exp Antineoplastic Agents/	968862
2	Antineoplastic.mp.	443786
3	exp Antineoplastic Protocols/	128729
4	exp Chemotherapy, Adjuvant/	36059
5	Anticancer.mp.	62162
6	chemotherapy.mp.	348713
7	anticancer agents.mp.	9386
8	(cancer drug* or cancer medecine*).mp.	8378
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	1154989
10	dispensing.mp.	6125
11	filling.mp.	48270
12	exp Drug Labeling/ or labeling.mp.	213146
13	disposal.mp.	54197
14	handling.mp.	96987
15	Storage.mp.	148358
16	exp Counseling/	40443
17	exp Drug Information Services/	12106
18	tracking.mp.	49131
19	reporting.mp.	126664

20	drug selection.mp.	1565
21	exp Education, Pharmacy, Graduate/ or exp Education, Pharmacy, Continuing/	1647
22	training.mp.	311157
23	preparation.mp.	256856
24	(certification* or accreditation*).mp.	44808
25	(toxicity or adherence).mp.	413151
26	10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25	1708225
27	(pharmac* adj2 (outpatient or community)).ti,ab.	4861
28	exp Community Pharmacy Services/	3663
29	Community-based pharmacy.mp.	14
30	retail pharmacy.mp.	164
31	(Outpatient* pharmacy or Out-patient* pharmacy or Outpatient* pharmacist* or Out-patient* pharmacist*).mp.	328
32	(Community-based pharmacist* or community pharmacist*).mp.	1724
33	(take home or ambulatory pharmacy).mp.	2287
34	(community adj (pharmacy or pharmacies)).mp.	5053
35	(speciality adj2 (pharmacy or pharmacies or pharmacist*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	2
36	27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35	8859
37	9 and 26 and 36	112
38	limit 37 to (english language and last 10 years)	89

Table 3. Ovid Healthstar Search Strategy

	Search Term(s)	# of Hits
1	Antineoplastic Agents.mp. or exp Antineoplastic Agents/	413095
2	Antineoplastic Combined Chemotherapy Protocols/ or cancer chemotherapy.mp.	105635
3	(Anticancer drug* or anticancer agent*).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	15985
4	(cancer drug* or cancer medecine*).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	4980
5	1 or 2 or 3 or 4	448496
6	Medication Errors/ or dispensing.mp. or exp Community Pharmacy Services/	18288
7	filling.mp.	31895
8	Labeling.mp. or exp Drug Labeling/	57227
9	disposal.mp.	44044

10	handling.mp.	59246
11	Drug Storage/ or storage.mp.	79836
12	exp Counseling/	37366
13	exp Drug Information Services/ or exp Databases, Factual/	101007
14	tracking.mp.	32400
15	exp Education, Pharmacy/ or exp Education, Pharmacy, Continuing/	5609
16	reporting.mp. or Adverse Drug Reaction Reporting Systems/	114677
17	selection.mp.	252582
18	training.mp.	252924
19	preparation.mp.	121882
20	(certification* or accreditation*).mp.	43162
21	(toxicity or adherence).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	226763
22	6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21	1335420
23	(Outpatient* pharmacy or Out-patient* pharmacy or Outpatient* pharmacist* or Out-patient* pharmacist*).mp.	316
24	(pharmac* adj2 (outpatient or community)).ti,ab.	4540
25	exp Community Pharmacy Services/	3380
26	Community-based pharmacy.mp.	15
27	drug store*.mp.	217
28	(retail pharmacy or retail pharmacies).mp.	343
29	(Community-based pharmacist* or community pharmacist*).mp.	1611
30	(ambulatory adj pharmac*).mp.	68
31	(community adj (pharmacy or pharmacies)).mp.	4641
32	(speciality adj2 (pharmacy or pharmacies or pharmacist*)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	2
33	23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32	6504
34	5 and 22 and 33	64
35	limit 34 to (english language and last 10 years)	37

APPENDIX B. GUIDELINES OF SAFE USE AND HANDLING OF THCD.

Table 1. Australia's Guidelines

Author/ Organization Year	Recommendations
Carrington et al., 2010a	**The following is a summary of recommendations made in the guidelines** • All staff involved in the management of cancer and its therapy must have the relevant knowledge and skills, and be competent to perform the tasks. • Appropriate staffing numbers and skill mix for all disciplines should be in place to ensure that safe practices can be followed effectively. • Procedures and policies should be in place to provide direction and clear instruction on working practices to staff involved in providing chemotherapy and targeted therapy. • All staff should have access to information applicable to the patient and the treatment, including diagnosis, patient's history, pathology results and the treatment plan. • All chemotherapy and targeted therapy should be prescribed on the basis of a documented, referenced protocol and a treatment plan documented for all patients. • Protocols should outline all therapy, dosages and scheduling relevant to the treatment. • The medication order for chemotherapy and targeted therapy should present the treatment information in a clear, consistent and unambiguous manner and include all supportive therapy associated with the protocol. Computer generated or pre-printed forms are preferable to handwritten orders. • All treatment should be clinically verified by a pharmacist prior to dispensing. • The pharmacist should have access to the patient information relevant to the treatment. • All chemotherapy and associated therapy should be clinically verified by a nurse and the therapy checked against the order by two nurses prior to administration. • Oral chemotherapy should be subject to the same procedures for prescribing and dispensing as parenteral therapy and labeled with clear instructions to minimize potential administration errors by the patient. • Patients should be given both written and oral information about their treatment to include all medications, expected side-effects, how to take supportive medication and who to contact in the event of an emergency or severe adverse events. • A system should be in place for reporting adverse events, incidents and near misses with regular audits carried out to identify error-prone areas or processes that require modification.
Carrington et al., 2010b	**The Clinical Oncological Society of Australia (COSA) guidelines for the safe prescribing, dispensing and administration of cancer chemotherapy** **Note:** Only information related to pharmacist is reported below ***Competency and skills*** • The pharmacist carrying out the verification of the order should have the appropriate training, knowledge and skills in cancer chemotherapy as defined by the SHPA Standards of Practice for Clinical Oncology Pharmacy.

Author/ Organization Year	Recommendations
	• Pharmacists with insufficient knowledge or experience in cancer treatment should not be delegated to manage patients receiving chemotherapy and related treatment. • The application of competency testing for the verification and dispensing of chemotherapy should be considered for all staff involved in these tasks. ***Clinical verification*** • A written, up to date procedure for verification of the order should be available that includes an individual systematic check of all the components of the prescription. • Physical and staffing resources should enable the pharmacist to verify an order away from distractions and interruptions to maximize safety. • An independent check by a second person should be performed when possible. This should be a pharmacist with appropriate knowledge and skills in cancer therapy. • Calculations performed manually should be independently checked. • Where computerized systems are in place a validation process must be implemented to ensure accuracy of automated calculations. • In verifying the prescription the pharmacist must have access to the following information. *An original or legible copy of the medication order. Scans are preferable to faxes for clarity and legibility. *The prescription must be completed with the detail specified in the prescribing section of this document. *An order written on an appropriate chart must be made available to clinically verify the treatment for administration by ALL routes. A PBS script alone will contain insufficient information to enable safe dispensing of chemotherapy treatment and should not be supplied against a PBS script in isolation of other information. *Current diagnosis and relevant medical history. *Patient parameters (height, weight, BSA) and relevant laboratory values including blood counts, urea and electrolytes, liver function tests. *A patient treatment plan which includes details of the protocol being used. *Treatment history and patients medication profile/records including over-the-counter medications herbal medications, medication allergies and medication related adverse events. ***Oral anti-cancer therapy*** • Staff dispensing oral anti-cancer medicines in the community setting must have access to the above information to ensure they can confirm that the prescribed dose is appropriate for the patient. • Access to a pharmacist with experience in cancer treatment at the hospital where treatment is initiated should be available. ***Labelling*** A uniform labelling method must be applied to ensure easy identification of the medication, route, dose and patient in addition to the legal requirements for labelling.

Author/ Organization Year	Recommendations
	Preparation and delivery • The process of clinical validation of the order and the actual preparation of the chemotherapy and targeted therapy should be considered as two separate functions. • Preparation processes must be performed according to Australian standards and the SHPA Preparation of cytotoxic medications and the transportation of cytotoxic medications. • The preparation process must ensure that the therapy is stable in the required diluent for the required length of time. • There must be a reconciliation check with the product and the prescription before issue. • Where preparation is carried out off- site by a 3rd party there must be a process in place to ensure the final prepared product is checked by the pharmacist responsible for the clinical verification of the order. • The product should be checked against the original order before being handed over to nursing staff for administration. • The therapy must be delivered *to* "*the right place at the right time for the right person*" to enable treatment to commence. • All chemotherapy must be delivered separately from other medications in a plastic hard walled container dedicated for the purpose. Intrathecal chemotherapy has special requirements for preparation, transportation and delivery ***Dispensing intrathecal chemotherapy*** • All intrathecal doses for cancer therapy must be dispensed and packaged separately from other chemotherapy. • All intrathecal chemotherapy should be stored in a designated and clearly labelled storage container in the pharmacy until the patient is ready for the intrathecal administration. • This container must only be used for intrathecal doses. • On receipt of the intrathecal dose a signature should be requested by either the authorized nurse or doctor attending to the patient receiving the intrathecal therapy. Chemotherapy order details to be verified by the pharmacist (Table 1) and Details required for labelling chemotherapy and targeted therapy (Table 2) are provided in Appendix C
Carrington Christine, 2013	**Safe use of oral cytotoxic medicines** **Prescribing** Prescriptions for oral cytotoxic therapy should be clear and unambiguous. The term 'as directed' must not be used regardless of how long the patient has been on the therapy. Prescriptions should specify: • The generic drug name, number of tablets to be taken and frequency and duration of therapy • Whether the medicine is given on a cyclical or continuous basis. For example, capecitabine is frequently administered for 14 days of a 21-day cycle while

