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Oral Antimyeloma Therapy: Barriers to Patient Adherence and Tips for Improvement

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FEATURE

Oral Antimyeloma Therapy: Barriers to Patient Adherence and Tips for Improvement

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Multiple myeloma (MM) is a plasma cell disorder characterized by uncontrolled clonal plasma cell proliferation in the bone marrow, production of monoclonal protein in the blood or urine, and associated organ dysfunction.[1,2] As the second most common hematologic malignancy, MM is an important area of focus for clinical pharmacists. Fortunately, outcomes for MM patients have greatly improved recently with the explosion of novel agents such as immunomodulatory drugs, proteasome inhibitors, and monoclonal antibodies.[1-4]

Novel agents pose unique challenges to clinicians. In particular, many drugs currently being prescribed in MM treatment are oral.[5] Furthermore, continuous treatment has been a paradigm shift in MM, allowing for ongoing disease suppression, deeper responses, and improved progression-free survival.[6] But these changes are also associated with substantial burdens, such as treatment-related toxicities, financial toxicity, and decreased patient adherence because of complex dosing schedules.

What Is Adherence?

Adherence is defined as the "extent to which a patient's behavior coincides with instructions from a healthcare provider."[7] Nonadherence is associated with suboptimal drug efficacy, resulting in poor clinical outcomes and increased healthcare costs.[7] Medication nonadherence is identified as the largest driver of avoidable U.S. healthcare costs, accounting for more than $200 billion annually.[8-9] Because of the significant clinical and economic impact of nonadherence to oral therapies, it is vital that healthcare providers acknowledge and address adherence, especially in a disease that tends to follow a chronic disease trajectory where treatment is continuous. Unfortunately, data for understanding adherence rates among patients with MM and the impact of nonadherence on long-term patient outcomes are lacking. A recent article aimed to explain how medication adherence affects the burden of MM. An online survey was administered to 162 adult patients with MM. Better medication adherence was related to less impairment to work productivity and functioning, lower out-of-pocket costs, and fewer office visits.[10]

What Are the Barriers to Adherence, and How Can They Be Overcome?

Several oral drugs, including thalidomide, lenalidomide, pomalidomide, ixazomib, and panobinostat, are currently approved for use in treating MM.[4,11-18] These agents play an active role in both the upfront treatment of MM and the treatment of relapsed or refractory MM. In addition, in accordance with guidelines, patients are frequently prescribed supportive care medications that are important in preventing disease- and treatment-related complications.[19-23] These include oral anticoagulants, calcium and Vitamin D supplements, and antivirals. The addition of supportive care medications represents an essential component of treatment, which adds further complexity to the treatment regimen.

Multiple barriers to optimal adherence in MM patients exist (**Table 1**). The reasons for adherent behavior may differ according to the patient's situation and stage of myeloma treatment. Barriers to medication adherence are treatment-, patient-, physician-, and environment-related.[24]

Oral regimens including supportive care add significantly to the pill burden of patients. This issue is particularly relevant for older patients (the median age of onset of MM is 70 years) who may have multiple comorbid illnesses.[4] Increasing pill burden has been linked to worse adherence in other disease states.[25] Additionally, the incorporation of oral therapies has caused a shift in medication

Table 1. Oral Medications in Multiple Myeloma: Barriers to Adherence

Treatment-related barriers
Regimen complexity
Regimen toxicity
Risk evaluation and mitigation strategy program
Patient-related barriers
Polypharmacy
Cognitive impairment
Lack of social support
Physician-related barriers
Poor provider-patient communication
Environment-related barriers
Financial cost
Use of specialty mail-order pharmacies

responsibility. Although healthcare providers are traditionally responsible for the administration of intravenous medications, this burden has now shifted to patients, creating new challenges for healthcare professionals seeking to maintain medication adherence and ongoing clinical and laboratory monitoring.[26-28]

In addition, current treatment regimens are highly complex, and oral chemotherapy regimens require from patients a high degree of understanding. Chemotherapy doses and schedules are not consistent or linear and can be very hard for patients to understand. Initiation of treatment is often delayed significantly because many of these oral drugs are part of a risk evaluation and mitigation strategy (REMS) program, are primarily dispensed through a specialty pharmacy, and often require prior authorization. They are also expensive and place a financial burden on the patient.

Patient-related factors may include the patient's age and sex, a poor understanding of the disease and associated risks, a perception of being cured or having asymptomatic disease, a lack of belief in treatment benefits, cognitive impairment (e.g., forgetfulness), comorbid conditions, polypharmacy, and reluctance to change behaviors.[26,28-30] Although a cure for myeloma does not exist, it is important to understand how patients perceive their response to treatment because it may affect their attitude toward continued treatment.

Treatment-related factors, such as medication side effects and drug-drug interactions, can result in medication nonadherence when the patient is unprepared or unable to manage his or her symptoms. Patient education, both initial and ongoing, by the healthcare team—specifically, by a specialized pharmacist—could provide patients better guidance on recognizing these side effects and preparing strategies to both prevent and treat them. Many of the oral drugs we prescribe have unique adverse effects that the patient must be able to recognize at home and communicate to the healthcare team. For example, the immunomodulator drug class (including thalidomide, lenalidomide, and pomalidomide) can cause myelosuppression, peripheral neuropathy, gastrointestinal disturbances (such as diarrhea), rash, venous thromboembolism, and increased susceptibility to infection.

Physician-related barriers include poor patient-provider communication, lack of positive reinforcement from the healthcare provider, insufficient educational measures on the medication regimen or importance of adherence, and infrequent follow-up. This may hold true especially during the maintenance phase, when patients are seen only monthly.

Socioeconomic factors, such as lack of health insurance, medication cost, limited access to healthcare facilities or pharmacies, social lifestyle, lack of family or social support network, and inadequate supervision, are also strong determinants of medication nonadherence.

Because of these logistic, perceptual, physiologic, and social barriers to treatment, it is important that healthcare providers identify individual barriers to oral therapy and work with individual patients to isolate strategies that will enable them to take their medications as prescribed. In providing patient-centered oncology care, it is important to perform ongoing assessments of medication adherence to oral therapies. Direct methods include directly observed therapy, and indirect methods include use of patient questionnaires, patient self-report, and patient diaries or logs.[31]

Using pill containers with a microelectronic monitoring system allows for tracking of the opening of the pill container but can be expensive. Assessing prescription filling and insurance records is considered to provide the most accurate estimate of actual medication use over a period of time. However, prescription filling does not necessarily translate to pill consumption or provide information about whether the patient is taking the medication as prescribed. In addition, oral therapy for myeloma is often withheld because of treatment or disease complications, but the suspension of treatment may not necessarily be captured by this method.

It is well accepted that improving patient adherence requires a multifaceted approach and cannot rely on one method. Typically, models of adherence interventions are based on the key elements of patient education, behavioral interventions, and affective support, which may include symptom management, simplifying medication regimens, improving patient-provider communication, and relying on other specialized experts (e.g., pharmacists) to increase patients' knowledge and organize strategies to increase adherence rates. Lifestyle differences among patients mean that identifying individual barriers and tailoring adherence interventions to their individual needs is critical.

The frequency of monitoring and follow-up that are appropriate for the patient and the agent prescribed must be determined and defined in the treatment plan. It is recommended that an office visit be scheduled once per cycle for an assessment, and follow-up visits, calls, e-mails, or text-message reminders must be used as opportunities to reiterate the importance of adherence. During these follow-up visits, medication adherence must be assessed, and any identified barriers dealt with. Patients should be encouraged to use adherence aids and reminder cues to improve adherence outcomes. Reminders that can be used to improve patients' adherence to their oral therapies include pillboxes, pill diaries, and treatment

calendars. Phone or text-message reminders based on the dosing schedule are popular methods. Calendars, checklists, and medication charts may be used as refill reminders so that patients have an adequate supply of medications.

What Is the Role of the Clinical Pharmacist in Oncology Care?

Strategies for incorporating the services of a clinical pharmacist directly into oncology care delivery have been published.[32-34] For example, pharmacists have been integrated into hematology-oncology clinics with the aims of improving supportive care, enhancing the education of patients receiving chemotherapy, and improving efficiency in the chemotherapy infusion unit.[15] Additional areas of study include the assessment of pain, nausea, and vomiting; management of treatment-related side effects; palliative care; programs dedicated to monitoring oral anticancer regimens; and follow-up of patients undergoing hematopoietic stem cell transplantation.[32,34-38] The pharmacist who is integrated into the healthcare team can be involved with providing patient education, monitoring adverse effects of therapy, evaluating adherence to oral antimyeloma medication schedules, ensuring provision of drugs in a timely fashion, and assessing the appropriateness of supportive care in the overall treatment of the patient.

How Have We Sought to Improve Adherence in Multiple Myeloma Patients?

At the University of Illinois at Chicago (UIC), we hypothesized that a multidisciplinary collaborative physician-pharmacist MM clinic would improve patients' adherence to treatment and supportive care guidelines, managing treatment-related side effects, and navigating issues involving access to oral specialty medications (a collaborative clinic). Outcome measures were retrospectively compared to those of patients being treated by the same physician during the previous year, where ad-hoc pharmacist consultation was available upon request (a traditional clinic).

The collaborative clinic led to significant improvements in patients' adherence to supportive medications such as bisphosphonates (96% vs. 68%, $p = .0002$), calcium and vitamin D (100% vs. 41%, $p < .001$), acyclovir (100% vs. 58%, $p = .0009$), and Pneumocystis jirovecii pneumonia (PJP) prophylaxis (100% vs. 50%, $p < .0001$). Appropriate venous thromboembolism (VTE) prophylaxis in immunomodulatory agent (IMiD)-treated patients was prescribed in 100% versus 83% of patients ($p = .0035$). The median time to initiation of bisphosphonate (5.5 vs. 97.5 days ($p < .001$) and PJP prophylaxis after autologous transplant was shortened in the collaborative clinic (11 days vs. 40.5 days, $p < .0001$). Furthermore, the number (85% vs. 21%, $p < .0001$) and duration (7 days vs. 15 days, $p = .002$) of delays in obtaining IMiD therapy were also significantly reduced. Our collaborative clinic model could potentially be applied in other practice sites to improve the management of MM patients.

