STEPS TO SUCCESS:

Implementing Oral Oncolytics

Association of Community Cancer Centers
This publication is a benefit of membership.
ACCC
Association of Community Cancer Centers

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The Association of Community Cancer Centers (ACCC) is the leading advocacy and education organization for the multidisciplinary cancer care team. Approximately 23,000 cancer care professionals from 2,000 hospitals and practices nationwide are affiliated with ACCC. Providing a national forum for addressing issues that affect community cancer programs, ACCC is recognized as the premier provider of resources for the entire oncology care team. Our members include medical and radiation oncologists, surgeons, cancer program administrators and medical directors, senior hospital executives, practice managers, pharmacists, oncology nurses, radiation therapists, social workers, and cancer program data managers. Not a member? Join today at accc-cancer.org/membership or email: membership@accc-cancer.org.

For more information, visit the ACCC website at accc-cancer.org. Follow us on Facebook, Twitter, and LinkedIn, and read our blog, ACCCBuzz.

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KOOTENAI CLINIC CANCER SERVICES

ARIZONA ONCOLOGY

ALTA BATES SUMMIT MEDICAL CENTER COMPREHENSIVE CANCER CENTER

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INTRODUCTION

As the use of oral oncolytics increases, cancer programs face a number of challenges to ensure high-quality care for cancer patients. There are significant variations in how cancer programs are treating patients with oral oncolytics, and experts are calling on clinicians to extend the quality and safety agenda from parenteral to oral oncolytics.[1] Oral oncolytics offer a host of benefits for both patients and providers, but cancer programs need to be equipped to properly manage and monitor patients who are self-administering their treatments at home. Cancer programs also need to be proactive when providing financial advocacy services for patients who require oral oncolytics, since most of these therapies are associated with high out-of-pocket costs.[2]

ACCC launched an education initiative to identify barriers and best practices around oral oncolytics. This project, Steps to Success: Implementing Oral Oncolytics, included: a membership survey, site visits and focus groups at three ACCC member programs with strong processes in place to support patients prescribed oral oncolytics, phone interviews with additional member programs, and a series of webinars.

The three member programs that participated in focus groups were:

- **Kootenai Clinic Cancer Services**, Coeur d'Alene, Idaho. Participants included: Kim Christen, RN, BSN, OCN; Pam Cysewski, RN; Linda Evans, LMSW; Patricia Graham, RN, BSN, OCN; Cyndi Hallgren; Cindy Johnson; Kevin Mulvey, MD; Tena Nee; Jodi Schmidt, RN, BSN, OCN; and LuAnn Townsend, RN, BSN, OCN.
- **Arizona Oncology**, Tucson, Phoenix, and Northern Arizona. Participants included: Lela Conrad; Christopher DiSimone, MD; Linda Frisk, PharmD; Tracey Hedberg, NP; Carol Hemersbach; Sherri Noyes, MA; Ericka Perez, CPhT; and Stacey Silvain.
- **Alta Bates Summit Comprehensive Cancer Center**, Berkeley, California. Participants included: Rezena Aceret, RN, BSN, OCN; Rajesh Behl, MD; Julie Latini, RN, BSN, MHA, NE-BC; Vivian Leong, RN; Jeanne McCullough-Block, RN; Ross Simkover, PhD; and Clayton Warren.

These sites covered a wide range of practice size, location, patient demographics, and other key variables. While all of these sites had unique aspects to their cancer programs, they also shared common core elements to bolster the success of their oral oncolytic programs. Patti Hawkins, PharmD; Todd Murphree, PharmD; and Katie A. Won, PharmD; share additional strategies in "Spotlight Programs," page 21. This peer-to-peer resource guide serves to highlight these core elements and provides rationales to incorporate time-saving tools, goals, and effective practices into a formal process for monitoring patients on oral therapies in a way that works for your cancer program.

There are significant variations in how community cancer programs are treating patients with oral oncolytics...

SURVEY RESULTS: TRENDS IN ORAL ONCOLYTICS

ACCC conducted a membership survey in March 2016 to assess the current landscape of how cancer programs are managing patients on oral oncolytics. A total of 117 responses were obtained from a broad multidisciplinary perspective that included cancer program administrators (21 percent), medical oncologists (7 percent), nurses or nurse navigators (24 percent), pharmacists (35 percent), social workers (3 percent), and other members of the cancer care team (10 percent).

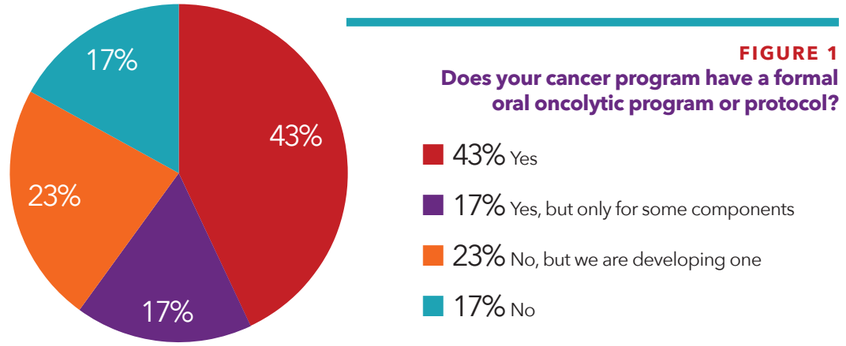


FIGURE 1
Does your cancer program have a formal oral oncolytic program or protocol?

Most of those that have established formal programs have placed either a pharmacist or nurse to lead the program. Some of the key trends from the survey include the following:

Variations in Dispensing

There are considerable variations in how cancer patients receive their oral oncolytic agents; some receive them from in-house or local retail specialty pharmacies, while others rely on mail-order specialty pharmacies. This wide variability exists at every cancer program because some payers or manufacturers require the use of specific pharmacies to dispense certain medications.

Delays with Mail-Order Specialty Pharmacies

Most cancer programs rely on mail-order specialty pharmacies for some or all of the oral oncolytics they prescribe. Unfortunately, use of these pharmacies can lead to delays. Figure 2, below, shows some of the leading sources of these delays (n=84).