Author/ Organization Year	Recommendations
	temozolomide may be administered for 5 days of a 28-day cycle. The start and stop dates for a cycle should be clear. • The day on which tablets should be taken. For example, methotrexate is most commonly given as a once-weekly dose. Fatal errors have occurred when methotrexate has been prescribed to be taken daily or when the incorrect strength of tablets has been prescribed • Wherever possible the quantity prescribed should be the quantity needed for one cycle (cancer chemotherapy) or one month (for example methotrexate for rheumatoid arthritis).Preferably, repeat prescriptions should not be issued as doses may change according to adverse effects and therapeutic response. • If a repeat prescription is issued within the Pharmaceutical Benefits Scheme regulations, the patient should be directed to destroy any repeats or return them to the prescriber if treatment is changed or stopped. • Patients should always be advised on the action to take should they experience an adverse event. ***Dispensing and supplying oral cytotoxic treatment*** • The dispensing of oral cytotoxic therapy includes verification of the prescription for the patient and their condition, and appropriate supply in a safe and timely manner • *For cancer chemotherapy the pharmacist should have access to the treatment plan, the chemotherapy protocol and relevant patient parameters including height and weight and recent laboratory results.* • *The pharmacist should ensure that the relevant supportive medicine has been prescribed or is available to the patient.* • Interactions between chemotherapy, other prescribed drugs, and over-the-counter and complementary medicines can cause changes in the efficacy and safety of oral chemotherapy. Low-dose aspirin can be used with weekly methotrexate. The risk associated with lower doses of methotrexate used in rheumatoid arthritis therapy is much less • Conversely cytotoxic chemotherapy can alter the effectiveness of other drugs. *A complete medication history should be taken from the patient or carer before dispensing a prescription and potential interactions should be discussed.* • If a dose administration aid is required by the patient, then oral cytotoxics must be packed separately from the patient's noncytotoxic medicines ***Medicine labelling*** • The labelling of oral cytotoxic therapy should clearly state the dose and the number of tablets to be taken. • The label for weekly dosing for medicines such as methotrexate and vinorelbine should include the term 'once a week' and specify the day the dose should be taken. Cytotoxic chemotherapy can be carcinogenic, mutagenic and teratogenic. • A warning sticker should be placed on all containers of cytotoxic chemotherapy tablets and capsules, in accordance with local health and safety policy. • An adhesive purple sticker with the wording 'cytotoxic, handle with care' is recommended.

Author/ Organization Year	Recommendations
	• A warning label must be placed on administration aid packs that identify the contents as cytotoxic. • Oral cytotoxic tablets and capsules should not be broken or crushed as this can increase the risk of exposure and alter the bioavailability of the medicine ***Information for the patient*** • *Patients should be given verbal and written information that includes dose instructions.* Some oral cytotoxic medicines need to be stored securely in a refrigerator, for example chlorambucil and melphalan. • *Patients should be advised that oral cytotoxic medicine should only be taken out of the dispensed packaging immediately before a dose.* • To minimize exposure of carers and family members to cytotoxic medicines, patients should be advised that self-administration is preferable. • If administration by a carer is required then disposable gloves should be worn. • Unused tablets must be returned to the local pharmacy or original supplier and not disposed of at home. • Medication guides, patient calendars and dose administration aids are often useful to help patients follow complex dose regimens, particularly those on multiple medicines. • Adherence to oral therapy is important to maximize the benefits and reduce the risks of treatment. This should be discussed with the patient. • If appropriate, Consumer Medicine Information leaflets should be given to patients, however the context in which cytotoxic chemotherapy is used often limits their suitability. Patient information leaflets on many of the commonly used cancer chemotherapy protocols can be found on the eviQ Cancer Treatments Online website. • Patients should be advised of the importance of notifying dentists, doctors and other healthcare professionals who may be involved in their care about their cytotoxic therapy. ***Identifying and managing adverse effects*** • Cytotoxic chemotherapy causes many adverse effects such as nausea, vomiting, bone marrow suppression, stomatitis, diarrhea, hand-foot syndrome, peripheral and central neurotoxicity, renal and liver dysfunction and hair loss. The effects require careful monitoring, and supportive therapies may be needed to minimize them. • Antiemetics should be prescribed according to the emetogenic potential of the chemotherapy. Nausea and vomiting can continue for several days after a dose of chemotherapy and the duration of antiemetic therapy should take this into consideration. Guidelines exist for prescribing antiemetics with cancer chemotherapy. • Blood counts need to be frequently checked with cytotoxic therapy. Patient monitoring, including laboratory tests and the parameters for initiating the next cycle of chemotherapy, should be clearly defined in the protocol or treatment plan. For example, a neutrophil count of greater than 1 x 10^9 is usually required for a cycle of cancer chemotherapy to proceed.

Author/ Organization Year	Recommendations
	• Particular care should be taken with patients when the cytotoxic therapy is taken continuously, for example cyclophosphamide or chlorambucil, as severe myelosuppression can develop. Cytotoxic chemotherapy can adversely affect liver and renal function and these should be monitored before each course of therapy.
Clinical Oncological Society of Australia, 2008	**Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy** **Note:** This guidance is intended for a multi-disciplinary audience however only information related to community pharmacy are reported below. **Dispensing of Chemotherapy and Related Treatment.** **The Role of the Pharmacist** ***Responsibility*** • The clinical verification of the drug order • The clarification and resolution of any identified discrepancies with the prescriber. • The accurate dispensing of chemotherapy, targeted therapy and related treatment. • Ensuring the appropriate preparation of treatment and that all components of the prescription are supplied in a timely and safe manner. • Ensuring that all professional and legal responsibilities with respect to dispensing are met. ***Competency and skills*** • The pharmacist should have the appropriate training, knowledge and skills in cancer chemotherapy as defined by the SHPA Standards of Practice for Clinical Oncology Pharmacy Services. • Pharmacists with insufficient knowledge or experience in cancer treatment should not be delegated to manage patients receiving chemotherapy and related treatment. • The application of competency testing for the verification and dispensing of chemotherapy should be considered for all staff involved in these tasks. ***Clinical Verification*** • A written, up to date procedure for verification of the order should be available. • Resources should enable the pharmacist to verify an order away from distractions and interruptions to maximize safety. • An independent check by a second person should be performed when possible. • Calculations performed manually should be independently checked. • For computerized systems, a validation process must be implemented to ensure accuracy of automated calculations. • In verifying the prescription the pharmacist must have access to the drug order. ***Oral anti-cancer therapy*** • Staff dispensing oral anti-cancer medicines in the community setting must have access to the above information. • In addition, access to a pharmacist with experience in cancer treatment at the hospital where treatment is initiated should be available. ***Labelling***

Author/ Organization Year	Recommendations
	• A uniform labelling method must be applied to ensure easy identification of the drug, route, dose and patient. ***Preparation and Delivery*** • The process of clinical validation of the order and the actual preparation of the chemotherapy and targeted therapy should be considered as two separate functions. • Preparation processes must be performed according to Australian standards and the SHPA Preparation of cytotoxic drugs and the transportation of cytotoxic drugs. • The preparation process must ensure that the therapy is stable in the required diluent for the required length of time. • There must be a reconciliation check with the product and the prescription before issue. • Where preparation is carried out off-site by a 3rd party there must be a process in place to ensure the final prepared product is checked by the pharmacist responsible for the clinical verification of the order. • The product should be checked against the original order before being handed over to nursing staff for administration. • The therapy must be delivered to 'the right place at the right time for the right person' to enable treatment to commence. • All chemotherapy must be delivered separately from other drugs in a plastic hard walled container dedicated to the purpose. • All intrathecal doses for cancer therapy must be dispensed and packaged separately from other chemotherapy. • All intrathecal chemotherapy should be stored in a designated and clearly labelled storage container in the pharmacy until the patient is ready for the Intrathecal administration. • This container must only be used for Intrathecal doses. • On receipt of the intrathecal dose a signature should be requested by either the authorized nurse or doctor attending to the patient receiving the intrathecal therapy. ***Dispensing Intrathecal chemotherapy*** • All intrathecal doses for cancer therapy must be dispensed and packaged separately from other chemotherapy. • All intrathecal chemotherapy should be stored in a designated and clearly labelled storage container in the pharmacy until the patient is ready for the Intrathecal administration. • This container must only be used for Intrathecal doses. • On receipt of the intrathecal dose a signature should be requested by either the authorized nurse or doctor attending to the patient receiving the intrathecal therapy. The chemotherapy order details to be verified by the pharmacist and Details required for labelling chemotherapy and targeted therapy are provided in Appendix C, table 1 and table 2 respectively.

Author/ Organization Year	Recommendations
Clinical Oncological Society of Australia and Cancer Pharmacists Group, 2013	**Requirements for clinical pharmacy services for every cycle of chemotherapy** ***Pre-treatment medication interview with patient*** The pharmacist is responsible for medication reconciliation, identification of potential medication issues (e.g. due to co-morbidities and previous adverse drug reactions), and counselling about pre and post treatment medicines. ***Pre-treatment clinical review of intended treatment plan*** • The pharmacist should work to medical staff and nursing to confirm doses based on weight and body surface area (BSA), manages anticipated medication issues (e.g. due to co-morbidities and previous adverse drug reactions), renal, cardiac and liver function. • The time required for the pre-treatment medication interview and review is 30 minutes. ***Clinical review of patient prior to each cycle*** • The pharmacist verifies the dose of every medicine in the cycle of therapy, according to the protocol, patient treatment plan and patient parameters. Prior to each cycle of chemotherapy the patient's weight, BSA, renal function, FBEs, LFTs and U&Es are reviewed and if required, changes to the doses of chemotherapy and support medicines are made. • The pharmacist clarifies and resolves any identified discrepancies with the prescriber. Clinical verification for each cycle of chemotherapy required on average 13 mins per patient per cycle (range 42-12 mins). 37% of orders required further communication to progress the order to the supply stage and took on average 4.6 mins per patient. • The total time required per cycle for clinical validation is 17.6 minutes. ***Manufacture, release and administration of each dose*** • The pharmacist is responsible for accurately preparing each chemotherapy medicine, in an appropriate delivery device, under controlled conditions to ensure that each dose is ready for administration without further manipulation. • Following a final check, all chemotherapy, fluids and support therapies are dispensed and made ready for the patient in a timely and safe manner. ***Discharge medicine provision and advice*** • The patient receives discharge medicines including medicines to control nausea and vomiting and pre-medications to be taken prior to the next cycle of chemotherapy. • The pharmacist counsels the patient on the use of all these medicines. ***The chemotherapy order details to be verified by the pharmacist is provided in Appendix C table 1***
EVI Q, NR	**Seven steps in the verification process for oral antineoplastic prescriptions.** • ***Prescription***

Author/ Organization Year	Recommendations
	Does the prescription adhere to standards as determined by relevant state Poisons and Therapeutic Goods Regulations? • **Protocol** Many oral antineoplastic drugs are given as part of a treatment protocol. A well written prescription should contain the name of the specific protocol being used. This may be an eviQ Treatment Protocol or a local protocol. • ***Patient*** Patient specific details, including height and weight, are often required for a comprehensive and accurate verification of an oral antineoplastic prescription. • **Administration** Does the patient understand how to take the medication? Information on drug administration can be found within the eviQ Treatment Protocol, including: • Whether the treatment is continuous or intermittently dosed • Timing of doses and requirements for dosing in relation to food • Any supportive therapies which may be indicated (e.g. antiemetics). It is the pharmacist's role to ensure all administration instructions are clear and unambiguous, and the patient knows when to commence the medication. • ***Calculations*** Calculations should always be checked even if done by the prescriber. Calculations which may be required to verify the doses of oral antineoplastic drugs include: • Body surface area (BSA) or weight (kg) based calculations using the treatment protocol ; • Rounding of doses to tablet/capsule size; • Dose adjustments. • **Test results** It can be difficult to access a patient's test results in the community pharmacy setting; however the patient may be able to share their results with you. If concerned discuss with the prescriber. • **Sign off** By verifying a prescription and signing-off the pharmacist acknowledges that a complete and comprehensive process has been undertaken to ensure that the medication given to the patient is as safe as possible for them. Additional aspects of the sign-off include dispensing the prescription, supplying the medication and counselling the patient or carer. **Dispensing and supply** • The labelling of oral antineoplastic drugs should clearly state the dose and the number of tablets to be taken.