Conclusion

Myeloma is a complex disease, and patients must adhere to difficult treatment regimens. Integrating the clinical pharmacist—who can focus on providing patient education and improving patient-related symptoms, while helping patients avoid additional side effects and drug interactions with the antimyeloma treatment—into the healthcare team is important. Future studies of myeloma treatment should focus on patient adherence and evaluate the long-term effects of nonadherence on disease- and patient-related outcomes. ●●

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Continuing to Learn About Our Chosen Profession: An Oncology Pharmacy Book Group

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Karen's Perspective

Several years ago, a resident gave me a present at the end of his rotation. It was a copy of *The Emperor of All Maladies*, the Pulitzer Prize–winning book by Siddhartha Mukherjee about the history of cancer and its treatment. The resident mentioned that he thought I would enjoy it, and I was touched by his thoughtfulness. But despite my good intentions to read it, the book sat on my shelf for a year or two.

After seeing advertisements for the television series of the same name, I decided I should actually buckle down and read the book—and I was immediately amazed at its eloquence. I wanted to give the resident an equally stunning piece of literature, so I went to Amazon and looked at the "Customers who bought this item also bought" section. After I had thrown more than a few items into my virtual cart, a new hobby was born. I started reading oncology-related books in earnest.

Several months later, I ran into Christine Walko, coauthor of this article, at a conference. I had just read a remarkable book about a patient's experience with metastatic melanoma, and I remembered that Chris was interested in that type of cancer. I casually mentioned the book as something she might enjoy. We met again at the same conference a year later, and she jokingly commented that I should start an oncology book group … and so I did.

Chris's Perspective

My love of reading is hardly a surprise, given that my mother was a school librarian. A comfy chair, a furry feline foot-warmer, a glass of full-bodied cabernet, and a riveting page-turner became a rare but enjoyable indulgence that helped me unwind as I grew older. Though I enjoy a variety of literature genres, historical fiction and nonfiction became part of the mix after I read *The Devil in the White City,* by Erik Larson. *The Emperor of All Maladies* was my choice as I sat in front of a crackling fireplace over the holidays in the snowy South Hills of Pittsburgh in 2011. I remember reading chapters discussing the history of cancer between current studies published in the *Journal of Clinical Oncology*. The progress we had achieved since those early days of nitrogen mustards was remarkable and made me feel more connected with my profession.

I also was lucky enough to have a patient who told me personal stories about working as a chemist at Cal Tech and training under Linus Pauling. I felt in some ways that I was getting a glimpse of history and meeting someone who had worked with a celebrity (it was then that I fully embraced my hidden science nerd). I began seeking out books that augmented my understanding of aspects of my field through the connection of engaging stories in a similar and personal way. My favorites still include humorous stories—such as *The Disappearing Spoon* (the author Sam Kean is one of my favorites!)—about the elements in the periodic table.

During her lecture on chronic leukemias for the Board Certified Oncology Pharmacist recertification program, Karen mentioned how she had accidentally found the book *The Philadelphia Chromosome,* and that had me not only hunting through Amazon for that book but also filling my cart with four more that she had recommended by the end of her lecture. Fortunately, when she was asked to continue to feed my addiction for enriching literature, she obliged and started our online book group.

Our Book Discussion Group

Our Facebook discussion group, the Oncology Pharmacy Book Group, has been open for about a year and currently has 92 members. We post comments about various books related to oncology and other aspects of the medical profession—our thoughts, reviews, and recommendations. As I look back at the books on which our group has posted comments, I see that they can be divided into three broad categories:

Books About Oncology and the Science Behind Its Treatment

Such books are typically heavily focused on the "hows and whys" of cancer—why cancer occurs, how a particular genetic defect was discovered, or how a specific drug was developed.

Examples:

- *The Philadelphia Chromosome: A Genetic Mystery, a Lethal Cancer, and the Improbable Invention of a Lifesaving Treatment*, by Jessica Wapner.

(continued on p. 17)

Prepare for the Worst, Hope for the Best: Pharmacy Preparedness and Advanced Planning for Natural Disasters

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In 2017, the United States was plagued with memorable natural disasters, including devastating hurricanes and blazing wildfires that caused catastrophic destruction, left thousands of people stranded, and led to hundreds of deaths. The 2017 Atlantic hurricane season was extremely active, with three Category 4 hurricanes making landfall in the United States: Harvey, Irma, and Maria. (My own experience with emergency preparedness was acquired when I was working at Texas Children's Hospital in Houston before, during, and after Hurricane Harvey.) Adding insult to injury, the immediate damage rendered by these hurricanes included Puerto Rico's considerable pharmaceutical manufacturing industry. The downstream effects of the destruction have significantly disrupted production and continue to affect the nation's healthcare system because of the numerous drug and supply shortages that have resulted.

Natural disasters threaten the ability to provide optimal patient care for a variety of reasons, while at the same time causing an increased demand for healthcare services. Not only do these events potentially destroy pharmacies that house vital medications and supplies, but natural disasters can inflict anything from minor injuries to severe traumas on individuals, who in turn require medical attention.[1] Furthermore, in some cases the anticipated course of a natural disaster changes direction and subsequently affects another region unexpectedly, or the timeline of the storm is prolonged compared to the initial forecast.[2]

The unpredictable nature of disasters makes preparation exceptionally difficult, and for that reason emergency preparedness and advanced planning are integral to navigating a pharmacy through the storm.[3] Natural disasters vary according to the region of the country, so it is important to consider the location when doing advanced planning.[1] It is imperative that the different phases of natural disasters are evaluated both individually and collectively when an emergency response plan is being developed.

Phase 1: Preparation

Pharmacy leaders should be familiar with the ability of the local, state, and federal government to provide assistance, including drugs and medical supplies, during a declared natural disaster.[4] State governors play an essential role in coordinating resources and soliciting additional aid when necessary.[5] Further, pharmacy leadership in conjunction with the hospital administration should work closely with local distributors and wholesalers to institute an ordering process during emergencies so that the inventory of critical medications and supplies can be maintained. The disaster plan for the pharmacy should outline this procedure clearly and appropriately.[3]

Before developing a pharmacy disaster plan, the director of pharmacy or designee needs to clearly understand the hospital-wide emergency system for natural disasters in order to effectively align the plan for pharmacy response. During a disaster, the pharmacy often oversees the medication management and procurement for the hospital and potentially the surrounding region, depending on the location of the facility. The director of pharmacy or designee should identify key stakeholders and assign specific roles in the pharmacy disaster plan. It is common for the pharmacy disaster plan to have a designated pharmacist that works closely with the hospital administration in the event of a natural disaster, as well as a pharmacy administrator on call to be the single point of contact for the pharmacy staff. The role of this designated pharmacist is dynamic and entails several responsibilities, including, but not limited to, informing the pharmacy administrator on call when to communicate with the staff, obtaining additional medication supplies as needed, and reallocating staff members to high-demand areas in the pharmacy. Effective communication throughout the activation of a pharmacy disaster plan is crucial.[3]

Advanced planning should include creating a list of essential medications to have in stock, including the amount and storage location for each drug. This list should be made through collaborative, interprofessional efforts with emergency medicine and infectious disease physicians to ensure appropriateness. A reasonable inventory is considered to be a 72- to 96-hour supply on hand for the essential medications on this list. In the days or hours leading up to a potential natural disaster, the inventory should be closely inspected to ensure that the supply is not past the expiration date and that the quantity on hand is sufficient. Other considerations for medication management are having a flow diagram of assigned high-acuity areas for the stocking of emergency medications and knowing where and how the surplus inventory will be stored during the emergency, what to do in the event of a power outage or generator failure, and how to handle medication needs if the patients are evacuated.[2,3]

The pharmacy disaster plan should set clear expectations for the role of each pharmacist and tecÚician shift to allow for the continuation of efficient patient care throughout the natural disaster. Clinical pharmacists are indispensable to a staffing plan for an emergency response, as will be discussed in the section on Phase 2. Pharmacy staff members should be adequately trained on their role in the pharmacy disaster plan, and their competence in emergency preparedness should be evaluated at least annually through an assessment deemed appropriate by the department of pharmacy. Many institutions offer drills to prepare for emergencies, such as natural disasters, and pharmacists should be allowed and encouraged to participate.[2-4]

Phase 2: Response

Several studies have evaluated the training that prepares practicing pharmacists to respond during natural disasters and have examined the role of pharmacists during these events and gaps in knowledge regarding emergency preparedness.[6] Ideally, each role to be carried out by a pharmacist and the responsibilities of each shift during an emergency response will be clearly outlined in the pharmacy disaster plan. Not only does this alleviate confusion and eliminate gaps in coverage, but it gives each pharmacist the ability to focus on explicit tasks and specific responsibilities and makes every pharmacist accountable. Pharmacists should be assigned to a role they are best suited to fill. It is crucial to develop a robust training program with different competencies for each role so that pharmacists meet the requirements assigned to that shift during an emergency response.[7]

When a natural disaster strikes unexpectedly or lasts longer than expected, pharmacists play a crucial role in maintaining the medication use system so that medications can be delivered and dispensed, but unique challenges can arise. Pharmacists may need to make do with limited resources and a dwindling medication supply when shipments cannot be delivered. Pharmacists are essential to analyzing the inventory on hand and working with the medical team to determine therapeutic substitutions.[7]

Clinical pharmacists contribute an unmatched knowledge of navigating the medical record, have established relationships with their respective teams and nursing partners, and possess the critical-thinking skills required for processing the acute demands of potential mass triage situations caused by the damage of a natural disaster. Generally, the daily demands of a clinical pharmacist can be quickly translated to the need to emergently respond during a natural disaster. In addition to the traditional activities completed by a pharmacist daily, clinical pharmacists can actively participate in code response, provide direct patient care, and efficiently provide drug information in response to questions from both the medical team and patients. Many clinical pharmacists work closely with the interprofessional team to facilitate transitions of care, which is useful during a natural disaster when the census can exponentially increase with an added need to triage patients based on acute presentation.[2] The staffing plan in a pharmacy disaster plan should account for the need to have clinical pharmacists present for the duration of the natural disaster and involvement in each of the phases.