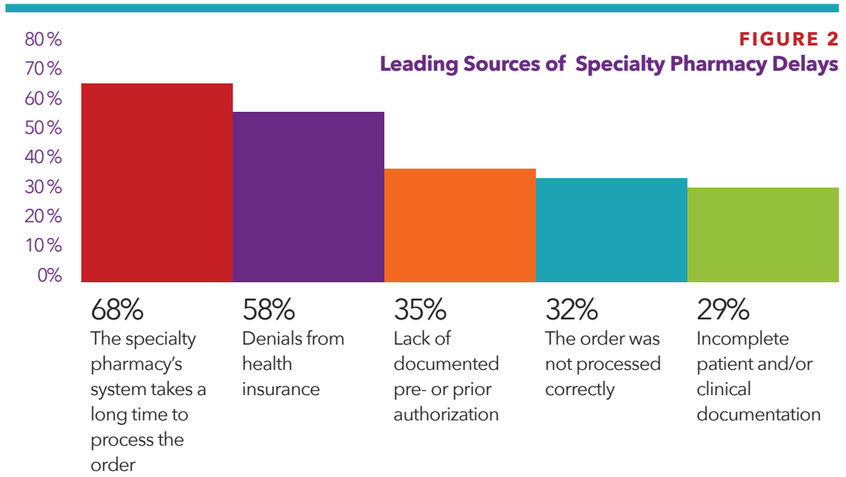


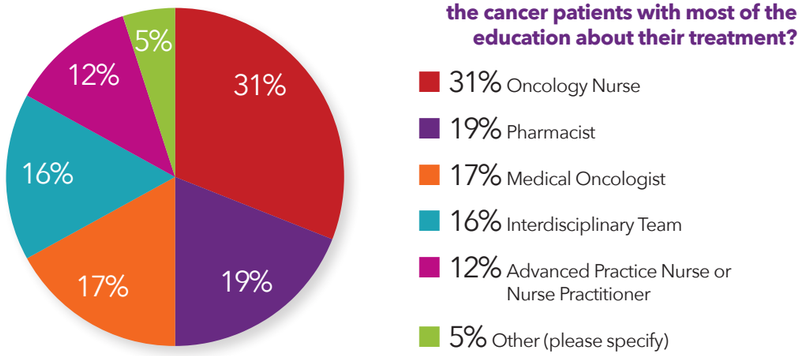
FIGURE 2
Leading Sources of Specialty Pharmacy Delays

SURVEY RESULTS: TRENDS IN ORAL ONCOLYTICS

Educating Patients

There are considerable variations in how cancer programs in the community are educating patients who are prescribed oral oncolytics.

FIGURE 3
When initiating oral oncolytics, who provides the cancer patients with most of the education about their treatment?



- 31% Oncology Nurse
- 19% Pharmacist
- 17% Medical Oncologist
- 16% Interdisciplinary Team
- 12% Advanced Practice Nurse or Nurse Practitioner
- 5% Other (please specify)

When patients are educated about their oral oncolytics, most cancer programs are covering the basics about the medication and key side effects. However, studies of clinical documentation quality have revealed that there are still opportunities to improve patient education and documentation specific to:

1. Drug-drug and drug-food interactions
2. Planned duration and schedule of treatment
3. Plan for missed doses

When patients are educated about their oral oncolytics, most cancer programs are covering the basics about the medication and key side effects.

SITE VISIT 1: KOOTENAI CLINIC CANCER SERVICES

Kootenai Health is a community-owned 246-bed hospital in Idaho, serving more than 13,000 inpatients and 180,000 outpatients every year. In 1987, Kootenai Health opened Kootenai Clinic Cancer Services at Coeur d'Alene, and the program has continued to grow. Now, patients may choose to receive care from two full-service facilities, Kootenai Clinic Cancer Services at Coeur d'Alene or Kootenai Clinic Cancer Services at Post Falls. Furthermore, patients living in the two northern counties of Idaho can choose to receive chemotherapy close to home at Kootenai Clinic Cancer Services at Bonner General Hospital in Sandpoint. Kootenai Clinic has been accredited by the American College of Surgeons Commission on Cancer (CoC) since 1990. In 2011, it received the CoC Outstanding Achievement Award for cancer care.

Oral Oncolytics Program

In May 2015, a multidisciplinary taskforce at Kootenai Clinic Cancer Services used Lean Six Sigma methodology to develop a formal oral oncolytic protocol for prescribing and dispensing oral chemotherapy. The protocol is a physician-driven process overseen by a collaborative nurse who works closely with the physician. The protocol defines the roles and responsibilities for each department and/or staff member, and includes an electronic checklist (Figure 4, pages 7–8) that has been integrated into the cancer program's OncoEMR by Flatiron Health. There are defined roles for each department or staff member with assigned tasks linked to the checklist. Departments and staff assigned include:

- Physician
- Collaborative nurse
- Specialty pharmacy team
- Pre-authorization team
- Social services team
- Nurse navigator
- Patient services coordinator
- Triage nurse

After the medical oncologist enters an order for an oral oncolytic agent in OncoEMR, the collaborative nurse initiates the process-driven checklist, which links the different tasks managed by assigned departments and/or staff members. The cancer care team uses a secure messaging platform to send brief requests and updates to ensure efficient management of processes on the checklist. Treatment plans are based on electronic templates within OncoEMR. These treatment plans are specific to each oral oncolytic agent and include a templated list of monitoring tests and follow-up schedules. Kootenai's oncology pharmacists have been working with their clinical staff to develop and implement templates around each oral oncolytic agent so that required monitoring tests are automatically incorporated into the follow-up care plan. View Kootenai's standard operating policy for prescribing and dispensing oral chemotherapy in its entirety at: accc-cancer.org/oraloncolytics.

FIGURE 4
Kootenai Clinic Cancer Services Oral Chemotherapy Checklist
(page 1)

Please complete your portion of the list, save, DO NOT SIGN, and then send back to the Collaborative RN

1. **MD Alerts Collaborative RN of New Oral Chemotherapy Orders**
   - ❑ Collaborative RN prints consent and facilitates MD/patient signature
   - ❑ Chemocare.com educational materials are provided to the patient and documented; discuss multidisciplinary team meeting (MTM) and offer to schedule an appointment with pharmacy
   - ❑ Ensure MD has sent script to KH Specialty Pharmacy; same day
   - ❑ Ensure regimen has been entered by MD; same day
   - ❑ Discuss MTM with patient
   - ❑ Contact the following people via jabber: Pre-auth, Specialty Tech, Social Work, and Navigator
     Date: _____ Initial: _____
   - ❑ Forward to pharmacy CDA inbox, pre-auth, and social work

2. **Pharmacy CDA Inbox**
   - ❑ Check insurance for filling instructions and coverage
   - ❑ Does medication need to go for pre-authorization?
     Yes: _____ No: _____
   - ❑ Enter dispensing information into pharmacy pick-up appointment and delete 0.25 CL
   - ❑ Planned arrival date of drug: _____
   - ❑ Any other pending information? _____
     Date: _____ Initial: _____
   - ❑ Forward to Collaborative RN

3. **Pre-Authorization**
   - ❑ Check insurance for approval
   - ❑ Forward insurance letter to Collaborative RN and Patient Services Coordinator
     Date: _____ Initial: _____
   - ❑ Forward to Collaborative RN

4. **Social Work**
   - ❑ Check for patient assistance as needed
     Co-pay assistance: _____ *-or-* Drug acquisition: _____
   - ❑ Planned arrival date of drug: _____
     Date: _____ Initial: _____
   - ❑ Forward to Collaborative RN

Patients are instructed to contact the triage nurse when they receive their medications so that a series of weekly monitoring phone calls can be initiated.