Author/ Organization Year	Recommendations
	• The intended period of therapy including start and stop dates for short term or intermittent treatment should be clearly stated on the dispensed label of an antineoplastic drug. • If the drug is to be taken on days 1 to 4 inclusively then the label must specify the actual calendar dates. • The label of weekly dosing for medicines such as methotrexate and vinorelbine should include the term 'once a week' and specify the day of the week the dose should be taken. An additional label should also be added: This dose of 'drug x' is taken WEEKLY. • If the prescriber has not included these details on a prescription, the pharmacist should firstly speak with the patient. They are often familiar with the day of the week that they take their medication or the start and stop dates. The pharmacist also need to contact the prescriber. This is x of y number of containers containing the same medicine. Please use the contents of one container before starting another. • 'As directed' should never be used to label oral antineoplastic medications regardless of the doctor's instructions or of the patient's knowledge of the dosing regimen. • Pharmacist should contact the prescriber to provide clear instructions for labelling any oral antineoplastic drugs. • Doses should be rounded to the nearest tablet size. If not, the prescriber should be contacted to confirm a measureable dose. • Oral antineoplastic tablets and capsules should not be broken, split or crushed as this can increase the risk of exposure and alter the bioavailability of the medicine. • If the patient is required to take TWO different strengths of tablets to make up the dose then the dose instructions must include the number of tablets to take of each strength and the total dose. • Steps must be taken to highlight the different strengths of the same drug to aid patient understanding
SHPA Committee of Specialty Practice in Cancer Services, 2007	**SHPA Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer SHPA Committee of Specialty Practice in Cancer Services** ***Prescription Verification*** • Prior to dispensing a prescription for oral chemotherapy it must be screened by a pharmacist with experience in cancer chemotherapy who will accept responsibility for the clinical safety of the prescription. • To ensure optimal and appropriate treatment, all chemotherapy must be prescribed in the context of a referenced protocol and ideally on a specifically designed chemotherapy prescription form. • The prescriptions must state clearly for each course of treatment, the drug, dose, route and frequency of administration, intended start date, duration of treatment, and where relevant, the intended stop date. • Pharmacists must have access to a documented treatment plan and to full copies of the relevant protocol. Pharmacists must:

Author/ Organization Year	Recommendations
	*ensure that prescribed doses, treatment intervals and administration details are appropriate to the patient's demographics, tumor type, hematological and biochemical profile, organ function and chosen Treatment protocol; *Verify that the maximum and cumulative doses of all chemotherapy doses prescribed are not exceeded; *Check that all chemotherapy drugs listed in the protocol have been prescribed including those to be administered by other routes; *Check that additional supportive drugs relevant to the treatment protocol have been prescribed and are appropriate for the protocol, the length of the course and the patients, e.g. antiemetic's, colony growth stimulating factors; *Be aware of the toxic and therapeutic effects of the medicine and identify interactions with other drugs; *Ensure that the appropriate medicines are supplied in an efficient and timely manner according to the patient's treatment plan; and *verify with the original prescriber any anomalies identified during this checking process. Incorrect or missing details must be corrected by the prescriber prior to dispensing. • All cancer chemotherapy must be subject to a second independent check to verify all prescribing and dispensing details. • The second check must include a clinical check, label check, contents check and a check to ensure the correct Number of tablets has been supplied. Pharmacists carrying out this task must have the training and skills in cancer chemotherapy. • If such a pharmacist is not available then a pharmacist or nurse with competency in chemotherapy and with access to specialist advice relating to cancer care must carry out this task. • Where a patient is admitted to hospital and is already receiving oral chemotherapy the original prescriber must be contacted to verify all details of the treatment including the dose, frequency of administration, duration of treatment and, where relevant, the intended stop date. • A documented treatment plan and a copy of the relevant protocol must be obtained before supply or administration of the medicine is made. ***Quantity to Supply*** • Pharmacists should only supply the quantity of tablets/capsules requires for that cycle of treatment. • The use of whole packs may pose a risk to patients if they contain more tablets than are needed for the cycle. • The decision to issue whole packs must be based on the judgement of pharmacists experienced in cytotoxic chemotherapy and may depend on local policy. • If a whole pack is issued then the following label must be added: *You will have xxxx Number of tablets remaining at the end of this course. Please return unused tablets to your pharmacist for destruction or for use for your next course of chemotherapy.*

Author/ Organization Year	Recommendations
	• Where a hospital inpatient commences a course of oral chemotherapy that will continue after discharge from hospital then the total quantity of tablets/capsules the patient requires for the entire course should be supplied. • In these circumstances it is appropriate to supply oral chemotherapy with directions for outpatient use and instruct the nursing staff to return the remaining tablets to pharmacy for inclusion in the patient discharge medication on discharge from hospital. • If an inpatient is receiving oral chemotherapy at the time of discharge to complete a course that has commenced as an inpatient it is important to consider the Number of tablets the patient needs from the time the patient is due to leave the hospital, taking into account any morning or midday doses. • Where a patient is admitted to hospital and is already receiving oral chemotherapy the doctor must make a decision as to whether the treatment should continue. • In many cases this may require consultation with the original prescriber. • Where a decision is made to continue with treatment the patient's own supply should be used wherever possible. • Pharmacists should verify the suitability of the medicine for use by patients in the hospital. If a new supply is required the quantity supplied must be appropriate for that course. • Oral cytotoxics must not be made available as imprest or ward stock. • Repeat prescriptions preferably should not be issued for oral chemotherapy due to the risk of mis-dosing. • However, many prescribers may use this option within the Pharmaceutical Benefits Scheme (PBS) regulations and this will depend on local policy. • Chemotherapy doses may change according to blood results, adverse effects and therapeutic response. • If a repeat prescription is presented for a second or subsequent course then the pharmacist must confirm with the prescriber and patient that there has been no change to the dose or overall treatment since the original prescription was issued and before supply is made. If treatment is changed or stopped the patient must be directed to destroy any repeats or return them to the doctor or pharmacy to avoid any inadvertent dispensing. ***Labelling*** • Labelling for cytotoxic chemotherapy should use generic names particularly where there is more than one manufacturer for the product. • Where local policy dictates the use of trade names a reference should be included in the labelling to the generic name. • As well as standard labelling requirements the directions on the label must include: *Clear and unambiguous dosing instructions; 'as directed' must never be used regardless of the doctor's instruction or of the patient's knowledge of the dosing regimen; *The intended period of treatment (i.e. Number of days); *Start and stop dates for short-term or intermittent treatment.

Author/ Organization Year	Recommendations
	*The total dose required. If patients are required to take two different strengths of tablets to make up the dose (e.g.capecitabine 150 mg and 500 mg) then the instructions must be labelled with the Number of tablets to take and the total dose. Steps must be taken to highlight different strengths of the same tablets/capsules to aid patient understanding; *All boxes/bottles must contain a label. Boxes must never be taped together with a label on one box. When more than one container of the same medicine is given then the following label (or similar) must be used: *This is x of y Number of containers containing the same medicine. Please use the contents of one container before starting another;* *Doses of chemotherapy that are intended to be taken weekly (e.g. methotrexate, lomustine, vinorelbine) must include on the label the term 'once a week' and specify the day the dose is due, e.g. once a week on a Tuesday. An additional label should also be added: *This dose of 'drug x' is taken WEEKLY. Check your dose carefully;* *A label indicating appropriate storage requirements must also be added (if required); *Cautionary and advisory labels as required must be added to the container; and *Dispensed containers of cytotoxic drugs (e.g. capsules) must be clearly labelled with a cytotoxic warning sticker in accordance with local health and safety requirements. • Suggested labelling is a permanent, adhesive purple cytotoxic warning label with the distinctive warning: *Cytotoxic, Handle with Care* ***Health and Safety*** • Oral chemotherapy must be handled in a manner which avoids skin contact, the liberation of aerosols or powdered medicine into the air and cross-contamination with other medicines. • Preference should be given to manufacturers that package tablets and capsules in protective strip packaging. If there is a need to cut the blister strips then it must be ensured that the tablets/capsules are not exposed. • The use of gloves to dispense oral cytotoxic drugs is recommended and hands must be washed thoroughly after each dispensing. • Loose tablets/capsules must be counted using designated counting trays and spatulas labelled specifically for that purpose. • Counting machines must not be used and the actual tablets or capsules must not be touched. All trays and spatulas must be cleaned after each use with water and detergent. • When tablets/capsules are supplied in glass bottles then pharmacists must confirm whether other containers are suitable for dispensing or whether it is essential that the glass bottles be used to avoid any adverse storage effects on the drug. • Child-proof caps must be used when dispensing non blister packs of containers of oral chemotherapy for use outside the healthcare setting. • When a dose administration aid (e.g. Webster pak) is needed by the patient then this must be filled by the pharmacist dispensing the chemotherapy and labelled with relevant instructions and a cytotoxic warning label. • Other non-cytotoxic medication must not be placed in the same pack.