Phase 3: Recovery

When preparing for the recovery period following a natural disaster, it is important to be familiar with the prescribing practices of your institution and region, which can aid in planning for medication needs relevant to the patient population. It is imperative to consider the setting for which the advanced planning is taking place and then properly using multiple data sources, such as trends in medication purchases from wholesalers, to compile a list of medications that may be needed after a natural disaster.[8] Although this is a critical part of the recovery phase, it should be accounted for during advanced planning in the preparation phase.

During this time, it is entirely possible that records for patients cannot be accessed or that there will be limited availability of physicians to write prescriptions for both acute emergency medications and vital chronic therapies. Plans should cover such an event, including a workflow for handwritten labeling and dispensing of medications and instructions on seeking reimbursement if possible after the natural disaster recovery period.[1] Again, this should be addressed in the advanced planning and be part of the pharmacy disaster plan.

It is increasingly common for emergency preparedness training to be incorporated into pharmacy school curricula. These learning experiences range from simulations of mass triage and dispensing scenarios during introductory pharmacy practice experiences (IPPEs) to participation in programs run by public health organizations. The inclusion of unique experiences like these in curricula should be considered as a valuable interprofessional learning opportunity for healthcare professional students to practice the skills necessary to work in teams during response to natural disasters.[6]

A discussion about emergency preparedness and advanced planning for natural disasters would be incomplete without stressing the importance of developing a personal plan for these potential events. Whether it is learning how to adequately prepare your home for a natural disaster or arranging care for your dependents, developing a plan for your family is just as integral as understanding the emergency response procedure at your place of employment. Several online resources are available to help formulate this plan, including those from the American Red Cross and the Department for Homeland Security and the websites of a number of insurance companies. ●●

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Preparing for the Board Certified Oncology Pharmacist (BCOP) Examination

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Three oncology pharmacists who have obtained BCOP certification share their tips on preparing to take the exam.

What year did you finish residency?

Cambareri: I completed my PGY-2 specialty oncology residency in 2015.
Hanna: I completed my PGY-2 specialty oncology residency in 2016.
Segal: I completed my PGY-2 specialty oncology residency in 2013.

When did you pass your BCOP examination?

Cambareri: I passed the exam in the fall of 2015.
Hanna: I passed the exam in the fall of 2016.
Segal: I passed the exam in 2016.

How did you decide when to take your BCOP exam?

Cambareri: I decided to take the BCOP test the fall after I completed my residency training because of how familiar I felt with the diversity of topics in hematology/oncology at that point in my professional career. I was also going into a position working with solid tumor outpatients, and before shifting my mindset completely to that area, I wanted to harness the residency experiences I had just had in pediatrics, hematology, and inpatient care and use the time I had between completing my residency and starting my new position to focus on studying.
Hanna: I took my BCOP examination the fall following residency because I felt I was well prepared during my training to sit for the test, and I was aware of the examination style and format from having sat for the Board Certified Pharmacotherapy Specialist (BCPS) exam after my PGY-1 training.
Segal: I waited 2 years after I completed my residency before I took the BCOP exam. I did this because I felt that I needed to develop and hone my practice skills. Unfortunately, it took more than one attempt to pass my BCOP exam, but I did succeed in 2016. According to the Board of Pharmacy Specialties (BPS) website, the purpose of the exam is to "validate that a pharmacist has the advanced knowledge and experience to optimize outcomes for patients with malignant diseases." My residency more than adequately prepared me for the foundational content on the exam. However, one critical item was missing, and that was experience. For this domain, I would need to function autonomously as a clinical oncology pharmacist, answering pertinent drug information questions, recognizing and responding to complex patient issues, and assisting in the design of oncology care plans.

What, if anything, did you do during your residency that helped you prepare for taking the BCOP exam?

Cambareri: Personally, I study and learn best by making handouts and taking notes. I felt that the handouts and notes I had made and kept up to date throughout the year for topic discussions with tables, pictures, references, and de-identified patient case examples served as my peripheral brain of experience. These were a huge help when I reviewed them in tandem with the other study materials I had while preparing for the BCOP exam.
Hanna: During my PGY-2 training, my program provided me with the American College of Clinical Pharmacy (ACCP)/American Society of Health-System Pharmacists (ASHP) Oncology Pharmacy Preparatory Review Course to serve as a reference throughout the year. This course is designed to help oncology pharmacy practitioners prepare for the BPS Oncology Pharmacy Specialty Certification examination and obtain broad and detailed updates to their knowledge in oncology. During the first half of residency, weekly discussions with my program director covered different topics in an open-conversation format, and it was expected that the residents would lead the topic discussions to ensure a solid foundational knowledge of the material during the latter half of the residency year. I used the days leading up to the discussions to read the chapter and used guidelines, manuscripts, and video material to research concepts I did not understand.
Segal: You have numerous opportunities to prepare for the exam while you are completing your residency. Take advantage of the learning opportunities provided to you when your interprofessional colleagues ask a question about a drug. Another strategy is to use active learning while staffing. Staffing is a great opportunity to apply your learning to individual patients. While verifying orders, remind yourself of important elements of your learning such as drug class, mechanism of action, dose-limiting toxicities, and drug metabolism. Having a firm foundation in the knowledge of specific medication properties will help tremendously both during your residency and as you prepare for the BCOP exam.

Looking back after taking the BCOP, what would you have done differently during your residency?

Cambareri: In retrospect, I wish I had looked at all the areas I would be tested in on the BCOP exam and noted the less common malignancies and supportive care issues that fall outside of the ASHP requirements for residency training. I would have ensured that I had exposure to these topics and discussed them during my residency training.

Hanna: During the long 60-day wait for the results after I took the BCOP exam, I realized that I could have studied differently during residency. I could have placed a stronger emphasis on reviewing national guidelines (for example, those from the National Comprehensive Cancer Network [NCCN] and the American Society for Clinical Oncology [ASCO]) and focused more on strong or category-1 recommendations. The content of the exam was heavily focused on scenarios seen in day-to-day practice and the role of the clinical oncology pharmacist in treatment, management, and patient education.

Segal: Hindsight is 20/20, but one way to enhance your experience during residency and gear it toward preparing for the exam is to constantly ask questions of your preceptors and yourself as you gather responses to questions about drugs or prepare for topic discussions. This will help foster a deeper understanding of a specific topic and set the stage for active learning.

After your residency, what approaches did you take to prepare for the BCOP exam? For example, what resources did you use or would you recommend for studying? What study routine or schedule did you follow? In retrospect, which tactics were helpful, and which ones weren't?

Cambareri: After I completed my training, I devised a plan of home study that included compiling and dividing by subject all the topic discussions I did during residency, the most recent ACCP/ASHP Oncology Pharmacy Preparatory Review and Recertification Course for Oncology, and NCCN guidelines. I then made a schedule of review and used the size of the topics to decide how much time to allot to them. To help keep up my motivation, I alternated between studying topics that were difficult for me and those that were comfortable for me. I saved reviewing biostatistics until the end so that all the formulas would stay fresh in my mind. While studying, I made a one-page note per topic, so that as I began to progress through the topics, I could review those pages at the beginning of every study session and benefit from the constant repetition. These one-pagers covered the areas I struggled with and also the major points related to the disease. Having a reasonable schedule and these one-pagers kept me on task and helped me continually review while I studied. By the end of my studying, I had condensed the many pages I had printed to about 20 pages, which made it much easier for me to review and focus in the days leading up to the exam.

Hanna: Following residency, I felt well prepared to sit for the exam; however, it was important for me to obtain the new ACCP/ASHP review course materials (generally released annually in June) and run through the material another time. I felt that this would add to my knowledge base, help me outline the updated material, and aid in solidifying the education I had received from my residency. My study methods included reading through a chapter and watching the provided review video as a guide. I dedicated a 2- or 3-hour window each day for studying. With regard to statistics, I wrote key concepts and equations in a notebook to use for review. Additionally, I reviewed the BCPS review course chapter on statistics because the main concepts did not differ from those for the BCOP.

The ACCP/ASHP Oncology Pharmacy Preparatory Review Course was the main resource I used to study for the examination. Preceptor- and resident-led discussions allowed me to build a solid foundation during residency training. The BPS's BCOP examination is designed to test concepts that are foundational for oncology pharmacy practice.

Segal: I used a variety of resources to prepare for the BCOP exam. These ranged from developing outlines and highlighting these outlines with all the colors of the rainbow to purchasing review courses. Ultimately, what I found to be most effective was the ACCP/ASHP review course, the High-Yield Med Reviews webinar on statistics, review of drug monographs, review of guideline recommendations, sample questions from the BPS website, and lots of repetition.

The ACCP/ASHP review course is probably one of the most useful tools for preparing and reviewing for the BCOP exam. The course walks a reader through the entire management of a disease state. Although the book content is excellent and thorough, I found the audio recordings of the lectures to be extremely helpful. I would often listen to the lectures daily while working out at the gym or driving home from work. This form of repetition would help keep me on track and ensure that information remained fresh. The ACCP/ASHP review course isn't without its potential drawbacks, though. There is the potential for the newly graduated resident to study the wrong thing, such as learning the *entire* TNM staging for breast cancer. It's important for the test taker to remember that this is a test of practice and application—it's about applying knowledge of literature to specific patients or determining appropriate treatment and care plans for a patient. As a pharmacist, you are the drug expert. It is imperative that you know how to apply your drug knowledge to a specific patient or treatment algorithm.

I found the statistics webinar from High-Yield Med Reviews to be an excellent resource for biostatistics. The content was pertinent, and it was presented in a way that was easy to understand. Of course, it is also important that pharmacists review the most current guidelines on supportive care.

What other tips do you have for successfully passing the exam?