SITE VISIT 1:
KOOTENAI CLINIC CANCER SERVICES

FIGURE 4
Kootenai Clinic Cancer Services Oral Chemotherapy Checklist
(page 2)

5. **Collaborative RN**
   - ❑ Once pre-authorization and assistance is completed and medication is en route, have MD move regimen to accurate date
   - ❑ Ensure follow-up calls are scheduled
   - ❑ If mail-order prescription, call patient to see if he or she has received the drug
   - ❑ Ensure lab work is complete
   - ❑ If regimen includes a radiation consult, ask Radiation RN for treatment status and start date
   - ❑ Enter combined modality pop-up
     Date: _____ Initial: _____
   - ❑ Forward checklist to Navigator and Patient Services Coordinator to book chemo-teach (patient education session) and pick up prescription

6. **Patient Services Coordinator**
   - ❑ Alert Navigator to schedule chemo-teach via task
   - ❑ Schedule MTM appointment with pharmacy as requested by Navigator or Collaborative RN; if patient declines, enter text note titled "MTM declined" and delete appointment
   - ❑ Schedule pharmacy pick-up appointments if needed
     Date: _____ Initial: _____
   - ❑ Forward to Collaborative RN

7. **Navigator**
   - ❑ Schedule chemo-teach
   - ❑ Provide patient with chemo-teach instructions and discuss MTM
     Date: _____ Initial: _____
   - ❑ Forward to Collaborative RN

8. **Collaborative RN. Sign the Final Checklist ONLY Once:**
   - ❑ The checklist is complete
   - ❑ The start date is known
   - ❑ Follow-up appointments are scheduled
   - ❑ The regimen is moved appropriately
     Date: _____ Initial: _____

Steps to Success

Kootenai Clinic Cancer Services shares these successful strategies for implementing an oral oncolytics program.

Provide Financial Advocacy Services

Since Idaho did not expand Medicaid, many patients still lack healthcare coverage. Kootenai's collaborative nurse partners with the pre-authorization and social services teams to coordinate financial advocacy services for these patients. All patients undergo psychosocial distress screening. To conduct these screenings and capture information, Kootenai uses forms based on NCCN guidelines, which are built into OncoEMR. Based on distress screening results and patient interaction, the collaborative nurse identifies patients who may experience financial distress and works with social services to find patient assistance programs and other resources. Kootenai Clinic Cancer Services has dedicated financial advocates and social workers who are skilled in finding patient assistance and drug co-pay programs offered by disease foundations and manufacturers.

Develop a Robust Patient Education Program

After a patient is prescribed an oral oncolytic, Kootenai's nurse navigator schedules a dedicated patient education visit to comprehensively review the plan of care. Patients are instructed to bring all of their outpatient medications with them so that pharmacy can review the entire medication list and look for potential interactions. Patients receive a binder of information, along with handouts and drug information provided by Chemocare.com, which is linked to OncoEMR. Some cancer patients also receive additional education from the oncology pharmacists when they pick up their prescriptions.

All patients are encouraged to participate in the Medication Therapy Management service offered by the oncology pharmacists. These services include medication therapy reviews, pharmacotherapy consults, anticoagulation management, immunizations, health and wellness programs, and many other clinical services. Pharmacists provide medication therapy management to help patients get the best benefits from their medications by actively managing drug therapy and by identifying, preventing, and resolving medication-related problems. Although Kootenai's pharmacists are not currently reimbursed for providing Medication Therapy Management services, staff makes an effort to engage primary care and other community providers and educate them about the importance of these services for cancer patients.

Patients are instructed to bring all of their outpatient medications with them so that pharmacy can review the entire medication list and look for potential interactions.

SITE VISIT 1:
KOOTENAI CLINIC CANCER SERVICES

Steps to Success
(continued)

Establish In-Office Dispensing & Collaborate with Specialty Pharmacy

When the order for the oral oncolytic reaches Kootenai's pharmacy, a dedicated pharmacy technician routes the order either to Kootenai's on-site dispensing specialty pharmacy or to an outside specialty pharmacy. Approximately 50 percent of oral oncolytics prescribed at Kootenai Clinic Cancer Services are filled on-site. When orders are filled by outside specialty pharmacies, Kootenai staff informs patients that a specialty pharmacy will be filling their prescription and reminds patients to answer their phones when the specialty pharmacies call to confirm the prescription. Some of the prescriptions processed by outside specialty pharmacies are delayed due to the pharmacy performing their own prior authorization—even if one was already completed by Kootenai staff. Because Idaho has many rural and mountainous regions, Kootenai pharmacists arrange for the specialty pharmacy to ship medication directly to Kootenai Clinic Cancer Services so that patients who live in areas where it may be difficult to receive packages can easily pick them up.

Put in Place Effective Processes for Patient Monitoring

Patients are instructed to contact the triage nurse when they receive their medications so that a series of weekly monitoring phone calls can be initiated. During the monitoring phone calls, the triage nurse fills out an electronic form. If the patient reports side effects, this form is forwarded to an advanced practice provider who then reviews the form and assesses the severity of reported toxicities. Use of this two-person team—triage nurse and the advanced practice provider—helps ensure that Kootenai Clinic Cancer Services is aware of and can address potentially serious side effects in a timely fashion.

SITE VISIT 2: ARIZONA ONCOLOGY

Arizona Oncology, an affiliate of the US Oncology Network, has more than 70 physicians throughout the state in over 30 locations, including: Chandler, Cottonwood, Deer Valley, Flagstaff, Glendale, Green Valley, Nogales, Phoenix, Prescott Valley, Safford, Scottsdale, Sedona, and Tucson. As an affiliate of the US Oncology Network, Arizona Oncology is united with 1,000 physicians nationwide. Arizona Oncology participates in clinical trials through US Oncology Research, which has played a role in 50 FDA-approved cancer therapies. Arizona Oncology uses iKnowMed (by McKesson Corp.) as its EHR and has incorporated Clear Value Plus for evidence-based regimen clinical decision support at the point of care. Clear Value Plus presents value pathways that are powered by NCCN Clinical Practice Guidelines in Oncology.