Author/ Organization Year	Recommendations
	• Crushing or cutting of tablets and opening of capsules must not be carried out in the pharmacy outside a Class II cytotoxic drug safety cabinet because of the unacceptable risk of exposure. • In situations where a fraction of a manufactured dose has been prescribed then an alternative formulation should be sourced or the prescriber should be contacted to discuss alternate dosing regimens that use whole tablets. • Doses may be rounded up or down where the actual dose is close to the strength of a whole tablet. Alternate day dosing to make up the total weekly dose is a method that is frequently employed. (e.g.if cyclophosphamide is to be given as 175 mg daily for 2 weeks this may be given as 200 mg on one day and 150 mg on the next as alternate day dosing to ensure the correct total dose). • This method however is not suitable for all cytotoxic drugs and specialist advice must always be sought. • If the medicine is to be administered via a nasogastric tube, or if patients are unable to swallow tablets/capsules, appropriate formulations must be obtained from manufacturers with the facilities to compound non-sterile cytotoxic drug preparations. • Currently the availability of such facilities is limited. • A cytotoxic drug safety cabinet used to prepare aseptic parenteral cytotoxics should not be used to prepare non-sterile items. • The risk of particulate contamination and cross contamination of the cabinet and the cleanroom is very high • All layers of the packaging and containers for use in hospital and outside the health care setting must have a cytotoxic warning label, including the outer bag that contains the supply. • Oral cytotoxic drugs must be identifiable by all workers and must be stored on designated shelves or in an area clearly labelled with cytotoxic stickers ***Patient Education and Information*** • All patients and/or carers must be educated on how to take their medication to ensure they receive optimal benefit of chemotherapy and to minimize any opportunity for medication administration errors. • This education must be carried out by staff who have received appropriate training. • When medicines are handed to patients by non-pharmacy staff or where the supply is made to a non-oncology ward in a hospital or nursing home, procedures must be in place to ensure nursing staff are aware of the nature and effects of the treatment being given and steps to take in case of an adverse event. • Chemotherapy has many unavoidable toxicities and patients must always be counselled before they start treatment as to the overall nature of these effects and what to expect. • Pharmacists must ensure that they work in conjunction with the medical and nursing staff in providing this type of information to ensure accuracy and appropriateness. In some cases, patient counselling may be carried out by the oncology pharmacist or as part of a formal patient education session but this will depend on local policy.

Author/ Organization Year	Recommendations
	• Clear written instructions and/or medication guides for both chemotherapy and supportive therapy are essential in this setting along with the use of consumer medication information (CMI). • Diaries may be used by patients to help them remember when to take medications and to record any adverse effects. • The nature and context in which chemotherapy drugs are used often limits the availability or suitability of CMIs, as chemotherapy may be used outside the Therapeutic Goods Administration indications or as part of a protocol which may induce possible effects not listed in CMIs. • Guidance on how to use CMI may be found in the SHPA Standards of Practice for the Provision of Consumer Medicines Information by Pharmacists in Hospitals. • CMI must be given if available, and in addition institutions may have developed their own information leaflets which are suitable for use. • Pharmacists must ensure that information contained in any such leaflet has been verified and approved by the hospital drug and therapeutics committee or similar professional judgement must be used when deciding on appropriate and relevant information. • Patients may be given a wealth of information from many members of the team caring for them and may become confused with too much information. • Patients must be provided with details of accessible 24-hour contact with medical, nursing and pharmacy staff to whom they can direct queries. • This information must be given on the first visit and reinforced on subsequent visits. • Questions on compliance, treatment tolerability, and adverse events must always be addressed at each visit to the pharmacy. ***Resources*** • Resources should be sufficient to ensure the above procedures are able to be performed in a safe and accurate manner for staff and patients. ***Staffing structure and levels*** • There should be sufficient suitably qualified staff to dispense all prescriptions in the manner described above. ***Staff training and education*** • Pharmacists dealing with oral cytotoxics must have appropriate training and skills in cancer chemotherapy as defined by SHPA Standards of Practice for the Provision of Clinical Oncology Pharmacy Services. • If such a pharmacist is not available then a qualified pharmacist with competency in chemotherapy treatment and with access to specialist advice relating to cancer care must carry out this task. • Staff with insufficient knowledge or experience in cancer treatment must not be delegated to manage the supply of oral chemotherapy. • Nurses and other staff in the inpatient setting should be educated on the precautions necessary to minimize the risks associated with handling and administering oral chemotherapy. ***Quality***

Author/ Organization Year	Recommendations
	• The fundamental quality components of the provision of pharmaceutical care of patients receiving oral chemotherapy for cancer are referred to in previous sections. • Implementation of the standard ensures the quality of service provision. • Further quality principles and measurements applicable to this standard are referred to in the SHPA Standards of Practice of Clinical. • Pharmacy and for the provision of clinical oncology services. ***Documentation*** • Documentation should include the treatment plan and a copy of the relevant protocol where appropriate. Provision of a CMI and other relevant patient information must be noted
State government Victoria, 2010	**Recommendations to be followed before prescribing, dispensing or administering oral chemotherapy for cancer** ***Check the information provided from the treating oncologist and patient*** • Review documentation to establish that there is ready access to a treatment plan with contact details for the treating oncologist or hematologist. • Establish if the patient has been provided with instructions for which days they should take their orally administered cancer chemotherapy and which days they should not (this may be in the form of a calendar or schedule). • Determine if the patient is taking any other medicine, either prescribed or over the counter, that may interact with the orally administered cancer chemotherapy. • Establish if the patient requires or has recently had a blood test (and if so request the results) and ask the patient for their current weight and height. • Establish if the patient is already taking the orally administered chemotherapy and if they have experienced any side effects. ***Check the treatment plan against the prescription*** • The treatment plan should include: *Patient details including height and weight. *The diagnosis. *Details of the prescribed protocol (sometimes called a regimen or pathway). *Including the treatment schedule. *Instructions for the timing of blood tests. *Directions for any dosage changes. *Instructions on when to refer the patient back to the treating specialist or a hospital emergency department, setting (eg severe side effects such as fever, weight loss, abnormal blood tests, or on a set date or number of treatment cycles). *Name and contact details for the oncology specialist. • Ensure that prescribed dosages and directions are consistent with the information provided in the treatment plan: *Check the orally administered chemotherapy dosage. Some cancer chemotherapies are based on patient

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	weight or body surface area. You may need to perform a body surface area (BSA) calculation which gives a value as m^2 before calculating the medication dosage. *Check if the orally administered chemotherapy regimen or dosage should be altered as a result of significant changes in patient parameters such as patient weight, blood tests or side effects. • Clarify any unclear or confusing instructions regarding the dosage, regimen, or monitoring requirements with the treating medical oncologist prior to prescribing, dispensing or administering the treatment. • Where possible, supply only the required quantity of medication to complete a given cycle, (rather than the PBS quantity/manufacturer pack which may exceed requirements.) • Check that supportive therapies (for example, antiemetics for nausea and vomiting) are prescribed or have already been supplied. ***Ensure the patient and/or carer understands the prescribed instructions for the oral chemotherapy.*** • Take particular care that the patient clearly understands the cycle length, the number of days on active treatment, when not to take the treatment and laboratory test requirements. Consider providing a calendar with the days clearly marked with when to take active treatment if not already available. • Ensure the patient understands the indication for each medication, the expected side effects, management of side effects and has contact details for specialist advice. ***Ensure the patient and/or carer understands how to handle and store the prescribed oral chemotherapy*** • Orally administered chemotherapy that is cytotoxic, must be clearly labelled and any containers used clearly identified with a purple cytotoxic warning (ancillary) label by the dispensing pharmacist. *Oral cytotoxic medications must be swallowed whole (not cut or crushed). *Oral cytotoxic medications should not be filled in a dose administration container (for example, Dossette, Webster pack) with other medications. If a dose administration container is necessary, the cytotoxic medication must be filled in a separate, clearly labelled 'cytotoxic' container to other medications. The container must be well sealed to avoid accidental opening. *If oral cytotoxic medications are to be administered by a carer or staff in an aged care facility, instructions must be supplied to use protective gloves (for example, powder free nitrile or latex gloves) when handling to avoid occupational exposure. *Carers and staff should also be instructed that cytotoxic exposure may also occur through exposure to body fluids and waste. Appropriate instructions must be available for handling of bodily fluids and linen or clothing contaminated with bodily fluids. Precautions should continue for up to seven days after the completion of a treatment cycle.

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	• All medication must be stored as per temperature requirements and safely out of reach of children.

Table 2. The Netherland's Guidelines

Author/ Organization Year	Recommendations
Simons-Sanders & Crul, 2013	-Clinical rule Clinical rule on safe methotrexate prescribing and dispensing • Every prescription for methotrexate should be checked for indication. • The pharmacy computer or the CPOE can be set to give an alert for each dose of methotrexate, whether it is correct or not, to facilitate the checking process stated above • Methotrexate should only be stored in the hospital pharmacy and not on the wards. • Each methotrexate weekly prescription should be dispensed for a maximum of one week; this should be recorded per patient with the date of dispensing, in order to prevent another employee from dispensing the methotrexate again the next day. • In the hospital pharmacy store, a message should be displayed in the methotrexate area reminding everyone not to dispense for more than one week. • Physicians, nurses and pharmacy technicians should be trained about methotrexate. Standard operating procedure about processing a methotrexate medication order for a clinical patient • All methotrexate products are at product level in the CPOE (Theriak and Navision Pharma), flagged as consultation medicine to ensure that medication orders for these products are always caught in the buffer zone. This means that every methotrexate medication order is reviewed by a pharmacy technician and a hospital pharmacist before being dispensed; • Orders for methotrexate solution for injection or infusion, methotrexate tablet, or liquid preparation for clinical patients, are entered into the CPOE by the physician or nurse, or submitted as a medication order to the distribution department of the hospital pharmacy. In the latter case, the pharmacy technician of the distribution department enters the order in the CPOE; • On entering methotrexate into the CPOE, the medication order is transferred to the medication alert buffer of the pharmacy technician and the hospital pharmacist on duty; • Every day, a distribution pharmacy technician has 'methotrexate duty' to coordinate orders and dispensing, and to communicate with the preparations department about methotrexate injections, infusions and methotrexate liquid preparation, and the logistics department about methotrexate tablets; • The preparations department dispenses methotrexate for injection (on indication of psoriasis, rheumatism or Crohn's disease) or infusion (oncological indications); methotrexate liquid preparation for paediatric oncology can only be dispensed on the basis of a medication order authorized by a hospital pharmacist; the logistics department dispenses methotrexate tablets; and

	• The labels of the methotrexate syringes for indication of psoriasis, rheumatism or Crohn's disease, and the labels of methotrexate IV solutions, are provided with a bar code for administration recording purposes.