Cambareri: I think knowing how best you learn and study is key. I personally do better alone and through making notes and handouts. However, if you learn best in groups or through lectures, sync your study schedule with the method that works best for you and

give yourself a reasonable schedule and enough time to prepare. I also think it's important to remember while preparing that you definitely know more than you think you do—and take comfort from that. It's also important to know and accept that you can't possibly know everything. However, the most important thing to remember is that the training and real-life experiences you have had in oncology have armed you well with the deductive reasoning and critical-thinking processes needed to take and pass this certification exam.

Hanna: Several elements are important to consider while preparing for the exam. BPS uses a rigorous review process in its analysis of the questions to ensure that the material is heavily supported by a strong body of literature. Therefore, questions on the examination tend not to fall in the "gray area" and are concepts that a clinical oncology pharmacist should know. As an example, one is more likely to be tested on a category-1 recommendation (based on high-level evidence) from the NCCN rather than on a category-2B or category-3 recommendation (based on lower-level evidence).

It is also important to note that BPS does not expect one to have memorized large randomized controlled trials and meta-analyses. It is unlikely that you will be asked to recall a specific data point or outcome from a trial unless it is practice changing. Instead, BPS is likely to assess examinees' ability to critique and review provided data points in assessing various outcome measures. While studying from the ACCP/ASHP review course (both book and videos), I found it often difficult to distinguish between these elements. It is expected that faculty members have different teaching styles; however, some were significantly more statistically focused regarding trials and outcomes than others. I found this difference in approach to be stressful at times, and it skewed my perception of the exam. It is important to remain focused on the overall general concepts. For example, if a faculty member chooses to discuss the clinical trials of checkpoint inhibitors in second-line metastatic bladder cancer (IMvigor 210, CheckMate 275, Keynote 045, etc.), remember that although these data are important, they support the use of drugs that are a category-2B recommendation in this setting rather than pembrolizumab (category 1). The takeaway point here would be differentiating pembrolizumab from other agents as a category-1 recommendation.

Segal: I would recommend that pharmacists who are preparing for board certification spend time reviewing the most current ASCO and NCCN guidelines for supportive care as well as survivorship management. Last—though it may sound silly to say this—as a pharmacist, you must know your drugs. It is imperative that pharmacists have a thorough understanding of each anticancer agent's mechanism of action, dosing, administration dose-limiting toxicities, potential dosing modifications because of renal or hepatic impairment, and adverse-effect profile. Residents should start building a library of information on available anticancer agents and refer to it often. For practice questions, I found that the past sample test questions from BPS were a useful resource for how questions might be framed. Answering the ACCP/ASHP review course questions is also an effective way to test your knowledge.

Studying with a group may be an effective way to stay on track and will allow you to consult other colleagues about specific disease management. If you have difficulties finding a study partner, I encourage you to post on the HOPA listserv. Other pharmacists are often also in need of study partners and are more than willing to study remotely with you. ●●

Pharmacogenomics: From Bench to Electronic Health Record

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Pharmacogenomics (PG), a form of personalized medicine, has many applications to oncology.[1] *Pharmacogenomics,* sometimes used interchangeably with the term *pharmacogenetics,* has great potential to optimize medication therapy outcomes for both primary cancer treatment and supportive care by improving efficacy and safety when it is translated to the clinical setting.[2,3] Although barriers to implantation have been identified, some background information and practical tips will help those who work in oncology begin the process of routinely integrating PG information into patient care.[4]

The Science

Gene variation can be inherited (germline) or acquired (somatic). Germline gene variations are inherited and may be associated with developing cancer (e.g., *BRCA1* and breast or ovarian cancer) or producing variation in drug-metabolizing, enzyme, and transporter genes, which determines medication efficacy and toxicity.[5] **Table 1** provides a summary of germline gene variations for medications commonly used in cancer patients. For medications in which metabolism leads to inactive products, it is important to note that variation in at least one of the two copies of a drug-metabolizing gene is sufficient to produce reduced metabolic capacity, with increased systemic exposure often requiring a preemptive dose reduction. This principle was demonstrated by a St. Jude research group for thiopurine methyltransferase and mercaptopurine and has been carried forward for many medications.[6] Patients with two reduced-function variations usually require significant dose reductions or substitution of an alternate therapy. Likewise, for medications that require metabolism for the pharmacologic effect, reduced gene activity can lead to ineffective therapy. It is also important to consider the supportive care medications used for pain, depression, neuropathy, nausea and vomiting, and infections; in these cases PG information can improve both safety and efficacy.[3]

Somatic gene variations are acquired variants, mostly within the tumor, that may predict response to a medication. **Table 2** provides a summary of somatic gene testing for currently approved medications.

The concept that genetic expression profiles for a tumor can define the biology was first demonstrated for mixed lineage leukemia (MLL) and has evolved into use of the tumor's genetic characteristics to research and define therapy.[7] Pembrolizumab is the first medication to be approved for use in cancer patients on the basis of demonstration of genetic variation, either microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) solid tumors, and not a specific tumor type.[8] Using somatic

Table 1. Germline Gene Variation and Clinical Application

Medication	Gene(s)	Clinical Application
Allopurinol	*HLA-B*	Prediction of adverse effects
Belinostat	*UGT1A1*	Dose adjustment
Codeine	*CYP2D6*	Indication Dose adjustment Use of alternative therapy
Capecitabine, Fluorouracil	*DPYD*	Indication Dose adjustment
Mercaptopurine	*TPMT*	Dose adjustment Use of alternative therapy
Ondansetron	*CYP2D6*	Dose adjustment Use of alternative therapy
Phenytoin	*CYP2C9* *HLA-B*	Dose adjustment Prediction of adverse effects
Rasburicase	*G6PD*	Indication
Tacrolimus	*CYP3A5*	Dose adjustment
Tamoxifen	*CYP2D6*	Indication Dose adjustment (based on metabolism to endoxifen)

Table 2. Association of Somatic Gene Variations and Cancer Treatment

Malignancy	Gene	Medication
Acute Lymphoblastic Leukemia	*BCR-ABL*	Dasatinib
Acute Myeloid Leukemia	*IDH2*	Enasidenib
	FLT3	Midostaurin
Acute Promyelocytic Leukemia	*PML-RARA*	Arsenic Trioxide, Tretinoin
Breast Cancer	*HER2-neu*	Trastuzumab, Ado-Trastuzumab Emtansine, Fulvestrant, Lapatinib, Abemaciclib, Exemestane, Neratinib, Palbociclib, Pertuzumab, Ribociclib
	HER2-neu (-), ESR	Fulvestrant (+ palbociclib)
	Estrogen receptor, progesterone receptor	Anastrozole, Exemestane, Lapatinib, Letrozole, Tamoxifen
	BRCA1	Rucaparib
Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma	17p deletion	Ibrutinib, Venetoclax
Chronic Myelogenous Leukemia	*BCR-ABL*	Bosutinib, Dasatinib, Nilotinib, Ponatinib
Colorectal Cancer	*KRAS*	Panitumumab
	KRAS, EGFR	Cetuximab
	Microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR)	Nivolumab, Pembrolizumab
Cutaneous T-cell Lymphoma	*IL2RA*	Denileukin Diftitox
Gastric Cancer	*PD-L1*	Pembrolizumab
Gastrointestinal Stromal Tumor	*KIT*	Imatinib
Melanoma	*BRAF*	Cobimetinib, Dabrafenib, Nivolumab, Trametinib, Vemurafenib
Non-Small Cell Lung Cancer	*EGFR*	Afatinib, Gefitinib, Osimertinib, Erlotinib
	PD-L1	Pembrolizumab
	ALK	Alectinib, Brigatinib, Ceritinib
	ALK, ROS-1	Crizotinib
Ovarian Cancer	*BRCA1, BRCA2*	Olaparib, Rucaparib
Solid Tumors	Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)	Pembrolizumab

variations has also paved the way for precision medicine trials such as the National Cancer Institute (NCI) MATCH or umbrella trials, in which the therapy is determined by genetic variation(s) and not tumor histology.

From Bench to Clinical Recommendations

Clinical translation of pharmacogenetic information is available from several sources in addition to the primary literature. The U.S. Food and Drug Administration (FDA) maintains a website for pharmacogenetic information in product labeling.[9,10] Of the 269 PG entries for more than 100 medications, the majority (102) are for oncology agents (**Table 3**).

The Pharmacogenomics Knowledgebase (PharmGKB) is a National Institutes of Health (NIH)–funded international comprehensive resource that provides curated information about the relationship between genetic variation and medication response.[11] The information includes pharmacogenomic-guided dosing guidelines, pharmacogenomic information included in product labels for medications from several countries, medication metabolic pathways, clinical annotations (summaries of evidence for relationships between gene variations and medications), variant annotations (summaries of single-gene variation and drug response), and very important pharmacogene (VIP) summaries.

The Clinical Pharmacogenetics Implementation Consortium (CPIC) has developed a rigorous procedure to develop clinical guidelines for how actionable pharmacogenetic information can be used to optimize medication therapy.[12] The guidelines provide a translation from genotype (e.g., diplotype, *1/*3) to phenotype (e.g., intermediate metabolizer) to a concrete clinical recommendation (e.g., reduce starting dose by 20%). In addition to the basic supporting information for the recommendation, the CPIC guidelines include clinical decision support algorithms. The guidelines are updated periodically. **Table 4** lists guidelines for the medications used in cancer patients.[13,14] A comparative summary of available PharmGKB and CPIC guidelines is available on the PharmGKB website (www.pharmgkb.org).[15]

Table 3. Pharmacogenetic Information in Package Labels

Disease	Number of PG Entries
Oncology	102
Psychiatry	33
Infectious Diseases	29
Neurology	18
Cardiology	15
Gastroenterology	14
Anesthesiology	9
Hematology	9
Pulmonary	8
Rheumatology	7
Endocrinology	5
Inborn Errors of Metabolism	5
Gynecology	4
Urology	4
Dermatology	3
Dental	1
Dermatology and Gastroenterology	1
Toxicology	1
Transplantation	1

Precision medicine services, which involve a pharmacist as a critical team member, have also evolved for cases in which treatment, usually for patients with refractory or rare tumors, is determined by genetics.[16-19] These publications highlight the critical role that pharmacists can play in translating pharmacogenomic information into clinical care.