Oral Oncolytics Program

Arizona Oncology is focused on maximizing convenience, access, and financial and educational support for patients who receive their oral chemotherapy medications from an in-office dispensing practice. It established a series of 12 in-office dispensing specialty pharmacies throughout the state. These in-office dispensing specialty pharmacies help facilitate patient access and reduce out-of-pocket expenses, ultimately providing patients with a less fragmented experience.

Arizona Oncology pharmacists and pharmacy technicians play a key role in ensuring that patients receive their oral oncolytics appropriately. The oral oncolytics program was developed by Arizona Oncology's pharmacist, with support and input from practice leadership and other members of the multidisciplinary care team.

Currently, Arizona Oncology's EHR, the iKnowMed Generation 1, is not integrated with e-prescribing for oral oncolytics, so medical oncologists must enter the treatment regimen into the EHR and then duplicate this entry to create an e-prescription. The next generation of iKnowMed, scheduled for implementation in 2017, may offer the ability to reduce some of the current workflow redundancy. Because Arizona Oncology is also participating in the Centers for Medicare & Medicaid's Oncology Care Model (OCM), members of the IT department have met with clinicians to modify templates and create data dashboards that Arizona Oncology can use to review its own data and drive continuous quality improvement. The in-office dispensing specialty pharmacy uses QS/1 Pharmacy Management Software to manage prescriptions and its inventory of oral oncolytics. The QS/1 software also provides a convenient retail pharmacy portal for patients.

These in-office dispensing specialty pharmacies help facilitate patient access and reduce out-of-pocket expenses, ultimately providing patients with a less fragmented experience.

SITE VISIT 2: ARIZONA ONCOLOGY

FIGURE 5
Arizona Oncology: In-Office Dispensing Process

Physician Decision & Patient Teaching

- Physician determines oral therapy, enters prescription in EHR, and ePrescribes to in-office dispensing technician.
- Depending on physician preference, patient education is completed by physician or advanced practice provider during the office visit, or a chemo teaching appointment is set up as a separate office visit with advanced practice provider.
- Oral consent form, Figure 6, page 12, is reviewed with patient and signed. Patient receives a copy.
- Documentation of chemo teaching is entered into the EHR.
- Starter kits may be handed out at the time of chemo teach.

In-Office Dispensing Technician Coordination

- In-office dispensing technician runs prescription through QS/1 (pharmacy management software).
- If in-office dispensing technician cannot fill the prescription, it is sent out to required specialty pharmacy; in-office dispensing technician documents this in the EHR and notifies patient.
- If the prescription can be filled, the in-office dispensing technician notifies patient and begins coordination for delivery.
- For high-dollar, single-source drugs, staff automatically research co-pay assistance.

Follow-Up

- Follow-up occurs within 1 week by advanced practice provider or physicians, depending on the site and provider preference.
- In-office dispensing technician follows up on refills and documents this follow-up in EHR.
- At all office visits, the adherence form, Figure 7, page 13, is completed and reviewed by the provider.

FIGURE 6
Arizona Oncology Oral Consent Form

Patient Last Name _____ Patient First Name _____

Medical Record Number _____

Diagnosis _____

Goals of Therapy _____

Planned Duration of Treatment _____

Treatment Regimen & Schedule _____

I hereby authorize Dr. _____ and his or her designated nurse to begin oral treatment that may include oral chemotherapy. I understand that other health professionals may help my doctor provide this treatment. I have received a detailed explanation of my treatment plan, including, at a minimum, chemotherapy drugs, doses, anticipated duration, and goals of therapy. Possible alternative methods of treatment and the risk of injury despite precautions have been explained to me. No guarantee or assurance has been given by anyone as to the results which may be obtained. I have been given the opportunity to ask questions concerning the above therapy and these questions have been answered to my satisfaction. I understand that I may withdraw my consent for treatment and stop treatment at any time and such withdrawal will not prejudice my future medical care.

I understand that chemotherapy medications may have short-term and long-term side effects. A provider has talked to me about the side effects (listed right) that I might experience because of my treatment. I could have side effects from my treatment that are not listed here. Each patient can respond differently to treatments.

Safe handling of chemotherapy: **Keep in a safe place and out of the reach of children**.
- Wash hands before and after handling oral medications. Wash any areas that come in contact with chemotherapy.
- Store at room temperature or refrigerate as directed on the label. Do not crush tablets or open capsules.
- Do not dispose of in trash or down the sink. Disposal is available at many local law enforcement centers. The FDA website (http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm) may provide further information.

I understand that I can contact a healthcare provider at this office at any time if I have questions, and that I should call the office for any of the following: temperature greater than 101° F, bleeding, uncontrolled pain, shortness of breath, chest pain or discomfort, uncontrolled vomiting, persistent diarrhea, dizziness, or any other unusual or worrisome symptoms. The phone number for the office is: _____.

I have read the above statement and understand the potential risks and benefits of my therapy and agree to accept treatment.

_____
Patient Signature (or Legal Representative) Date

I have explained the treatment, expected response and goals, side effects, and risks to the above signed patient.

_____
Provider Signature Nurse Signature Date

Pregnancy SHOULD be avoided during treatment. Fertility risks and options may be reviewed.

- ❑ Allergic-Type Reactions
- ❑ Bladder Damage
- ❑ Bleeding
- ❑ Brief Periods of Forgetfulness
- ❑ Changes in Appetite or Weight
- ❑ Constipation
- ❑ Cough or Sore Throat
- ❑ Dehydration
- ❑ Diarrhea
- ❑ Dizziness or Headache
- ❑ Edema/Fluid Retention
- ❑ Fatigue/Tiredness
- ❑ Hair Loss
- ❑ Hand/Foot Syndrome
- ❑ Heart Damage
- ❑ Inability to Sleep
- ❑ Kidney Damage
- ❑ Liver Damage
- ❑ Life-Threatening Complications
- ❑ Low Red Blood Cell Count (Anemia)
- ❑ Low Platelets (Bruising/Bleeding)
- ❑ Low White Blood Cells (Infection)
- ❑ Lung Damage
- ❑ Menopausal Symptoms
- ❑ Menstrual Irregularities
- ❑ Mouth Sores
- ❑ Muscle or Joint Aches or Back Pain
- ❑ Nausea, Vomiting, Abdominal Pain
- ❑ Numbness or Tingling
- ❑ Reproductivity/Fertility Changes
- ❑ Sexual Effects
- ❑ Shortness of Breath
- ❑ Skin Rash/Sensitivity to Light
- ❑ Thyroid Damage
- ❑ Visual Changes