Table 3. United Kingdom's Guidelines

Author/ Organization Year	Recommendations
BOPA, 2010	**The BOPA Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines (January 29, 2010)** • The updated version of The BOPA Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines was published in 2013 and was described in this table.
BOPA, 2010	**Guidance to Support BOPA Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines (March 2010, Expired 2012).** The BOPA Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines is described below (Updated version). **Training Requirements** • All prescriptions for anticancer medicines must be verified by *an oncology pharmacist, who has undergone specialist training, demonstrated their appropriate competence and is locally authorized/ accredited for the task.'* This is a required of the DH 'Quality and Safety of Chemotherapy Services'. • A single pharmacist must be identifiable as having validated the prescription. It is recognized that there may be some delegation/ sharing of verification to suit service models, i.e. technician checking. • All members of staff undertaking the role must have demonstrated suitable competence and be locally accredited for the task. It is recommended that local competency training programs for verification of oncology pharmacy. • Staff include as a minimum: *A documented training program listing the areas of competency and knowledge required. *A list of specific competencies that must be obtained, note BOPA competencies provide a template of suitable competencies as does the Skills for Health PHARM56 standard. The Specialist Curriculum Group are also developing competencies for clinical pharmacy that include oncology (http://www.specialistcurriculumgroup.org/). *A period of supervised verification of chemotherapy prescriptions. During this period all prescriptions should be double checked by trained and competent pharmacist(s) and log sheet recording each prescription/ item maintained. Note a suitable minimum number of items for the log sheet should be agreed locally. It is suggested that 50 items should be the minimum and must include a variety of different prescriptions that reflect local case mix. *Signature of pharmacist clinical lead responsible for cancer services confirming that the individual is competent and entry into Trust list of 'designated pharmacists' who are competent to verify cancer medicine prescriptions.

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	• It is recognized that in some organizations it may not be possible to always ensure that all oral prescriptions are verified by a trained oncology pharmacist e.g. when oral prescriptions are presented to dispensary staff. Trusts must therefore ensure that appropriate training and accreditation on the safety aspects of oral anticancer medicines is provided to any pharmacy staff involved in dispensing and supply of these medicines. Oral SACT poses the same as risks as IV SACT. Trusts should work towards only having trained oncology pharmacists checking all prescriptions for SACT. • In order to support dispensary staff involved in the dispensing and supply of oral anticancer medicines, there must always be available in the organization a trained oncology pharmacist who is able to provide oncology pharmacy advice to dispensary staff. • Further work is ongoing in defining specific educational competencies outlining the knowledge and understanding that an appropriately trained pharmacist verifying a prescription must have. • The Centre for Pharmacy Postgraduate Education (CPPE) has produced a distance learning package 'Cancer: in relation to pharmacy practice' which provides 10 hours of training. It is suggested completion of this package could be used as part of the background knowledge that underpins the competency training.
BOPA, 2013	**BOPA Standards for Pharmacy Verification of Prescriptions for Cancer Medicines (2013)** ***The Purpose of the BOPA Standards***[h] • The Department of Health requires that all chemotherapy prescriptions should be checked and authorized by a pharmacist. • The National Cancer Action Team report into the 'Quality and Safety of Chemotherapy Services' published in August 2009 states 'All chemotherapy prescriptions should be checked by an oncology pharmacist, who has undergone specialist training, demonstrated their appropriate competence and is locally authorized/ accredited for the task.' • The Scottish Government Health Department sets out its guidance in the Chief Executive Letter 30 (2012) • Guidance for the safe delivery of SACT. It states "All prescriptions for SACT are verified by a suitably trained pharmacist in accordance with legislative requirements, national standards and local policy prior to dispensing and release from pharmacy". • This document describes what key steps a pharmacist must take when checking prescriptions for anticancer medicines. • For the purposes of this document this will be referred to as '**Verification'**. Verification provides assurance that the prescribed treatment is tailored and correct for the patient and their specific disease.

[h] This the updated version of BOPA Standards for Clinical Pharmacy Verification of Prescriptions for Cancer Medicines (January 29, 2010)

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	• It provides a check on treatment accuracy and is essential to avoid medication errors. Cancer medicines must not be administered to, or taken by patients until an appropriately trained pharmacist has verified the prescription. ***1. The scope of the BOPA standards*** • This document does not describe any novel clinical practice; it brings together established pharmacy practice and presents it in the form of standards. • This document can be used alongside the performance criteria listed in 'PHARM56/ PHARM57: Verifying a prescription for chemotherapy against a protocol/ without using a protocol' listed on the Skills for Health website. • This guidance applies to parenteral and oral administration of SACT including chemotherapy and non-cytotoxic medicines. • This document must be used in conjunction with local organization/ Cancer Network/Health Board Policies on Medicines Management and safe use of SACT and the following national guidance documents: *Royal Pharmaceutical Society Professional Standards for Hospital Pharmacy July 2012. *Manual of Cancer Service Standards. Chemotherapy Measures DOH 2011. *Dispensing and Supply of Oral Chemotherapy and SACT in Primary Care. Royal Pharmaceutical Society January 2011. *Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy: DOH 2008. *HSE Information Sheet MISC615- Safe Handling Of Cytotoxic Drugs,9/03. *National Patient Safety Agency (NPSA) Rapid Response Report. 'Risks Of Incorrect Dosing of Oral Anticancer Medicines.' 22Jan08. *Scottish Government Health Department CEL (2009) 21: Safe Administration of Intrathecal Cytotoxic Chemotherapy. *Scottish Government Health Department CEL 30 (2012) – Guidance for the safe delivery of systemic anticancer therapy. -Northern Irish Chemotherapy Service Standards. -Welsh Cancer Standards 2005 WHC (2005)051 Cancer Services in Wales: Publication of National Cancer Standards and the implication for Commissioners and Providers, through the Cancer Networks, 2009 (Sarcoma Services), 2010 (Rehabilitation of Adults with Cancer) and Northern Irish Cancer Standards. -The National Cancer Action Team report into the 'Quality and Safety of Chemotherapy Services' published in August 2009. -PHARM56: Verify prescription for chemotherapy against a protocol available at http://www.skillsforhealth.org.uk/. ***3. Putting the Standards into Practice*** • The BOPA Standards have been updated to reflect the changing nature of SACT use. • The BOPA standards have been simplified to seven core steps with associated secondary steps to be applied as appropriate depending on configuration of local services.

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	• Local teams should review their pharmacy verification practice and clearly document in local policy where the different levels of verification are required. • Pharmacy staff verifying prescriptions for oral anticancer medicines should operate to the same safety standards used when verifying anticancer medicine prescriptions for all other routes of administration. • SACT must be prescribed in the context of an approved protocol and prescribed via electronic prescribing system. The 2011 English Cancer Standards, measure 11-3S-139 states: '*There should be a database driven, electronic prescribing platform for chemotherapy'.* Similar directives exist for Scotland and Wales. • A rigorous validation process for e-prescribing must be in place to ensure accuracy of calculated doses. These systems must have on-going maintenance and have suitable arrangements for supervision of their use by appropriately qualified staff. Where electronic systems are not yet available/commissioned SACT must be prescribed on designated prescription forms (pre-printed regimen specific). • It is considered good practice to document identified pharmaceutical care issues that need to be monitored with SACT as part of the verification process, particularly for IV chemotherapy. This can be in a structured care planning template, as part of the electronic patient records or in the chemotherapy notes. • Clinical capacity for pharmacists to verify chemotherapy prescriptions and deliver pharmaceutical care to cancer patients must be monitored as part of the chemotherapy service capacity. • BOPA has defined specific educational competencies outlining the knowledge and understanding that an appropriately trained pharmacist verifying a prescription must have. • More detailed guidance to assist pharmacists in undertaking each of the steps required for verification is available in 'Supporting Guidance' document. ***4. Professional Responsibilities*** • Overall responsibility for the safe use of SACT and ensuring these Standards are in place should sit with an appropriate senior clinical lead within each organization. • Pharmacists verifying prescriptions are one part of the overall medicine optimization process for SACT. • This document does not describe standards for the clinical monitoring of patients receiving SACT. Pharmacists must define their responsibilities in areas where there is overlap to determine who has primary responsibility. • Chemotherapy services are varied, it is recognized that there will be differences in pharmacists' responsibilities depending on the set up of their service. • If a pharmacist prescriber (NMP) initiates a prescription a pharmacist is still required to verify the prescription. The Royal Pharmaceutical Society of Great Britain state that NMPs must 'ensure separation of prescribing and dispensing whenever possible.