From Clinical Recommendations to Electronic Health Record (EHR)

To successfully implement a PG program in your institution, determine the model that best suits the institution's needs.[20,21] As part of this assessment, identify the physical space requirements and financial, tecÚical, and human resources that will be required. In addition, the cost of the PG testing and the opportunities for reimbursement should be reviewed. Many models may be implemented. Specialized clinics or PG consultation services may require additional staff members. Implementation of an electronic program may require fewer clinician staff additions but may also require a short-term increase in developer resources if the EHR can support customization.

Executive leadership support for establishing a PG program is essential. Guidelines should then be established for implementing the clinical program. A multidisciplinary subcommittee of the pharmacy and therapeutics committee that includes physicians, pharmacists, laboratory medicine personnel, nurses, and information tecÚology (IT) representatives should be formed to establish and maintain the PG program within the EHR.

Table 4. Clinical Pharmacogenetics Implementation Consortium Guidelines for Medications Used in Cancer Treatment

Medication	Gene(s)
allopurinol	*HLA-B*
azathioprine	*TPMT*
capecitabine	*DPYD*
carbamazepine	*HLA-A, HLA-B*
codeine	*CYP2D6*
fluorouracil	*DPYD*
mercaptopurine	*TPMT*
ondansetron	*CYP2D6*
oxcarbazepine	*HLA-B*
phenytoin	*CYP2C9, HLA-B*
rasburicase	*G6PD*
tacrolimus	*CYP3A5*
tamoxifen	*CYP2D6*
thioguanine	*TPMT*
voriconazole	*CYP2C19*
warfarin	*CYP2C9, CYP4F2, VKORC1*

The multidisciplinary committee should establish the criteria for medication-gene pairs to be included in the program, the expected behavior of the clinician, and other restrictions or requirements. Involving laboratory medicine personnel is critical in establishing procedures for genomics testing, for reviewing the turnaround times for results, and for establishing a process for notification of results. Collaboration between the laboratory medicine and IT departments determines how the results will be stored and whether the results can be used for electronic clinical decision support.

Deciding which Clinical Laboratory Improvement Amendments (CLIA)–certified pharmacogenetic test will be used, and whether to use a single test or a multigene array, is crucial to implementing the program; the connection from the lab to the EHR may ultimately determine which test is implemented.[22,23] Haga and colleagues surveyed clinical testing laboratories in the United States.[23] Seventy-six of 111 labs offered PG testing. Thirty-one labs offered only single-gene testing, 30 offered multigene testing, and 15 offered both single- and multigene testing. The multigene array covered 295 genes.

Rules should be established for clinical decision support (CDS) according to best practices.[24] CDS will be based on retrieving and evaluating a pharmacogenomic lab result that automatically provides a recommendation to the clinician at the time of medication ordering. However, many institutions that have implemented a PG program use manual interpretation of the result before a recommendation is available for the clinician's review. Ideally CDS should be able to accommodate results for multiple drug-gene associations. For example, in patients under consideration to receive phenytoin, the presence of the *HLA-B* allele predicts for serious

dermatologic reactions, and having one or more reduced-function alleles of *CYP2C*9 requires dose adjustment.[14]

Before activation of a PG program, prescribers, pharmacists, nurses, laboratory staff, and patients should be educated about the program. Education material should be created for the patients and be readily available to the provider. Genetic counselors should also be available.

The program's effectiveness should be monitored, reviewed, and reported regularly to the pharmacy and therapeutics committee. A process should be implemented for periodic review of established guidelines and for creation of new guidelines.

As an example of how effective CDS can facilitate using PG information, O'Donnell and colleagues analyzed 2,279 outpatient encounters in which PG information was provided at the point of care. Medication orders with high pharmacogenomics risk (odds ratio = 26.2 [9 – 75.3]; $p < .0001$) or cautionary pharmacogenomics risk (odds ratio = 2.4 [1.7 – 3.5]; $p < .001$) were changed more frequently when PG information was provided.[25]

Broad implementation of PG requires preemptive testing because the current PG information is most useful when initiating a new therapy. Germline gene variations, many of which are associated with medication therapy, do not change during a patient's lifetime. Therefore, if the patient is tested early in life, the information can be used to guide medication use across the patient's lifespan. Although some institutions have adopted this approach, several barriers to wide distribution of this information exist.[4,26-28] Klein and colleagues identified 229 publications that included information about PG implementation, barriers, and solutions.[4] The major common barriers identified, especially for countries outside the Untied States, are (1) a secure and suitable information tecÚology platform, (2) integrated clinical decision support, (3) regulations, (4) reimbursement, and (5) PG education.

Suggestions for overcoming these barriers include (1) working with EHR vendors to improve the receiving, storing, and displaying of PG information; (2) establishing a standard for PG CDS; (3) implementing preemptive PG programs; (4) collecting evidence to show cost-effectiveness; (5) conducting focus groups to define educational needs and garner stakeholder buy-in; (6) using pharmacists to bridge the communication of genotype information to the provider and patient; and (7) developing a framework for dealing with regulatory issues.

Conclusion

Applying PG information routinely in patient care, especially for oncology patients who are susceptible to adverse effects, should become a standard of care. Pharmacists should be the focal point and a resource for personalized medicine teams and should drive the translation of PG information into patient care through the EHR. ●●

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Continuing to Learn About Our Chosen Profession: An Oncology Pharmacy Book Group *(continued from p. 7)*

- *The Emperor of All Maladies: A Biography of Cancer*, by Siddhartha Mukherjee
- *Dark Remedy*, by Trent Stephens and Rock Brynner
- *The Serengeti Rules: The Quest to Discover How Life Works and Why It Matters*, by Sean B. Carroll

These books often resonate with me in a romantic way, reminding me of my childhood love of science and why I chose pharmacy as a major all those years ago. They also serve as a powerful tribute to the innumerable hours logged by scientists throughout centuries of progress that came before us—and as a truly humbling reminder of how much farther our chosen field has to go.

Books About the Imperfect Nature of Medicine and Health Care

These books provide a perspective on the numerous external factors that continue to disrupt medical progress. Examples:

- *Complications: A Surgeon's Notes on an Imperfect Science*, by Atul Gawande
- *The Immortal Life of Henrietta Lacks*, by Rebecca Skloot
- *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs*, by Jerry Avorn
- *Better: A Surgeon's Notes on Performance*, by Atul Gawande

Books in this category often highlight the outside influences that can delay or even entirely derail drug accessibility. From human behavior and finances to the process of informed consent, the course of medical progress has not been a linear one. I find the backstories of these medical detours worthy of reflection. Their authors often offer their perspective on how the process can be improved, which is always worthy of consideration. The personal stories also offer connection between the macro and micro (i.e., human) level of these aspects that are administrative parts of our daily lives.

Books from a Cancer Patient's Perspective

Although they are not always scientifically accurate, these books are written from the unique perspective of a patient with cancer. The individual's view of his or her fate, account of coping strategies, and views of the medical profession are always moving. Examples:

- *When Breath Becomes Air*, by Paul Kalanithi
- *A Series of Catastrophes and Miracles: A True Story of Love, Science, and Cancer*, by Mary Elizabeth Williams
- *Into the Funhouse: An Unpredictable Story of a Relentless Leukemia*, by Walter Harp
- *Everybody's Got Something*, by Robin Roberts

I'll be very honest and admit that after nearly 2 decades as an oncology pharmacist, my empathy occasionally wanes as I get caught up in paperwork, students' questions, pharmacy inspections, mandatory meetings, and life in general. Books like these make me stop in my tracks and remember exactly why I love my job: I am taking care of patients. The books often make me pause to reflect on how strong, clear, and beautiful these patients remain in dark times. They also remind me of the individual stories that make up every descending Kaplan-Meier curve we see in each published manuscript and the human beings behind the data we use to make our standard treatment recommendations.

Our shared hobby has expanded our minds and hearts in ways that we didn't expect and continues to renew our energy for working in the field we love. We have thoroughly enjoyed hearing our colleagues' thoughts and recommendations. We're already looking forward to the next books on our lists!

Interested in joining our discussion? We'd love to have you—you can find us at Oncology Pharmacy Book Group on Facebook and tell us your favorite oncology reads! ●●

CAR-T Cell Program Development: A Tale of Two Institutions

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With the groundbreaking approval in 2017 of two chimeric antigen receptor T-cell (CAR-T) therapies, tisagenlecleucel (Kymriah) and axicabtagene ciloleucel (Yescarta), comes much excitement but also many administrative and logistical obstacles. The therapies involve lymphocyte collection, lymphodepleting chemotherapy, cell infusion, and finally, and perhaps most important, management of unique side effects. This process may seem straightforward, but CAR-T cell administration from start to finish is complex and requires the expertise and input of a multidisciplinary team to ensure success. Below we outline the processes used by two separate institutions with extensive experience implementing a CAR-T cell program.

Don't Put the CAR-T Before the Horse: Practical Aspects of Implementing Commercial Chimeric Antigen Receptor T-Cell Therapies

Maxwell A. Brown, PharmD

Memorial Sloan Kettering Cancer Center (MSKCC) recently published a review describing its process for establishing and implementing a commercial CAR-T cell therapy program. The authors identified eight workflow tasks that are essential for the development of a successful CAR-T cell therapy program.[1] In this article, I will briefly discuss each workflow component from the perspective of a pharmacist.

Task 1. Patient Referral, Selection, and Evaluation

The demand for CAR-T cell therapy will presumably be high because it has received considerable media attention in both the medical and public sectors. As a result, institutions must develop rigid guidelines for screening, identifying, and selecting patients who are eligible to receive these products. Given that the wholesale cost of the commercial CAR-T cell products ranges from $373,000 to $475,000,[2] it is crucial for clinicians to ensure that patients meet the U.S. Food and Drug Administration (FDA)–labeled indications to prevent problems with reimbursement. In addition, financial coordinators and other administrative staff members should be involved early in the intake process to conduct insurance preauthorization and coordinate patient intake.