Other _____
_____

SITE VISIT 2:
ARIZONA ONCOLOGY

FIGURE 7
Arizona Oncology: Assessment of Oral Chemotherapy Adherence & Toxicity

Patient Name _____ Date _____ MRN _____

Date of Birth _____

Oral Drugs _____

Current Regimen & Schedule _____

Diagnosis _____

Provider/Clinician Reviewing Check-Off List with Patient _____

- ❑ Inquire if all questions and concerns about oral chemotherapy have been addressed.
- ❑ Verify that the patient understands how to take the prescribed oral chemotherapy (e.g., frequency, with/without food, whole or crushed, etc.). Oral chemotherapy medications should not be touched. Handle using disposable paper cup or gloves and wash hands before and after handling. Women who are pregnant or breastfeeding should avoid handling these medications. Store away from children and pets.
- ❑ Confirm that the patient filled/refilled the prescription as written and has reviewed prescription label for correct patient name and drug information and directions.
- ❑ Inquire about concerns about treatment costs.
- ❑ Ask patient if they have missed any doses.
  Number of doses missed per week or month: _____
  - Reason for missing doses: _____
  - Side effects (list): _____
  - Forgot: _____
  - Lifestyle and dosing schedule not compatible: _____
  - Cost of medication: _____
  - Provider/nurse recommended to skip: _____
  - Other reason: _____
- ❑ Verify that the patient understands what to do in case of missed doses.
- ❑ Assess for potential toxicity, asking patient if they have experienced any of the following:
  - Nausea/vomiting: _____
  - Diarrhea: _____
  - Fatigue: _____
  - Mouth sores: _____
  - Aches in muscles/joints/bones: _____
  - Rash: _____
  - Other: _____
- ❑ Nurse/staff/advanced practitioner/physician discussed side effects with patient and recommended:
  _____
- ❑ Suggestions for improved adherence:
  - Keep a journal of side effects, including timing around medication.
  - Keep track of when you need a refill and plan ahead before you run out.
  - Adjust time of taking medication to better fit into daily schedule.

Steps to Success

Arizona Oncology shares these successful strategies for implementing an oral oncolytics program.

Leverage Specialized Pharmacy Technicians

Through its in-office dispensing specialty pharmacies, Arizona Oncology is able to fill approximately 60 to 70 percent of oral oncolytics ordered by its medical oncologists; the remaining prescriptions are filled by third-party specialty pharmacies. Arizona Oncology has trained pharmacy technicians with expertise around each of the oral oncolytics. These specialized pharmacy technicians also serve as the primary point of contact when orders need to be filled by third-party specialty pharmacies. The in-office dispensing pharmacy technicians contact patients to coordinate delivery of medications dispensed by outside specialty pharmacies. When cancer patients are treated at an Arizona Oncology location that does not have an in-office dispensing specialty pharmacy, in-office dispensing pharmacy technicians serve as a liaison with the infusion pharmacy technicians at the primary site to coordinate care for the patient. In-office dispensing pharmacy technicians research insurance coverage and patient assistance programs and play a key role when patients require financial assistance. Arizona Oncology's pharmacist manages communication flow to the team of in-office dispensing pharmacy technicians; this pharmacist works closely with the technicians, keeping the team informed about new FDA-approved oral oncolytics, indication changes, adverse reactions updates, and information on financial assistance.

Develop a Robust Patient Education Program

Most of the patient education around oral oncolytics is provided either by the medical oncologist or an advanced practice provider. Clinicians use the treatment consent form as an outline to cover key educational topics and may supplement the conversation with resources from Chemocare.com, US Oncology, UpToDate.com, and other medical websites. UpToDate is an evidence-based, clinical decision support resource used to make point of care decisions, aiming to improve patient care and quality. Arizona Oncology is also running a pilot program to assess the use of digital tools to provide patient education. Patients may receive a digital tablet while they are waiting to be seen or the clinician may use a large interactive digital touch screen that is mounted on the wall to provide more in-depth patient education during an appointment.

In-office dispensing pharmacy technicians research insurance coverage and patient assistance programs, and play a key role when patients require financial assistance.

SITE VISIT 2:
ARIZONA ONCOLOGY

Steps to Success
(continued)

Put in Place Effective Processes for Patient Monitoring

Medical oncologists rely primarily on face-to-face visits to monitor their cancer patients who are on oral oncolytics. Offering in-office dispensing creates a more convenient patient experience; patients can walk to the pharmacy and coordinate refill pick-up immediately after their follow-up visit. Having a dispensing pharmacy on-site allows Arizona Oncology clinicians to make dosing modifications immediately. When patients come for their monitoring visit, they are given an oral chemotherapy assessment form, Figure 7, page 13, to complete that addresses toxicities, financial concerns, and adherence to treatment. The responses are uploaded into the EHR. Arizona Oncology is currently exploring ways to digitize this process and eliminate the paper-based forms.

Alta Bates Summit Medical Center, a 900-bed hospital with three campuses in Berkeley and Oakland, has been serving Alameda and Contra Costa Counties for more than 100 years. As a member of the Sutter Health Network and an Oncology Center of Excellence, Alta Bates Summit Medical Center provides comprehensive care for more than 2,000 newly diagnosed cancer patients each year. With the formation of a multidisciplinary cancer committee and consultative tumor board in 1976, the oncology program consists of radiation and medical oncology, hematology malignancies, multiple myeloma outpatient bone marrow transplantation, and therapeutic pheresis. The oncology program is certified by the American College of Surgeons Commission on Cancer (CoC) as an accredited community hospital comprehensive program, which also includes a comprehensive survivorship clinic. An active tumor registry currently follows 9,100 living patients. Oncology patients are hospitalized in a fully equipped oncology unit consisting of 23 beds, and a patient and family lounge.

Oral Oncolytics Program

After implementing EPIC as their EHR platform in 2014, the cancer center added the Beacon module and went live with computerized provider order entry (CPOE) in 2015. One of the medical oncology groups at Alta Bates Summit Medical Center includes five medical oncologists who each have one to two assigned oncology nurses. Three of the medical oncologists focus on treating patients with solid tumors and two focus on treating patients with hematologic malignances. The oncology nurses are responsible for following a Standard Work Process and using a flow sheet on EPIC. The nurses hold daily huddles (brief check-in meetings) with other members of the care team and carry out essential patient navigation functions. Treatment plans are entered into EPIC by the physician. The team has created electronic notifications to ensure that key structured data fields are filled out for each new patient as the treatment plans are entered (see Figure 8, right). Nurses are responsible for following their standard workflow, scheduling follow-up visits, lab monitoring, and assessing for toxicity and adherence. The medical assistants at the cancer center proactively call patients two days prior to each appointment to assess whether the patient has completed all the necessary follow-up labs and to remind the patient about their upcoming visit. The flowcharts, right, depict a standard chemotherapy process within the multidisciplinary team.