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	• Where a pharmacist is both prescribing and dispensing a patient's medication, a second suitably competent person should normally be involved in the checking process.' • Pharmacists verifying prescriptions for SACT must be able to recognize situations where they need to seek advice / support from appropriate sources; in particular, where the complexity required exceeds their own personal level of competence or where there is reason for concern about the individual's suitability for the prescribed treatment. • This document refers to pharmacists when describing verification, but it is recognized that suitably competent technicians may become involved in verification of chemotherapy. In this case organization's governance leads must ensure these staff have documented competency and that clinical and corporate governance approval has been given for this professional role development ***5. Limitations*** • The clinical role of pharmacy encompasses more than verification of individual treatment episodes. • Pharmacy staff improve the risk management of anticancer medicines by medication review; patient education, clinical monitoring of patients receiving anticancer medicines and direct clinical care to anticancer medicine patients. • Anticancer medicines are also used for non-cancer indications, e.g. methotrexate for rheumatoid arthritis, and pose similar risks to the patient. Guidance for verification of prescriptions of these medicines is outside the scope of this document. • Pharmacy departments should consider if any of the standards listed can be applied to the verification of these medicines and other high risk medications. • It has been acknowledged that in many centres prescriptions for oral SACT / outpatient prescriptions may be checked in an area where there is not access to patient notes/ treatment plans. This may be appropriate depending on the complexity of the regimen, ***6. The BOPA Standards*** **1. Check the Prescription:** Has the drug or regimen been prescribed in line with legislation and local prescribing policy? • Check the prescriber's details and signature are present and confirm they are authorised to prescribe SACT as appropriate. • Check that the prescription is clear, legible, and unambiguous and includes all details required for dispensing, labelling and administration. **2. Check the Prescription Against the Protocol and Treatment Plan**This will include as appropriate/relevant: • Ensuring the regimen has been through local approval processes e.g. clinical governance and financial approval and/ or is included on a list of locally approved regimens • Where there is access to either clinical notes, treatment plan or electronic record on first cycle check the regimen is intended treatment and is appropriate for

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	patient's diagnosis, medical history, performance status and chemotherapy history **3. Check Patient Details** •Check patient demographics (age, height and weight) have been correctly recorded on prescription as appropriate **4. Check Administration Details** This will include as appropriate/ relevant: • Checking there are no known drug interactions (including with food) or conflicts with patient allergies and other medication(s). • Checking the timing of administration is appropriate i.e. interval since last treatment and/or start and stop dates for oral chemotherapy. • Checking appropriate supportive care is prescribed. • Checking method of administration is appropriate. **5. Check Calculations:** Are the BSA and dose calculations correct? • Check all dose calculations and dose units are correct and have been calculated correctly according to the protocol and any other relevant local guidance, e.g. dose rounding / banding as appropriate. • Check prescribed dose is in line with previous dose reductions. • Check body surface area (BSA) is correctly calculated if needed for dose calculation. • There should be local agreement for frequency of monitoring and checking patient's weight. **6. Check Laboratory Results as appropriate**: • Check laboratory values, FBC, U&E's and LFT's are within accepted limits if appropriate • Check doses are appropriate with respect to renal and hepatic function and any experienced toxicities • Check other essential tests have been undertaken if appropriate **7. Sign and date prescription as a record of verification**
Medicines Safety Group, 2015	**Guidance to Support the Prescribing, Dispensing and Administration of Oral Anti-Cancer Medicines in Primary Care** ***Prescribing oral anti-cancer medicines*** • All patients prescribed anti-cancer medicines for cancer should have their treatment initiated by an oncologist or hematologist and be under the care of these specialist staff. • Ongoing prescribing for these patients should always remain the responsibility of the hospital-based oncologist or hematologist. • Sheffield Teaching Hospitals (STH) NHSFT has local policies in place regarding oral and parenteral chemotherapy. • All correspondence from STH should emphasize that oral anti-cancer medication for cancer treatment should be prescribed by a specialist only, with the exception of hydroxycarbamide, when prescribed under the shared care protocol.

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	• Verbal and written information is supplied to the patient by STH when oral anti-cancer medicines are prescribed for cancer. ***Dispensing oral anti-cancer medicines*** • Ongoing dispensing of oral anti-cancer medicines for patients with cancer should always remain the responsibility of the hospital pharmacy. • Appropriate links to cancer websites have been added to the NHS Sheffield Community Pharmacy • Signposting Guide to provide information to ensure the safe use of oral anti-cancer medicines. ***Administering oral anti-cancer medicines*** • The dose, frequency of administration and duration of treatment should be confirmed before administration of oral anti-cancer medicines prescribed for cancer. ***Exceptions Oral anti-cancer medicines used for non-cancer indications*** • Where oral anti-cancer medicines are used for non-cancer indications primary care may take over the prescribing. This should only occur when the patient is stabilized. The GP and hospital specialist team must agree who is to be responsible for prescribing and monitoring. • Shared Care Protocols for oral anti-cancer medicines, used for non-cancer indications, can be found here: *Mercaptopurine, Methotrexate. Hydroxycarbamide is prescribed on a limited basis for cancer indications by GP practices in close collaboration with the haematologists. This involves dispensing by community pharmacists. *The haematologists will communicate with the patient's nominated community pharmacist details of the current dose, as set out in the hydroxycarbamide shared care protocol. The Shared Care Protocol for hydroxycarbamide can be found
The National Patient Safety Agency (NPSA), 2008	**NPSA Guidance intended to promote the safe use of the medicines listed to treat cancer** Doctors, nurses, pharmacists and their staff must be made aware that the prescribing, dispensing and administering of oral anti-cancer medicines should be carried out and monitored to the same standard as injected therapy. This requires that: • Healthcare organizations should prepare local policies and procedures that describe the safe use of these oral medicines. • Treatment should be initiated by a cancer specialist. • All oral anti-cancer medicines should be prescribed only in the context of a written protocol and treatment plan. • Non-specialists who prescribe or administer on-going oral anti-cancer medication should have ready access to appropriate written protocols and treatment plans including guidance on monitoring and treatment of toxicity. • Staff dispensing oral anti-cancer medicines should be able to confirm the prescribed dose is appropriate for the patient, and that the patient is aware of the required monitoring arrangements, by having access to information in the written

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	protocol and treatment plan from the hospital where treatment is initiated and advice from a pharmacist with experience in cancer treatment in that hospital. • Patients should be fully informed and receive verbal and up-to-date written information about their oral anticancer therapy from the initiating hospital. • This information should include contact details for specialist advice, which can be shared with non-specialist practitioners. • Written information including details of the intended oral anti-cancer regimen and treatment plan including arrangements for monitoring, taken from the original protocol, should be given to the patient. • When shared with pharmacists and dispensing staff, this would enable the above dispensing requirements to be satisfied. • Full use should also be made of NHS cancer centre web sites to provide information for healthcare staff, patients and carers to ensure the safe use of oral anti-cancer medicines. **What form should the expert guidance from the specialist centre take?** • Written advice giving clear unambiguous instructions regarding the following: • Regimen and doses (including all oral anti-cancer medicines to be used and elective essential support drugs in addition to anti-emetics). Dosing may be mg/kg, mg/m2 or mg/frequency per day. • Route of administration. • Number of cycles intended. • Frequency of cycles and of administrations within a cycle. • Investigations necessary prior to starting the whole course. • Monitoring to be performed serially during the course (to detect/monitor both toxicity and response) and their intended frequency. • Guidance on management of toxicity and the possible need for dose modifications. • For palliative, curative and neo-adjuvant treatments (any treatment other than adjuvant); the maximum number of cycles after which the response to treatment is to be reviewed prior to continuing the course
Royal Cornwal Hospital, 2015	**The Safe Handling and Administration of Cytotoxic Products for the Treatment of Cancer** • The Safe Handling and Administration of Cytotoxic Products for the Treatment of Cancer includes prescribing, dispensing, training, transportation, administration and storage.
South East London Cancer Network (SELCN), 2012	**Standards For Dispensing And Supply Of Oral Anticancer Medicines (**only information related to primary care is provided below) ***Primary care*** • The dispensing of oral anticancer agents in primary care is unusual, as described above (section 4.2) there should be no prescribing of SACT in primary care. • Prescribing for supply by community pharmacies should be under the care of the oncologist in secondary care.

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	• Community Pharmacists should have copies of or access to the written protocols for each patient's protocol and treatment plan from the initiating hospital. • They should have contact details for an oncology pharmacist at the initiating hospital. • Before dispensing such drugs the community pharmacist should ensure that they are able to confirm the following: the prescribed dose is appropriate for the patient and the patient is aware of the monitoring arrangements. • Compliance: 100% of patients. ***Dispensary Standards*** • The pharmacist must ensure the directions on the prescription are clear and unambiguous and include, where relevant, the intended period of treatment, including start and stop dates. • The exact quantity of tablets/capsules required must be supplied. Where pack sizes or splitting or opening packs is likely to affect the integrity of the medication the pharmacist should contact the prescriber for clarification. Where an overage is supplied the pharmacist must ensure that the patient or carer is fully informed of how many tablets will be left and the exact stop date. • The quantity must be physically checked by counting the number of tablets/capsules. • A different member of staff should final check the prescription from the member of staff who dispensed the prescription. • All patients must receive a manufacturer's Patient Information Leaflet, with their oral anticancer medicines. • Pharmacy staff must not break or crush tablets, capsules must not be opened. Queries about difficulties in taking the oral form should be directed to a specialist pharmacist. Use of a suspension or solution is preferred and a suitable preparation must be obtained from an NHS hospital pharmacy or commercial compounding/manufacturing facility with appropriate safe-handling facilities. It must be noted that in many cases there are no liquid alternatives, in these cases refer back to original prescriber. • Use of compliance aids is not routinely recommended. If there is thought to be a need a risk assessment must be undertaken. • Label directions must be clear and unambiguous and include where relevant; the intended period of treatment; start and stop dates or the number of days expressed as **'for X days ONLY'** to indicate that the medicine is not continuous (for short term or intermittent treatment); an appropriate indication of the need for safe handling. Any ambiguities must be referred back to the prescriber. **Patient information/counselling** When pharmacy staff and other healthcare professionals supply the oral anticancer medicine to the patient they must ensure that the person receiving the medicines fully understands how and when to take their medicines. The member of pharmacy staff handing the drugs to the patient must also ensure the patient understands: • What to do in the event of missing one or more doses.

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	• What to do in case of vomiting after taking a dose. • Likely adverse effects and what to do about them. • The need to inform their health care team if they are taking any over the counter medications/ supplements. • Principles of safe handling, storage and disposal. • That if used, medicine spoons or measures should be used only for the purpose of administering the specific anticancer medicine, washed with warm soapy water after use and disposed of safely when no longer required. • Any drug specific advice regarding safely crushing of tablets or opening of capsules. **Compliance:** Examine Pharmacy procedures. ***Waste disposal*** • Pharmacists and pharmacy staff must be familiar with procedures for safe handling of cytotoxic medicines and disposal of waste. The RPSGB gives guidance on how to manage cytotoxic waste in Community Pharmacy http://www.rpsgb.org/pdfs/hazwastecommphguid.pdf. • Patients must be given advice on how to safely store their oral anticancer medicines and told where and how to return unused medicines for disposal.
Tray Parry, 2010	**Standarts for the safe use of oral anticancer medicine**. **Dispensing in primary care** It is NOT recommended that oral anti-cancer medicines are dispensed by community pharmacies unless a risk assessment has been undertaken and an appropriate framework has been developed A framework for community pharmacies dispensing THCD in NWCN include: • Suitability of drug/regimen, i.e. assessment of potential toxicity of the drug(s) and complexity of the regimen (more than one drug, pulsed schedule, variable dose). • Availability of drugs (wholesaler or direct). • Origin of prescription, primary or secondary care (the use of FP10(HP) prescriptions may be a barrier to the recommendation for regimen specific computer generated prescriptions). • Requirement for specialist clinical oncology pharmacy advice. • Requirement for Shared Care documentation. • Training requirements for primary care pharmacists. • Remuneration issues. • Handling and disposal of cytotoxic drugs (COSHH). • Out of hours support. Compliance : Trusts are required to declare if dispensing for their cancer patients is undertaken in primary care and provide evidence of their framework
Waters & Neame, 2012	**Systemic Anti-Cancer Therapy Care Pathway – Guidelines on the Safe Use of Oral Anti-cancer Medicines** **Dispensing in primary care** It is NOT recommended that oral anti-cancer medicines are dispensed by CP unless a risk assessment has been undertaken and an appropriate framework has been developed.