Task 2. Development of a CAR-T Consultation Service

A physician must be registered with the manufacturer as a CAR-T certified physician in order to be able to prescribe commercially available CAR-T cell products. Some institutions have developed a CAR-T cell consultation service consisting of physicians, pharmacists, nurses, and other healthcare providers who have expertise in CAR-T cell therapy. For example, at MSKCC the CAR-T cell consultation service is responsible for selecting appropriate patients for treatment with CAR-T cells, determining the use of commercial versus investigational CAR-T cell products, and providing comprehensive medical care to patients receiving CAR-T cell therapy.[1]

Task 3. CAR-T Cell Collection and Production

Patients who receive CAR-T cell therapy must first have autologous lymphocytes collected via leukapheresis. FDA-registered apheresis and cell-processing facilities must undergo a sophisticated contracting and quality assurance process with manufacturers to ensure that collection, manipulation, tracking, and other procedures meet the quality standards developed by each manufacturer. When it has been collected, the apheresis product is shipped to the manufacturer, where it is genetically engineered to express the CAR, and then shipped back to the treating institution.

Task 4. Bridging Treatment Strategies

The average time from apheresis until CAR-T cell infusion varies between products; for example, the median time from leukapheresis to delivery of axicabtagene ciloleucel is 17 days.[3] However, administrative delays and issues with cellular manufacturing could lengthen this period to several weeks or months. Patients with aggressive malignancies may require treatment during this time to prevent disease progression, and it is the combined responsibility of the CAR-T cell consultation service and the treating physician to determine the appropriate course of action.

Task 5. CAR-T Cell Infusion

In the days leading up to CAR-T cell infusion, a lymphodepleting chemotherapy regimen is administered to patients to allow for adequate *in-vivo* CAR-T cell expansion.[4,5] Organizations should consider developing electronic order sets for the lymphodepleting chemotherapy to simplify prescribing. In addition, certain institutions may involve pharmacy in the registration of CAR-T cell products to a given patient. Therefore, institutions should establish a clear process for verification and labeling of the CAR-T cell product prior to infusion. Other institutions may not involve the pharmacy and may instead have the cell therapy laboratory register the CAR-T product, given that CAR-T cells could be considered more a cellular therapy product than a drug product.

Task 6. Immediate Post-Infusion Care (Days 0 through 30)

The FDA mandates that any institution dispensing a commercially available CAR-T cell product must be enrolled in the risk evaluation mitigation strategy (REMS) program for that particular product.

The REMS program requirements for tisagenlecleucel and axicabtagene ciloleucel are quite similar and include live on-site REMS training, provision of a patient wallet card prior to CAR-T infusion, and a procedure to ensure that patients will remain within 2 hours of the institution for at least 4 weeks after the CAR-T cell infusion. However, most germane to the pharmacy department is the requirement that the institution maintain a minimum of two doses of tocilizumab for each patient receiving CAR-T cell therapy.[4,5]

Tocilizumab is a humanized monoclonal antibody directed against the interleukin (IL)-6 receptor and was approved by the FDA in tandem with tisagenlecleucel for the treatment of cytokine release syndrome (CRS), a potentially deadly complication of CAR-T cell therapy.[6] As a result of the FDA-mandated REMS program, the pharmacy department will need to develop policies and procedures to ensure maintenance of adequate stock of tocilizumab. Several strategies exist to accomplish this task, including but not limited to ordering and assigning tocilizumab vials to patients or establishment of a par level for tocilizumab in the pharmacy. An additional decision point for pharmacies will be the length of time to "reserve" tocilizumab vials for a given patient, a detail that is conspicuously left out of the FDA REMS program requirements.

Pharmacy staff should be well educated on the REMS program requirements for CAR-T cell therapy, including the purpose behind the 2-hour turnaround time for tocilizumab. Proper in-service training of the pharmacy staff about the detrimental consequences of delayed treatment of CRS and neurotoxicity should engage staff in the treatment of these patients and help ensure timely administration of tocilizumab. Development of electronic order sets to allow swift and painless ordering of anti-IL-6 therapy and other supportive medications will cut down on delays in treating CRS.

Task 7. Late Post-Infusion Care (Day 31 Onward)

Organizations must also develop effective procedures for transitioning the care of patients out of the hospital and into the outpatient clinic. This especially holds true for patients referred from physicians outside the institution performing the CAR-T cell infusion because the risk of CAR-T cell–related toxicities persists for several weeks after infusion.

Task 8. Regulatory and Reporting Requirements

The Foundation for the Accreditation of Cellular Therapy (FACT) and the FDA administer regulations for collection, manufacturing, and chain of custody of the CAR-T cell product. FACT also recommends that CAR-T cell therapy programs collect internal data regarding CAR-T cell therapy and submit their data to the Center for International Blood and Marrow Transplant Research (CIBMTR) database for collective analyses.[7] As mentioned, the FDA mandates compliance with a REMS program to ensure that the benefits of CAR-T cell therapy outweigh the risk of severe toxicities.

As organizations develop CAR-T cell therapy programs, numerous administrative, financial, and practical obstacles will need to be overcome. To address these challenges, institutions should leverage the experience of specialists from several disciplines. A multidisciplinary approach to the development of a CAR-T cell program infrastructure will allow organizations to incorporate this exciting and novel immunotherapeutic approach into their treatment armamentarium for patients with cancer.

Take-Home Point

I recommend that a pharmacy department within an institution initiating a CAR-T cell therapy program establish straightforward and perspicuous procedures for the ordering, maintaining, and dispensing of tocilizumab stock. Procedures should be documented in a formalized policy with clear assignment of responsibilities to avoid ambiguity and allow for streamlined auditing in the future.

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(The article continues on p. 20 with Zahra Mahmoudjafari's experiences.)

Commit-Arrange-Refine-Train: Developing the Foundation for a Successful CAR-T Program—A Pharmacist's Perspective

Zahra Mahmoudjafari, PharmD BCOP

Commit

Groundwork prior to administering CAR-T therapy includes development of standard operating procedures (SOPs) and order sets. SOPs that must be created include workflows for compliance with the REMS requirements (including training and adverse event reporting), guidelines for when to start lymphodepleting chemotherapy, frequency and methods of monitoring for toxicities (i.e., CRS and neurotoxicity), and planning for how and when patients will be transferred between units when they experience severe side effects.

SOPs for financial workflows, including insurance authorization and billing, should be established to avoid financial toxicity for both the institution and the patient. Because this product is a "medication" but is not stored in the pharmacy, one challenge has been to determine whether it is billed under the pharmacy budget or under another department entirely. Decisions regarding how and when to label the product will be institution-specific. Order sets should be developed for the lymphodepleting chemotherapy that is given prior to the re-infusion of cells, for admission, for the cell infusion itself, and finally for adverse-event management.

At our institution, the admission order set for CAR-T therapy is individualized and titled specifically for CAR-T patients. It contains many of the elements of a hematology/bone marrow transplant admission order set but has specific nuances for CAR-T patients, such as seizure prophylaxis. Additionally, at our institution the cell infusion is incorporated into the order set for the lymphodepleting chemotherapy. These order sets can be written or electronic, or even both. It is also helpful to build a treatment algorithm that addresses the management of the unique side-effect profile of this therapy; this treatment algorithm should be consistent with the order set for adverse-event management and should include monitoring and treatment parameters to ensure consistency. For example, at our institution we have incorporated the CARTOX10 assessment in the electronic medical record, where it can be easily accessed by the multidisciplinary team.[1]

Arrange

These agents are extremely expensive; therefore, the pharmacy and therapeutics committee should give careful consideration to their management, and a process to ensure proper insurance verification prior to a patient's receiving treatment should be established. In addition, the anti-IL-6 receptor antibody tocilizumab that is used in the event of acute toxicity should be considered for inclusion in the formulary if it is not currently readily available. Consideration should also be given to secondary agents such as siltuximab. Because of the high risk of adverse events, the FDA requires the inpatient pharmacy to stock a minimum of two doses of tocilizumab for each patient before CAR-T cell administration and to have it available for immediate administration within 2 hours.[2,3]

At our institution, we increased our par levels of tocilizumab in the inpatient pharmacy and have it available at our outpatient cancer location. Furthermore, when a patient is admitted for CAR-T therapy, the patient's chart documents that a minimum of two doses of tocilizumab have been verified. Processes should be established to ensure that the staff (both pharmacists and tecÚicians) are aware of the acute need for this medication, the location of the product, and the steps that need to be taken when a dose of tocilizumab is ordered for a patient.

One important caveat is to plan how a dose of tocilizumab would be administered during the initial admission in contrast to the workflow for an individual who is currently an outpatient but is later admitted because of delayed toxicities. Our institution, for example, has an "as needed" (PRN) entry of tocilizumab available on the medication administration record that is released at the time of a patient's admission for cell infusion and is discontinued when the patient is discharged. Because of the delayed risk for toxicities, patients may begin to experience symptoms and must be admitted, so establishing a guideline for how tocilizumab is ordered is critical.

Furthermore, the use of corticosteroids in this patient population can be controversial, and processes should be standardized to ensure that patients do not inadvertently receive corticosteroids during the initial admission or afterward when they are discharged—unless strictly indicated. Tools within the electronic medical record to promote the judicious use of corticosteroids include temporary contraindication or allergy warnings and best-practice advisory alerts.

Refine

Developing these new processes and tecÚological tools is no easy undertaking. Expect to go through several revisions before a final version, and even then, expect it to change again. Quality improvement processes certainly apply to CAR-T therapy. Plan to become close friends with your physician colleagues, leukapheresis staff, nursing team, and information tecÚology (IT) team!

Train

Training staff members to identify and manage side effects of CAR-T therapy is likely one of the most important undertakings of offering this therapy. In compliance with the REMS requirements, all staff members who prescribe, dispense, and administer this therapy must receive direct training. The manufacturer of each product provides the training materials, and this training must be documented and readily available for assessment if requested by the FDA. This education must be completed by the institution's designated REMS Authorized Representative; this individual can be a pharmacist.