FIGURE 8
Key Data Fields in EHR

Vitals
- Height
- Weight
- BSA (Calculated)
- BMI (Calculated)
- BP
- Pulse
- Respiratory
- Temperature

Toxicity Assessment

Distress Assessment

Tumor Markers

Oncology Flowchart

Continuous Infusion

Take-Home Oral Chemo Medication
- Drug
- Start date
- End date
- Daily dose (mg)
- Missed doses
- Current pill count

Supportive Care

Radiation Oncology

SITE VISIT 3:
ALTA BATES SUMMIT MEDICAL CENTER
COMPREHENSIVE CANCER CENTER

FIGURE 9
Flowchart of Standard Chemotherapy Process at Alta Bates Summit Medical Center

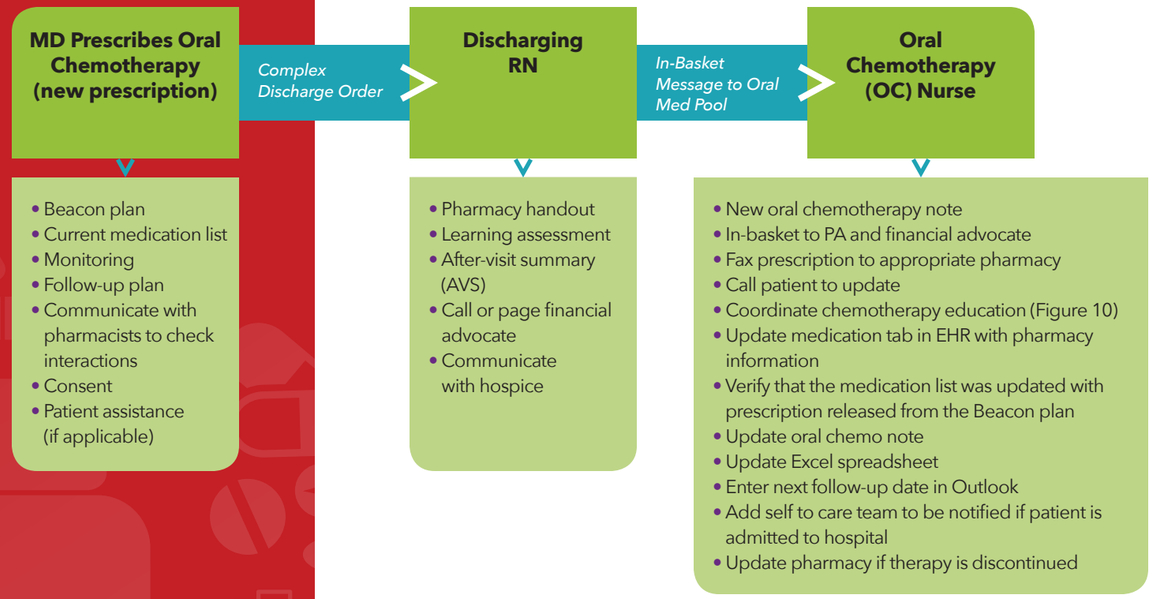
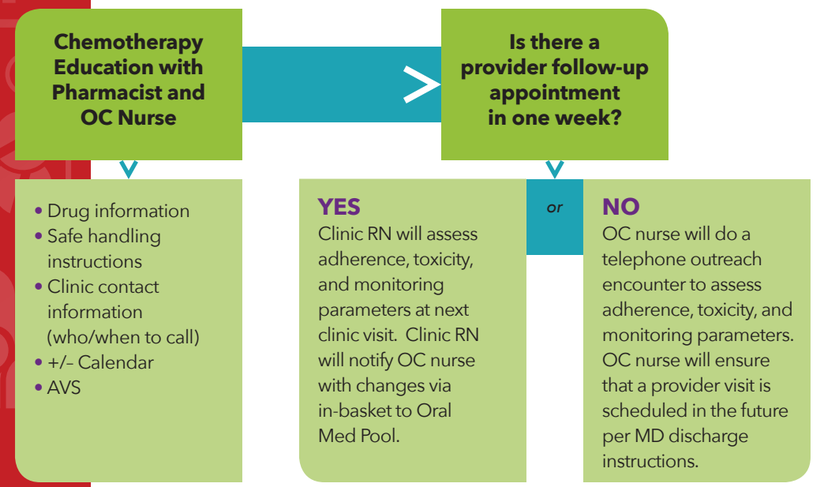


FIGURE 10
Flowchart of Standard Chemotherapy Education Process at Alta Bates Summit Medical Center



Steps to Success

Alta Bates Summit Medical Center shares these successful strategies for implementing an oral oncolytics program.

Collaborate with Specialty Pharmacy

At Alta Bates Summit Medical Center, the cancer center has a retail pharmacy but it does not dispense many oral oncolytics—hence, the reliance on outside specialty pharmacies has led nurses and pharmacists to take a proactive approach with communication and collaboration.

- When patients are started on oral oncolytics, the team sends the specialty pharmacy all the necessary information so that it can handle the preauthorization process with the insurance companies.
- The specialty pharmacies also receive an up-to-date medication list for each patient and assess the potential for any serious drug-drug interactions.
- The team has found that specialty pharmacies are effective at finding co-pay and patient assistance programs for patients who require financial assistance. The strong collaboration has led to patients "almost always" starting their oral oncolytics as scheduled based on their treatment calendars.

Put in Place Effective Processes for Monitoring for Adherence & Toxicity

As the cancer care team was treating patients with oral oncolytics, it became apparent that some patients were missing multiple doses or stopping therapy without informing their clinicians. The team wanted to improve its communication with patients and find ways to gather patient-reported feedback on their treatments. One of the medical oncologists—in collaboration with a nurse and the research team—piloted a study to evaluate the efficacy of using a mobile app that could remind patients to take their medications. This basic commercial app provided a useful reminder functionality for the patients who participated in this pilot, but it lacked the capabilities of feedback and communication with the care team. Based on this initial study, the team decided to explore development of a new mobile application that would include the scheduling functionality, as well as a capability to alert clinicians when patients miss three consecutive doses of their oral therapy. Additionally, clinicians want to have a better understanding behind the cause for non-adherence—particularly when patients miss multiple doses of their medication—via a medication tracking and reporting function in the app.

The team wanted to improve its communication with patients and find ways to gather patient-reported feedback on their treatments.