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	Such framework should address the following: • Suitability of drug/regimen, i.e. assessment of potential toxicity of the drug(s) and complexity of the availability of drugs (wholesaler or direct). • Origin of prescription, primary or secondary care (the use of FP10(HP) prescriptions may be a barrier to the recommendation for regimen specific computer generated prescriptions). • Requirement for specialist clinical oncology pharmacy advice. • Requirement for Shared Care documentation. • Training requirements for primary care pharmacists. • Remuneration issues. • Handling and disposal of cytotoxic drugs (COSHH). • Out of hours support. • Compliance : Trusts are required to declare if dispensing for their cancer patients is undertaken in primary care and provide evidence of their framework

APPENDIX C. THE CHEMOTHERAPY ORDER VERIFICATION AND LABELLING CHEMOTHERAPY

Table 1: Chemotherapy order details to be verified by the pharmacist[7;10;11]

Patient Body Surface Area (BSA) The patients BSA must be recorded on the chemotherapy order and an independent check carried out.
The drugs Ensure that all drugs have been prescribed according to protocol and that there are no omissions with respect to the requirements of the protocols including chemotherapy, targeted therapy, pre medication and supportive therapy. Check that additional medication has been prescribed. e.g. anti emetics, mesna. Verify they are appropriate for the protocol and the length of the course. Verify that the administration route for each drug is correct and is specified. Verify that the duration of infusion and diluent requirements are specified where needed. Verify that the frequency and sequencing (i.e. day 1, day 2 etc.) is correct. Ensure that the patient has no documented allergies / hypersensitivity reactions to any of the medication prescribed.
The doses Verify that all doses are correct according to protocol, patient weight, BSA, creatinine clearance. Verify maximum and cumulative doses are not exceeded for the dose or the course. Verify dose reductions are correct according to the protocol, patient parameters.
Scheduling Verify that the length of course and time interval between each cycle is appropriate for the protocol and tumour type. Verify that the appropriate time period has passed between last cycle and current cycle. It is important to maintain an up to date treatment history relating to all chemotherapy drugs, doses and treatment dates.
The patient blood counts and other results Verify that the absolute neutrophil count is appropriate for administration of the chemotherapy. Verify that the renal and liver function is appropriate for the dose of the drug to be administered. Where appropriate obtain results of other tests specific to certain drug toxicities, e.g. lung function prior to bleomycin, methotrexate levels, urine pH level for methotrexate, and ejection fraction for anthracyclines.
Protocol variations Verify that variations from the original protocol are valid for the patient and protocol. Ensure they are authorised by the prescriber and documented.
Drug-drug, drug-disease interactions A medication history should be taken by the pharmacist at the initial and subsequent cycles to include prescribed medication, over the counter and herbal medication and must take into account any changes in medication during treatment. The pharmacist must investigate and advise on any potential drug or disease interactions.
Adverse Drug reactions Details of previous and current adverse drug reactions should be verified with the patient and documented. Adverse drug reactions may occur with chemotherapy agents, targeted therapies and supportive therapy during treatment and appropriate recording and reporting must be ensured. Documentation of rechallenges and subsequent reactions is also essential.

Table 2. Details required for labelling chemotherapy and targeted therapy[7;10]

Patient's name and unique patient identifier
The name of the drug This should appear in the generic form. If the trade name is required this should not form the main part of the drug name Abbreviations and chemical names are not acceptable Clinical trial names must only be used in the context of approved clinical trials.
The strength of the drug Where the drug is in parenteral form the total dose should be expressed as a total concentration e.g. 25mg in 52 mL.
The form of drug and the drug diluent Where appropriate for infusional chemotherapy.
Intended route of administration for parenteral therapy Distinctive warning labels are to be placed on vinca alkaloids, "FOR INTRAVENOUS USE ONLY. FATAL IF ADMINISTERED BY ANY OTHER ROUTE". With the increasing use of chemotherapy given by the Intraperitoneal route steps should be taken to ensure drugs intended for administration by this route are clearly annotated.
The expiry date and storage conditions Where appropriate for infusional chemotherapy.
Cytotoxic warning label Chemotherapy must be labelled with a cytotoxic warning sticker in accordance with local Health and Safety requirements. Suggested labelling is a permanent, adhesive purple cytotoxic warning label with the distinctive warning; "Cytotoxic, Handle with Care". Cautionary and advisory labels must be added to the container as required.

APPENDIX D. COMPARISON OF NATIONWIDE REPORTING SYSTEMS

Table 1. Comparison of nationwide reporting systems[25]

Country	USA	Canada	Denmark	UK	The Netherlands
Name of reporting system	ISMP medication errors reporting program	Canadian medication incident reporting and prevention system	Danish patient safety database 2, DPSD-2	National reporting and learning system, NRLS	Central medication incidents registration, CMR
Year of the development	1975	1999	2004	2005	2006
Other types of incidents the system collects (beside medication incidents)	Device errors Hazardous condition	Only medication incidents	All types of incidents	All types of incidents	Only medication incidents
Voluntary to report to the system	•	•		•	•
Share information with government authorities	•	•	•	•	
Types of care organizations that could report incidents to the system					
Ambulance service	•			•	
Community pharmacy	•	•	•	•	•
Community optometry/optician service				•	
Dental service				•	
General practice	•	•	•	•	
Hospital	•	•	•	•	•
Mental healthcare	•	•	•	•	•
Residential/home	•	•	•		
Patients, relatives, carers	•	•	•	•	
Public	•	•			
The cumulative numbers of medication incident reports per 1 000 000 inhabitants in:					
1st year	7*	1	185	605	137
3rd year	14*	24	803	3078	607
5th year	23*	509	1239	6301	1495
Methods for inputting reports in the system					
Electronic interface/upload				•	•
Email	•	•			•
Internet form	•	•	•	•	•
Paper form	•		•		
Phone	•	•			•
Type of sharing information to participants					
Alert	•	•	•	•	•
Newsletter	•	•	•	•	•
Type of published reports					
Annual aggregate analysis			•	•	
Comparing different institutions/ settings				•	
Highlighting a specific issue/care setting	•		•		
Individual incident	•	•			
Individual participating care organization					•
Regional and/or local system				•	

*The numbers of reports are from the years 1998, 2000 to 2002. Around 1998 it was possible to report with an internet form to the US Institute for Safe Medication Practices (ISMP) and the numbers of reports refer to this period.

Appendix E. Accreditation programme for oral systemic anti-cancer therapies (SACT) counselling by pharmacy staff

Table 1. MCQ Test[52]

Appendix 1 MCQ test

1. What are the usual side effects of capecitabine, erlotinib, sunitinib and vemurafenib?
   a. Skin rash
   b. Diarrhoea
   c. Infection/fever
   d. A and b
   e. All of the above

2. Which of the following is/are considered benefits of oral anti-cancer therapy?
   a. An increase in oral anti-cancer therapies will result in an over capacity of IV infusions on day units
   b. The perception exists that patients prefer oral therapy
   c. Reduced complications from IV access (infections and blood clots)
   d. All the above are true
   e. Only b and c

3. Which of the following are TRUE about patient preference for oral therapy?
   a. Although oral monotherapy may avoid the inconvenience of a hospital visit, many combination therapies include parenteral therapy, and therefore require a hospital visit anyway
   b. Most oral anti-cancer therapies regimens are simple for the patient to manage
   c. Oral anti-cancer therapies will shift some aspects of managing oral anti-cancer treatment to the patient; not all patients are suitable
   d. All of the above
   e. Only a and c above

4. Which of the following is/are TRUE about concordance to oral anti-cancer therapy?
   a. Directly ask the patient
   b. Patient diaries, pill counts
   c. Concordance to oral therapies is generally very good, as illustrated by the excellent long term concordance to imatinib therapy
   d. All of the above
   e. Only a and b above

5. The risk of exposure can be minimised when handling oral anti-cancer therapies:
   a. No touch technique for carers/healthcare professionals – either using gloves or popping the medicine out of a blister pack
   b. The patient can touch the tablets/capsules as they are taking the therapy
   c. The patient should wear gloves
   d. A and b
   e. A and c

6. Which patient information sheets and/or disposables should be given to a patient unable to swallow capecitabine with a jejunsotomy?
   a. Dissolving oral anti-cancer tablets safely and an oral anti-cancer pack (containing 10 x gloves/10 x aprons/10 x masks/ 1 yellow waste bag)
   b. Oral/enteral syringes
   c. Giving an anti-cancer medicine through a feeding tube and an oral anti-cancer pack (containing 10 x gloves/ aprons/mask/1 yellow waste bag)
   d. A and b
   e. B and c

Table 1. MCQ Test (continue)

7. When should a patient/carer be given instructions how to take the anti-cancer medicine?
   a. Each cycle
   b. First cycle
   c. Second cycle if not understood at first cycle
   d. Only b
   e. B and c

8. A patient has oral anti-cancer tablets/capsules left over from the previous cycle, should they?
   a. Flush/throw them away
   b. Return to the hospital pharmacy
   c. Re-use or re-schedule if a high cost drug
   d. All of the above
   e. Only b and c

9. Which of the following statements is correct about commonly prescribed medicines which interact with oral anti-cancer therapies?
   a. Procarbazine interacts with food
   b. Erlotinib interacts with proton pump inhibitors and should be separated in time
   c. St. John's wort can affect the effectiveness of many targeted medicines
   d. All of the above
   e. Only a

10. Which of the following is TRUE about oral anti-cancer therapies?
    a. Includes traditional chemotherapy, targeted agents, teratogenic medicines
    b. Should not be handled by anyone who is pregnant or planning a pregnancy
    c. Wash hands after taking
    d. All of the above
    e. Only b and c