Training involves both the direct hematology/bone marrow transplant and intensive care unit clinical pharmacists taking care of the patient, as well as the central pharmacy staff, including those on the day, evening, and midnight shifts. The central

pharmacy staff must be trained to assess appropriate indications for corticosteroids (for instance, familiarizing themselves with the institution's algorithm and order set for CAR-T toxicity management) and ensure the timely administration of tocilizumab. SOPs, staff competencies, and even e-mail reminders alerting your pharmacy, nurse, and physician teams that a patient is being admitted for CAR-T therapy are essential to making sure that the staff is prepared to mitigate the unique side effects of this treatment.

Patient education should also be taken into consideration. As part of the REMS program, patients are provided a wallet card that lists potential side effects of the therapy and indicates when they should immediately seek medical attention. They should also be educated about the toxicities of the lymphodepleting chemotherapy preceding CAR-T. Their education should include guidance on how close they should stay to the hospital and for how long (for example, patients receiving tisagenlecleucel must be advised to stay within 2 hours of the treatment site for at least 4 weeks).

Despite the complexities involved in administering this novel treatment, this is an exciting time in cancer medicine. Pharmacists have a unique role in promoting the success of CAR-T therapy both now and in the future as we gain experience and as this modality continues to evolve. Developing and maintaining a strong foundation are integral to positive patient outcomes.

Take-Home Points

- *Build the team:* Engage all key stakeholders (pharmacists, pharmacy technicians, physicians, nurses, apheresis staff, and IT) sooner rather than later.
- *Create the path:* Develop standardized order sets to manage toxicities.
- *Polish for success:* Ensure that all pharmacists and technicians receive appropriate training. ●●

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Fluoroquinolone Prophylaxis After Hematopoietic Cell Transplantation: Results from a Retrospective Study Evaluating Infectious Risk Versus Benefit

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Hematopoietic cell transplantation (HCT) poses a risk for infection because many factors can compromise immune function. Prolonged neutropenia, immunosuppressive therapies, compromised mucosal barriers, and indwelling catheters are the main risks that can contribute to infection. As a result, current national guidelines recommend that providers consider antibacterial prophylaxis with a fluoroquinolone (FQ) in HCT patients when the anticipated duration of neutropenia is at least 7 days. Prophylaxis usually starts at the time of stem cell infusion and continues until the neutropenia resolves or empirical antibacterial therapy for a febrile neutropenia event is initiated. Despite FQ efficacy in preventing gram-negative infection, results for patient mortality have been mixed. Providers must weigh the benefit of antibacterial prophylaxis against the risk of infection with *Clostridium difficile* or multi-drug-resistant bacteria.

To facilitate these decisions, Dr. Amber Clemmons and colleagues designed a retrospective study that evaluated risks versus benefits of FQ prophylaxis for HCT patients. Their research, "Impact of Fluoroquinolone Prophylaxis on Infectious-Related Outcomes After Hematopoietic Cell Transplantation," was published online in October 2017 in the *Journal of Oncology Pharmacy Practice*.[1] Until winter 2013, prophylaxis with an FQ agent was standard practice for all adult HCT patients at their institution. Because of local susceptibility results, the institution ceased prophylaxis in HCT patients and restricted providers to the use of other FQ agents; levofloxacin was removed from the formulary. Clemmons and colleagues measured the effect of this change through retrospective analysis. The primary outcome found was the incidence of bacteremia in patients who received an autologous or allogeneic HCT from 2011 to 2015. Secondary outcomes included the incidence of febrile neutropenia, urinary tract infection (UTI), pneumonia, *C. difficile* infection, and susceptibility to bacteremia infections; they also examined time to discharge and 30-day mortality rates.

Two study groups were selected. The first (n = 105) received FQ prophylaxis with levofloxacin 500 mg by mouth daily from day +1 until engraftment or a febrile neutropenia event. The second (n = 74) received no FQ prophylaxis; patients were treated under the new institutional protocol. Additionally, granulocyte-colony stimulating factor (GCSF) was changed to day +5 for the non-FQ group, and the FQ group started GCSF on day +1. No other significant difference was reported in the demographics of the two groups. These two main groups were further divided into autologous (n = 115) and allogeneic (n = 56) subgroups. Results were provided for each of these groups.

The primary outcome of the study was a significant difference for microbiologically documented bacteremia between FQ and non-FQ groups (15.2% vs. 31.8%; $p < .01$). As a secondary outcome, the investigators found no statistical difference in rates of UTI. Rates of pneumonia when tested by sputum culture were not statistically significant; however, when tested by chest X-ray, a significant difference was found, with higher rates of infection in the non-FQ group. Incidence of *C. difficile* between the groups was not found to be significantly different. Febrile neutropenia rates were lower in the FQ group than in the non-FQ group (54% vs. 83%, $p < .0001$), and fewer patients in the FQ group met sepsis criteria than in the non-FQ group (33% vs. 53%, $p < .01$). No statistically significant differences were seen in median time to discharge or in 30-day mortality rates between the two groups.

In the autologous subgroup, the FQ and non-FQ cohorts had statistically significant differences in rates of febrile neutropenia (55% vs. 91%, $p < .0001$) and sepsis (25% vs. 52%, $p < .0034$). The number of microbiologically documented bacteremia patients was significantly lower in the FQ group (8.5% vs. 27.3%, $p = .0069$). The incidence of UTIs was not different between the groups. Rates of positive sputum culture pneumonia were not significantly different; however, positive chest X-ray pneumonia was statistically higher in the non-FQ group. The incidence of *C. difficile* (12.7% vs. 9.1%, $p = 1$), the median time to discharge, and the 30-day mortality rates were not significantly different.

In contrast to the autologous subgroup, in the allogenic subgroup, febrile neutropenia and sepsis were not statistically significantly different between the FQ and the non-FQ groups (52.9% vs. 68.2%, $p = .4$; 50% vs. 54.5%, $p = .73$). For the primary outcome, the number of microbiologically documented bacteremia patients was also not significant between the two groups (29.4% vs. 40.9%, $p = .4$). Positive sputum culture pneumonia, positive chest X-ray pneumonia, UTI, and incidence of *C. difficile* were not significantly different, nor were median time to discharge and 30-day mortality rates.

The investigators concede that the retrospective nature of the study created an imbalance in the number of patients in each group. They also concede that by combining the autologous and allogenic subgroups, they combined populations with different risk factors for bacterial infection, though this was in keeping with institutional practice. A last limitation was the protocol change of GCSF initiation from 1 day post-transplant to 5 days post-transplant; however, they conclude that it was unlikely this difference had an impact on outcomes.

As the authors of this article note, the use of prophylactic antibiotics continues to be contested because of the potential risk of the development of antibiotic-resistant bacteria. Despite these concerns, the results of this study indicate that the benefits of FQ prophylaxis outweigh possible risks. ●●

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Clinical Practice Guideline Update on the Outpatient Management of Fever and Neutropenia in Adults Treated for Malignancy

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The American Society of Clinical Oncology (ASCO), in partnership with the Infectious Diseases Society of America (IDSA), released a new clinical practice guideline, "Outpatient Management of Fever and Neutropenia in Adults Treated for Malignancy," on February 20, 2018.[1] This was an update to ASCO's 2013 "Antimicrobial Prophylaxis and Outpatient Management of Fever and Neutropenia" guideline, but it shifts the focus toward outpatient treatment of febrile neutropenia (FN) rather than prophylaxis.[2] To decrease confusion, prophylaxis was not discussed in this update and will be treated separately in a future guideline.

Mortality associated with FN has dramatically declined since the advent of empiric broad-spectrum antimicrobials.[3-5] Discussions of antimicrobial stewardship should now begin, and healthcare resources for FN can be carefully decreased in selected patients. To this end, the update provides strong guidance on determining which patients can safely avoid hospitalization through the use of prognostic tools; it outlines specific diagnostic assessments and recommends treatment approaches to maintain patients in the outpatient setting.

ASCO and IDSA's guideline development process consisted of a systematic literature review, critical appraisal, and final guideline approval. The review included six new updated meta-analyses and six new primary studies that were published after the release of the 2013 ASCO guideline. Major changes in the update are discussed below.

Traditionally the Multinational Association for Supportive Care in Cancer (MASCC) risk index or Talcott's Rules have been used to determine patients' FN risk (high versus low) and thus to identify candidates for outpatient therapy.[6,7] ASCO introduces a more recently validated tool, the Clinical Index of Stable Febrile Neutropenia (CISNE), which can predict major complications in patients with solid tumors. Results from the FINITE study demonstrated an increased accuracy in classifying the risk of FN complications with CISNE compared with the MASCC index or Talcott's Rules.[8] CISNE was specifically designed for patients with solid tumors who are clinically stable and who recently received mild- or moderate-intensity chemotherapy. According to ASCO, patients are initially scored via the MASCC index or Talcott's Rules. Those with a MASCC score lower than 21 and those meeting criteria for Talcott's groups 1–3 are deemed high risk and should receive inpatient therapy. Patients with a MASCC score of 21 or higher or in Talcott's group 4 are then assessed via CISNE. Patients with CISNE scores of 3 or higher should receive inpatient management; patients with a CISNE score of 1 or 2 can be considered for outpatient management. Of note, patients who have acute leukemia or who are undergoing hematopoietic cell transplantation are unlikely to meet the criteria for outpatient management. In addition, patients who are already receiving a fluoroquinolone for FN prophylaxis are not candidates for outpatient therapy. See tables 1–4 in the full guideline for a comprehensive list of risk stratification and scoring systems that can be used to identify patients appropriate for outpatient management of FN.