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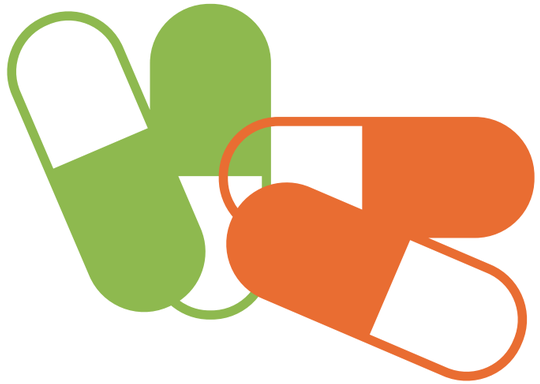
The team is currently planning a study using this second app. In the interim, the team will continue to work with their innovation department to design and build a continuously improved mobile app that will ultimately integrate with EPIC and allow the medication monitoring and adherence information to be entered directly into the patient chart. The team hopes to build an automated medication calendar that is personalized for each patient, and includes the start and end dates, the dates for lab tests, and the dates for follow-up appointments. All of those dates would automatically shift, based on real-time occurrences, such as the medications being delivered on a different date. By developing a mobile app that provides real-time communication between patients and clinicians, the care team believes this will significantly improve monitoring and adherence for cancer patients who are prescribed oral oncolytics. Additionally, enhanced safety and compliance via a useful monitoring system is a major benefit to the controlled environment of clinical trials.

Invest in an Ongoing Commitment to Quality

One of the medical oncologists serves on the cancer center's Quality and Safety Committee. His vision for developing and using a mobile app to improve monitoring for cancer patients has led to discussions with others across the Sutter Health Network. The mobile app in development for cancer patients may extend into other departments across Sutter Health and ultimately improve treatment monitoring and adherence for patients who have chronic conditions.

The medical oncology team is currently undergoing the QOPI (Quality Oncology Practice Initiative) Certification Program offered by ASCO. The process has led the team to evaluate its current standard work processes, and the team discovered opportunities to improve documentation quality around the goals of oral oncolytic treatment and patient consent to oral oncolytics. QOPI is developing specific quality measures focusing on compliance, with documentation standards and existence of policies and procedures for best practices around oral oncolytics.[3]



SITE VISIT 3:
ALTA BATES SUMMIT MEDICAL CENTER COMPREHENSIVE CANCER CENTER

Develop a Patient Education Program

Before providing patient education, nurses perform a structured health literacy assessment. This assessment allows nurses to effectively tailor their conversations with patients, ensuring adequate understanding and comprehension. Nurses employ a teach-back method for patient communication, supporting maximization of the patient's level of understanding. The oncology nurse and pharmacist coordinate the delivery of in-depth patient education and use drug-specific information provided by Lexicomp (a software program used to help healthcare professionals by providing drug and clinical information, delivered across multiple platforms, integrated into daily workflow). Given that the cancer center serves patients across a wide range of ethnicities, new patient orientation materials are provided in 11 different languages. Many patients in the region are well educated and highly informed; these patients frequently come to their visits with the latest information about treatment options and have a high-level of participation in online patient forums and patient support groups. Information patients bring to their appointments is regularly incorporated into the shared decision-making process between physicians and patients. In some instances, patients come misinformed because of poor-quality information that they discovered online. The clinicians at Alta Bates Summit are accustomed to guiding patients away from misinformation and non-clinically-vetted information through constructive conversations, providing patients with clinically accurate and unbiased educational materials and information.

The mobile app in development for cancer patients may extend into other departments across Sutter Health and ultimately improve treatment monitoring and adherence for patients who have chronic conditions.

SPOTLIGHT PROGRAMS

In addition to the three site visits, ACCC interviewed other member programs about their oral oncolytic processes and identified the following effective strategies:

HENNEPIN COUNTY MEDICAL CENTER

Develop patient education geared to underserved populations. At Hennepin County Medical Center, Minneapolis, Minn., emphasis is placed on reaching out to the community and focusing on underserved populations. Since many of its patients have limited English proficiency, the cancer care team decided to have its pharmacists provide education as patients are holding their pills in their hands. Hennepin County Medical Center is able to do this by having specialty pharmacies send the initial doses directly to the cancer center. Then, the oncology nurse will schedule an education visit for the patient where the pharmacist provides in-depth instruction while patients physically hold their prescriptions. When treating an underserved population, Hennepin County Medical Center has found that some patients do not have phones, which can cause delay when the specialty pharmacy cannot reach patients to confirm pick-up. In this case, Hennepin County Medical Center schedules a phone call with the pharmacy during the appointment time, so that the specialty pharmacy can speak to the patient directly.

NORTH MISSISSIPPI MEDICAL CENTER

Utilize patient assistance software. North Mississippi Medical Center, Tupelo, Miss., utilizes M&D Cares patient assistance software (mdcares.net), which serves as an electronic data repository of co-pay assistance, foundation funding, and free drug programs. Two patient assistance coordinators (both certified pharmacy technicians) and a nurse input patient data into this database—eliminating manual forms and visits to multiple manufacturer websites to search for free drugs or look up drug prices. The software automatically stores all patient data, including demographics and if patients are on multiple drugs; populates forms; and manages processed forms. More, the database constantly updates based on inventory. North Mississippi Medical Center reports saving patients $2 million to $3 million dollars a year, based on tracking the free drugs received compared to their original cost. The cancer center pays a monthly subscription for this web-based program.

CLEARVIEW CANCER INSTITUTE

Improve in-office dispensing. With the shift of oncology care to a greater number of oral cancer drugs, Clearview Cancer Institute, Huntsville, Ala., has been on the forefront of innovation in the area of in-office dispensing. Along with the pharmacists and pharmacy technicians required to dispense prescriptions, Clearview Cancer Institute employs a team of social workers to provide co-pay assistance and a three-person prior authorization team to complete all prior authorizations for oral drugs. Clearview Cancer Institute's pharmacy has developed a pharmacist-led education and adherence program. As part of this program, the pharmacist reviews pertinent lab values to assess for appropriateness of dose and toxicities. The pharmacist also contacts the patient once monthly to assess the patient for adherence and adverse effects. In the past year, Clearview Cancer Institute's pharmacy has achieved Accreditation Commission for Health Care (ACHC) specialty pharmacy accreditation and has become one of the first two pharmacies in the country to achieve ACHC's Oncology Distinction. These standards prove the high quality of care that community oncology practices provide through their oral dispensing programs, such as cost savings to the patient, close follow-up, and monitoring, and coordination with other members of the healthcare team. All of these initiatives have contributed to fast, affordable access to oral oncology drugs for patients and improved continuity of care.