MCQ answer sheet	
Please circle one answer per question. A score of at least 80% on the MCQ is required.	
1. a b c d e	6. a b c d e
2. a b c d e	7. a b c d e
3. a b c d e	8. a b c d e
4. a b c d e	9. a b c d e
5. a b c d e	10. a b c d e

Table 2. LCA Oral SACT Counseling Checklist [52]

Appendix 2 LCA oral SACT counselling checklist

Oral anti-cancer patient and carer education checklist	
Prior to first cycle This checklist must be completed with the patient/carer at the point of handing the medication to the patient either in conjunction with or following a pre-treatment consultation	Tick if discussed with the patient/carer
Instructions for taking	
Explain how and when to take the medicine including any treatment breaks	
If the patient is unable to swallow tablets or capsules or has a feeding tube, please refer to oral SACT counselling handbook for information on how to dissolve or open capsules (if appropriate for the oral anti-cancer medicine)	
Missed doses can be taken if near to the scheduled time. Otherwise, do not try and catch up or double the next dose. Wait until the next dose is due.	
In case of vomiting after taking a dose, do not repeat the dose and take the next dose at the normal time. If this occurs again, contact the chemotherapy team/24 hour advice line.	
Check patient aware of side effects and has received written information. Any side effects should be reported to their chemotherapy nurse or doctor.	
If the patient is taking any prescribed/over the counter medicine/supplement – the patient should inform their medical team.	
Return any unused oral anti-cancer medicine to the hospital pharmacy. Do not flush or throw them away (for high cost drugs see counselling handbook).	
Storage and handling	
The oral anti-cancer medicine should not be handled by anyone who is pregnant or planning a pregnancy (unless taking on the advice of medical team).	
If the carer is giving the anti-cancer medicine, they should not handle the medicine directly but wear gloves or push the medicine out of the blister pack (if applicable) directly into a medicine pot.	
Store the tablets/capsules in the container provided.	
Store the tablets/capsules in a secure place, away from and out of sight of children.	
Wash hands thoroughly after taking/giving the oral anti-cancer medicine.	
Check the patient understands how to take the treatment, by asking them to repeat back their instructions.	
Written information provided	
Taking an oral anti-cancer medicine patient information sheet	
Diary for taking oral anti-cancer medicine (if applicable)	
For swallowing difficulty only – give relevant factsheet if appropriate for the oral anti-	

Table 2. LCA Oral SACT Counseling Checklist[52]

cancer medicine and an oral anti-cancer pack with disposables (e.g. oral/enteral syringes) Dissolving oral anti-cancer tablets safely Opening oral anti-cancer capsules safely Giving an oral anti-cancer medicine through a feeding tube Giving an anti-cancer syringe by mouth	
Patient name	**Counselled/educated by**
Hospital number	**Pharmacist/Pharmacy technician/Nurse/Interpreter**
Signature and date	**Signature and date**

Before all subsequent cycles:

- Check the patient understood the checklist above and repeat if necessary
- Check any side effects experienced with their previous cycle were discussed with their medical team
- If a dose adjustment has been made, check the patient is aware why their dose has been changed and how many tablets/capsules they should now take
- Check they had no problems taking their previous cycle
- Check the patient understands how to take the treatment, by asking them to repeat back their instructions

Please retain a copy and/or endorse the prescription/electronic patient record as evidence counselling took place at each cycle.

Table 3. LCA Oral SACT Supervised Counselling record for Pharmacy Staff[52]

Oral SACT Supervised Counselling record for Pharmacy Staff					
Introduction					
For each supervised practice the trainee must: – Introduce self to patient and carer – Patient correctly identified (name, DOB) – Explains purpose of counselling – Follow the points below:	Tick if discussed/completed (comments overleaf)				
	Watch one	**Under Supervision**			**Teach one**
		1	**2**	**3**	
1. Prior to first cycle: **a) Instructions for taking**					
Explain how and when to take the medicine including any treatment breaks.					
If the patient is unable to swallow tablets or capsules or has a feeding tube, please refer to oral SACT counselling handbook for provision of a relevant factsheet and an oral anti-cancer pack and disposables, if appropriate for the oral anti-cancer medicine.					
Missed doses can be taken if near to the scheduled time. Otherwise, do not try and catch up or double the next dose. Wait until the next dose is due.					
In case of vomiting after taking a dose, do not repeat the dose and take the next dose at the normal time. If this occurs again, contact the chemotherapy team/24 hour advice line.					
Any side effects should be reported to their chemotherapy nurse or doctor					
If the patient is taking any prescribed/over the counter medicine/supplement, the patient should inform their medical team.					
Return any unused oral anti-cancer medicine to the hospital pharmacy. Do not flush or throw them away (for high cost drugs refer to counselling handbook).					

Table 3. LCA Oral SACT Supervised counselling record for Pharmacy Staff (continue)

APPENDIX 3: LCA ORAL SACT SUPERVISED COUNSELLING RECORD FOR PHARMACY STAFF

b) Storage and handling					
The oral anti-cancer medicine should not be handled by anyone who is pregnant or planning a pregnancy (unless on the advice of your medical team).					
If the carer is giving the anti-cancer medicine, they should not handle the medicine directly but wear gloves or push the medicine out of the blister pack (if applicable) directly into a medicine pot.					
Store the tablets/capsules in the container provided.					
Store the tablets/capsules in a secure place, away from and out of sight of children.					
Wash hands thoroughly after taking/giving the oral anti-cancer medicine.					
Check the patient understands how to take the treatment, by asking them to repeat back their instructions.					
Taking an oral anti-cancer medicine information sheet, manufacturer's leaflet and chemotherapy alert card given to patient.					
Able to assess patient/carer's ability to self-medicate: • ability to take medication correctly and monitor side effects • judge when to interrupt treatment and call the hospital if required					
Provides opportunity for questioning/discussing through interaction.					
2. Before all subsequent cycles					
Check the patient understood the checklist above, and repeat if necessary.					
Check any side effects experienced with their previous cycle were discussed with the medical team.					
If a dose adjustment has been made, check the patient is aware why their dose has been changed and how many tablets/capsules they should now take.					
Check they had no problems taking their previous cycle.					
Check the patient understands how to take the treatment, by asking them to repeat back their instructions.					

Table 3. LCA Oral SACT Supervised Counselling record for Pharmacy Staff (continue)

ACCREDITATION PROGRAMME FOR ORAL SYSTEMIC ANTI-CANCER THERAPIES (SACT) COUNSELLING BY PHARMACY STAFF

Supervised No.1 – Drug Cycle No Type of encounter (e.g. first cycle, swallowing difficulty, dose adjustment)

Trainee comments			
Assessor comments			
Assessor name	**Assessor signature**	**Date**	

Supervised No. 2 – Drug Cycle No Type of encounter (e.g. first cycle, swallowing difficulty, dose adjustment)

Trainee comments			
Assessor comments			
Assessor name	**Assessor signature**	**Date**	

Supervised No. 3 – Drug Cycle No Type of encounter (e.g. first cycle, swallowing difficulty, dose adjustment)

Trainee comments			
Assessor comments			
Assessor name	**Assessor signature**	**Date**	

Supervised (Teach one) – Drug Cycle No Type of encounter (e.g. first cycle, swallowing difficulty, dose adjustment)

Trainee comments			
Assessor comments			
Assessor name	**Assessor signature**	**Date**	

Table 4. LCA Accreditation Certificate for oral SACT counseling [52]

Name of pharmacist/pharmacy technician ..... & GPhC number: .....

Base Hospital: .....

Level of Practitioner: .....

LCA Accredited to counsel patients on oral SACT for the following specialist areas:

Solid tumour ☐

Haemato-oncology ☐

Paediatric oncology ☐

This pharmacist/pharmacy technician is competent/not competent* to counsel oral SACT according to the specialties detailed below across the LCA network

Name (Block capitals): ..... (List of assessors held centrally by the LCA)

Signature of Trust LCA-approved assessor: .....

Date of accreditation: ...../...../.....

This certificate is only valid in conjunction with completed supervised counselling record which should be presented for review when requested

***This certificate is valid for a period of twelve months from the date of accreditation. Re-accreditation is required in order to maintain LCA-accreditation*

Table 5. LCA Re-Accreditation Certificate for oral SACT counseling [52]

Name of pharmacist/pharmacy technician ..... & GPhC number: .....

Base Hospital: .....

Level of Practitioner: .....

Self-Declaration:

☐ I wish my name to remain on the local register for counselling patients on oral SACT prescriptions

☐ I have successfully completed a minimum of one assessed patient counselling

☐ I declare that I remain competent to counsel patients on oral SACT prescriptions

☐ I have read the training slides and am familiar with the oral SACT counselling handbook

Signature of pharmacist/pharmacy technician: ..... Date: ...../...../.....

This pharmacist/pharmacy technician is competent/not-competent* to continue to counsel patients on oral SACT according to the specialties detailed below across the LCA network

Solid tumour ☐ Haemato-oncology ☐ Paediatric oncology ☐

Name (Block capitals): ..... (List of assessors held centrally by the LCA)

Signature of Trust LCA-approved assessor: .....

Date of re-accreditation: ...../...../.....

This certificate is only valid in conjunction with completed supervised prescription log which should be presented for review when requested

***This certificate is valid for a period of twelve months from the date of accreditation. Re-validation is required in order to maintain LCA-accreditation*

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APPENDIX C: CONSULTATION PROCESS

Consultation/Feedback Requested	Response Received
CCO Executive Team	x
CCO Strategic Planning, Performance and Risk Management Committee	x
CCO Provincial Clinical Council	x
CCO Regional Vice-Presidents and Directors	x
CCO Systemic Treatment Program Clinical Leads	x
CCO Systemic Treatment Regional Quality Leads	x
CCO Program Teams	x
Health Technology Community of Practice	x
Patient and Family Advisory Council	x
BC Cancer Agency	
Alberta Health Service	x
Saskatchewan Cancer Agency	
CancerCare Manitoba	x
New Brunswick Cancer Unit	
PEI Cancer Treatment Centre	
Eastern Health	
Ministère de la Santé et des Services sociaux (Quebec)	x
Canadian Patient Safety Institute	x
Ontario Hospital Association	x
McKesson Specialty	x
Canadian Partnership Against Cancer	
American Society of Clinical Oncology	x
International Society of Pharmacy Practitioners	
College of Physicians of Ontario	
Innovative Medicines Canada	x
Health Quality Ontario	