KEY RECOMMENDATIONS: STEPS TO SUCCESS

The landscape of cancer care is evolving at a rapid pace and the use of oral oncolytics will continue to grow in the community. Experts are calling community cancer programs to "develop standard procedures for educating patients, reviewing and documenting treatment plans, and routinely monitoring patient adherence to oral anti-neoplastic therapies."[4] Given that all cancer programs are unique, they must design and develop their own procedures that will effectively ensure that cancer patients are receiving the highest level of care. As cancer programs adopt principles of precision medicine and strive to tailor treatment plans for each patient, they will have opportunities to improve how they work as teams to incorporate the initiation and monitoring of oral oncolytics into their process to ensure patients use these therapies safely and effectively.

Step 1.
Take a Multidisciplinary Team Approach

A multidisciplinary team approach ensures all departments are actively engaged in care, no pieces are missed, and resources are not wasted on duplication.

Step 2.
Assign Responsibilities

Assigning roles—regardless of job title—ensures that each person knows what he or she is responsible for and that nothing falls through the cracks.

Step 3.
Collaborate with Specialty Pharmacy

If your cancer program has an on-site dispensing specialty pharmacy, develop parallel processes when oral oncolytics need to be dispensed by an outside specialty pharmacy. The National Community Oncology Dispensing Association, Inc. (NCODA) was founded to strengthen community oncology practices with dispensing services. NCODA promotes pharmacists, nurses, technicians, and other healthcare providers in community cancer programs to connect with others and share valuable resources and information. This collaboration supports the continuity of care that is so critical for oncology patients who are prescribed oral medications. Even with an on-site dispensing specialty pharmacy, some oral oncolytics are required to be dispensed through outside specialty pharmacies based on payer and manufacturer requirements.

If your cancer program relies primarily on outside specialty pharmacies for oral oncolytics, develop strong collaborations through proactive communication and frequent follow-up with them. Ensuring that specialty pharmacies have all the necessary information pertaining to each patient's health insurance and medication list will facilitate their internal processes and reduce the likelihood of delays and potentially hazardous drug interactions. Also, be sure to remind your patients that a specialty pharmacy will fill

Remember that many cancer programs can improve how they explain and document what to do when doses are missed, safe handling instructions, and potential drug-drug and drug-food interactions.

KEY RECOMMENDATIONS: STEPS TO SUCCESS

their prescription and contact them. Missed phone calls can lead to processing delays. Cancer programs need to study and publish the processes, administrative burdens, financial impact, discrepancies, inconsistencies, and disparities occurring between the management of the on-site dispensing specialty pharmacy versus outside specialty pharmacies. If your patients have limited English proficiency, consider having them come in for an appointment where you can call the specialty pharmacy together to confirm their prescription with the help of an interpreter and process the order. Specialty pharmacy services for patients receiving oral oncolytics can include: (1) providing patient counseling and education on adverse effects and self-management strategies; (2) processing prior-authorization requests and helping patients find and navigate co-pay and other patient assistance programs; and (3) monitoring for toxicities and guiding appropriate dosing adjustments.[6]

Step 4.
Provide Financial Advocacy Services

Given the high out-of-pocket costs associated with oral oncolytics, it remains crucial for community cancer programs to provide effective financial advocacy services.[7,8] Hire and train dedicated financial advocates. Proactively screen and identify patients who are at high risk for developing financial toxicity. Be sure that all clinicians and providers are familiar with the types of patient assistance programs and resources that are available for their patients. Enrolling patients into a formal and structured pharmacist-driven adherence program can help overcome barriers to adherence, including cost-related challenges.[9] Many cancer programs have dedicated financial advocates, but other programs are training their pharmacy technicians and social workers to find co-pay and patient assistance programs. Ongoing assessment is important with each prescription as patients' financial status can change quickly over time. Strengthen or grow your financial advocacy services by participating in the ACCC Financial Advocacy Network (FAN), accc-cancer.org/FAN.

Step 5.
Develop a Robust Patient Education Program

Schedule a dedicated patient education office visit. Be sure to assess health literacy and understanding before reviewing important information. Remember that many cancer programs can improve how they explain and document what to do when doses are missed, safe handling instructions, and potential drug-drug and drug-food interactions. Oncology nurses who have special training around oral oncolytics can be more effective when using motivational communication techniques and help patients achieve a higher level of therapy-related knowledge.[10] Pharmacists can also have a key role in engaging and educating patients, lab monitoring, and improving medication adherence.[11]

KEY RECOMMENDATIONS: STEPS TO SUCCESS

Step 6.
Put in Place Effective Processes for Monitoring for Adherence & Toxicity

Studies show that adverse effects remains one of the leading cause for non-adherence to oral oncolytics.[12] Effectively assessing for potential toxicity begins when pharmacists are able to review the patient's medication list for potential drug-drug interactions.[13] Studies have shown that pharmacists often make recommendations and provide interventions that can lead to safer doses or avoidance of serious interactions. Many cancer programs may be asking patients about adherence, but the key components of the discussion may not be entering the patient's chart. When monitoring for toxicities, ensure that the right members of the team are reviewing the information and are notified when warning signs are present. Also, explore ongoing innovations that may provide real-time reporting capabilities so that patients who are experiencing serious adverse effects can receive appropriate interventions in a timely fashion. Since some specialty pharmacies may have pharmacists or nurses calling patients and asking them about adherence and toxicity, it is important to remind patients that the information they provide specialty pharmacies is not being captured and sent to their cancer care team. Ongoing research exploring the use of mobile apps to capture patient-reported outcomes for patients treated with oral oncolytics appears to be promising.[14] A number of independent specialty pharmacies have built unique management programs providing specialized counseling and monitoring for patients on certain oral oncolytics. These programs may include pharmacists reaching out to patients to encourage adherence, identify adverse events, and track discontinuation at specified time intervals.[15]

Step 7.
Maximize the Use of Technology

Given that technology can either be a hindrance or an enabler to providing better care, find ways to maximize the use of technology to streamline workflow processes and improve communication. CPOE can lead to reductions in prescribing errors and improvements in patient safety in the oncology setting.[16,17] However, some providers may still be struggling with the use of health IT. The role of medical scribes in community oncology settings may be worth considering, given that one recent study found that the use of medical scribes led to increased productivity and improvements in the quality of clinical documentation.[18] Find ways to reduce redundancies and to leverage data for continuous quality improvement. If patients are still filling out paper-based forms that are then scanned into their chart, consider ways to digitize the entire process. If staff are sending repeat faxes to outside specialty pharmacies, consider the use of secure electronic fax servers that may reduce clerical tasks.

Studies have shown that pharmacists often make recommendations and provide interventions that can lead to safer doses or avoidance of serious interactions.

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