Initial empiric therapy has not changed in the updated guideline and continues to follow standard guidelines from ASCO, IDSA, and the National Comprehensive Cancer Network (NCCN), which consist of monotherapy with an antipseudomonal beta-lactam unless the patient is unstable or has an allergy or when the presence of a multidrug-resistant (MDR) organism is suspected.[2,9,10] Patients who have been fully assessed and are deemed to be at low risk and those ready for outpatient management should receive oral empiric therapy with an antipseudomonal fluoroquinolone (ciprofloxacin or levofloxacin are now both considered first-line options) combined with amoxicillin/clavulanate. For patients with a penicillin allergy, clindamycin can be substituted for amoxicillin/clavulanate. Despite this recommendation, it is not common practice to employ both levofloxacin and amoxicillin/clavulanate. Many clinicians prescribe either ciprofloxacin with amoxicillin/clavulanate (because of poor streptococcal coverage with ciprofloxacin), levofloxacin monotherapy, or, in selected patients, a nonantipseudomonal-based therapy such as moxifloxacin, cefpodoxime, or amoxicillin/clavulanate.

Additional changes to the previous guideline include more direction on how to manage fluoroquinolone resistance, extended-spectrum beta-lactamase (ESBL)–producing gram-negative bacilli, carbapenem-resistant organisms, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci, and other MDR organisms. These patients should be considered for initial empiric therapy with intravenous antibacterials targeting their regional resistance patterns (for ESBL- producing bacilli: carbapenem; for carbapenem-resistant organisms: polymyxin-colistin, tigecycline, ceftazidime/avibactam, or ceftolozane/tazobactam; for MRSA: vancomycin, linezolid, or, if there is no evidence of pneumonia, daptomycin; and for VRE: daptomycin or linezolid).

The updated guideline strengthens confidence in clinicians' ability to manage FN in the outpatient setting. The introduction of CISNE has improved the ability to identify patients who can safely avoid hospital admission, reduce their length of stay in overcrowded emergency departments, reduce their exposure to MDR hospital-acquired pathogens, and improve their satisfaction by being treated in the comfort of their own home. This model of care is of utmost importance now and in the future, especially given the increased attention to the Oncology Care Model (OCM). OCM provides financial incentives for participating centers and encourages value-based care or high-quality cost-effective care. The

ASCO/IDSA guideline is an excellent resource to aid in maintaining safe, high-quality management of oncology patients while improving patient satisfaction and reducing the significant costs associated with hospital admission. ●●

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Highlights from HOPA's 2018 Annual Conference in Denver, CO (March 21–25)

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The city of Denver, CO, welcomed the Hematology/Oncology Pharmacy Association for its 14th Annual Conference at the Denver Convention Center, March 21–25, 2018. Each year HOPA's annual conference continues to evolve and offer more benefits to attendees. This year, the conference offered 23.5 hours of Accreditation Council for Pharmacy Education (ACPE) credit for onsite attendees and 17 hours of ACPE credit for virtual attendees. An increase in virtual attendance was seen: 150 attendees participated online in 2018. More than 1,200 attendees registered for the onsite meeting—a 15% increase from 2017.

The annual conference once again offered 8 hours of Board Certified Oncology Pharmacist (BCOP) credit this year. A new feature was added for attendees who were unable to attend the BCOP session in person—they can view all of the BCOP presentations online and then take the online tests to receive BCOP credit.

One preconference session, "Practice Management Boot Camp," was held, led by Lindsey Amerine, Victoria Brown, Kelly Scott-Rice, and Timothy Tyler. The session focused on the operational needs of clinical managers and directors. Key topics included payment precertification for oncology outpatients, formulary management strategies (including inventory management), development of a pharmacist navigator role, reimbursement strategies, and tools for making transitions from colleague to manager.

The JoÚ G. KuÚ Keynote Lecture, "'There will be drugs': Lessons from Lung Cancer's Therapeutic Oil Boom," was delivered by Ross Camidge, MD PhD. Dr. Camidge discussed recent developments in lung cancer drugs and provided commentary on how we will use these lessons in the future. He offered his perspective on prior experiences with drug development and also discussed future opportunities for drug development.

David DeRemer, Patrick Medina, Amy Pick, and J. Michael Vozniak discussed their career transitions and lessons learned in a session titled "Embracing the Mid-Career Crisis: Pivoting to New Career Challenges." The panel members spoke about the obstacles and benefits of mid-career changes.

Another notable presentation, "Improving Writing and Speaking Skills," was given by Rowena "Moe" Schwartz. Dr. Schwartz described her own experiences in writing and speaking and discussed tecÚiques for developing presentations to meet the needs of a particular audience.

Forty-six abstracts on completed research were accepted for presentation, along with 185 abstracts from trainees. Four abstract authors were given the opportunity to make platform presentations on their completed research. Sol Atienza and Erin Lydon presented "Oral Vancomycin for *Clostridium difficile* Prophylaxis in Autologous Stem Cell Transplant"; Andrea Ledford presented "The Evaluation of an Investigational Drug Service Software System in a Community Cancer Center"; Chrystia Zobinow presented "Safety of 30-Minute Nivolumab Infusion in Patients with Advanced Melanoma"; and Julianne Orr and Amber Clemmons presented "Randomized, Placebo-Controlled Trial of FOND (fosaprepitant, ondansetron, dexamethasone) Versus FOND+O (FOND plus olanzapine) for the Prevention of Chemotherapy-Induced Nausea and Vomiting in Hematology Patients Receiving Highly Emetogenic Chemotherapy Regimens: The FOND-O Study." Each presentation offered summaries of unique and interesting pharmacist-led research, highlighting the importance of pharmacists not only in clinical areas but also in operational areas.

HOPA's next annual conference, HOPA Ahead 2019, will be held in Fort Worth, TX, April 3–6, 2019. Learn more about the conference at www.hoparx.org.

Board Update

Members on the Move

Ryan Bookout, PharmD BCOP BCPS, HOPA President (2018–2019)
Blood and Marrow Transplantation Pharmacy Supervisor
Moffitt Cancer Center
Tampa, FL

It is hard to believe (at the time of writing) that summer 2018 has just begun and that by the time this issue of *HOPA News* reaches your mailboxes, it will be coming to a close. Where did the last 6 months go? Do oncology pharmacists really get the summer off? For me, working at the Moffitt Cancer Center on the campus of the University of South Florida, summer means just less traffic as I travel to and from the hospital every day. But a perk is a perk! For the rest of the working world (and for many of you), summer usually means that the kids are out of school, vacations are being planned and taken, and rain dodging and puddle jumping are actual exercises among a host of fun outdoor activities. However, HOPA members do not take summers off but are continuing their efforts to move the association forward on many avenues.

In response to our members' interest in the value and quality of care for cancer patients, the HOPA Quality Oversight Task Force (QOTC) was established. This task force will help us identify ways to incorporate healthcare quality and value into HOPA's strategic plan and its current and future initiatives. All parts of the HOPA structure—our committees, subcommittees, work groups, and task forces—will engage with the QOTC. The QOTC members are Emily Mackler (chair), Amy Seung (vice chair), George Carro, Steve D'Amato, Evelyn Handel, Julianne Orr, and Judith Smith. Watch for HOPA e-mails requesting volunteers, and be ready for many opportunities to develop from this group's work over the next year and beyond.

Another area of burgeoning excitement at HOPA relates to the continuation of our "Time to Talk" series. Our first venture in this area was "Time to Talk CINV." This patient-focused program on dealing with chemotherapy-induced nausea and vomiting was so well received that we reached out to our membership and industry partners to develop the next idea: "Time to Talk Immuno-Oncology." The Time to Talk Immuno-Oncology Task Force, chaired by Heidi Finnes, will be formulating ideas and generating projects over the next year. Other members are Amber Proctor (vice chair), Christopher Campen, Jessica Davis, Sara Fleszar, Kelly Fritz, Mimi Lo, Kristoffer Martinson, Brenna Rowen, and Chrystia Zobniw. Be on the lookout for opportunities generated by this task force as well.

Many of you have been asking whether the time has come for HOPA to have its own peer-reviewed journal. After much preliminary work by members of HOPA's Publications Committee and at-large board member Edward Li, a Journal Task Force has been formed to address this question and determine the best way for HOPA to accomplish this goal. The Journal Task Force is composed of Ashley Glode (chair), Megan Bodge (vice chair), Robert Mancini, Scott Soefje, Marisela Tan, and Christan Thomas. The excitement among this group is palpable, and we foresee many opportunities for our entire membership stemming from this group's efforts.

On HOPA Hill Day, June 13, 2018, HOPA members went to Washington, DC, to advocate for our oncology patients and their access to cancer and pain medications. HOPA members urged congressional leaders to support the Cancer Drug Parity Act (HR 1409), and in cooperation with the Patient Access to Pharmacists' Care Coalition, they advocated for passage of the Pharmacy and Medically Underserved Areas Enhancement Act (HR 592 and S 109). Because of the midterm elections being held this year, the Public Policy Committee and our partners in the District Policy Group decided that our best efforts would be to concentrate on one HOPA Hill Day this year. Those attending were Public Policy Committee members Timothy Tyler (chair), Sarah Hudson-DiSalle (vice chair), Justin Arnall, Megan Hartranft, Taylor Monson, Kathryn Schiavo, and Rebecca Tombleson. Twelve HOPA members applied

"You [HOPA members] make HOPA the phenomenal association that it has become and push the boundaries for what HOPA will be tomorrow."

through the Volunteer Activity Center and received travel grants: Brooke Bernhardt, Ashley Glode, LeAnne Kennedy, Sarah Kraus, Houry Leblebjian, Jeremiah Moore, Ginah Nightingale, Alexander Quesenberry, Jeff Reichard, Michelle Rockey, Katherine Saunders, and Philip Schwieterman. HOPA's board of directors were among this large HOPA contingent walking around DC and visiting many congressional offices throughout the day. Because of the wonderful turnout and excitement from such a large group, HOPA plans to make travel grants to attend HOPA Hill Day a yearly offering.

Finally, I want to say thanks to all of you for the dedication, energy, excitement, hard work, time, and thoughts that you pour into HOPA each day. You make HOPA the phenomenal association that it has become and push the boundaries for what HOPA will be tomorrow. Knowing this about you, I hope that you also took time to enjoy your summer! I hope that you took a break from the patient care, educational offerings, journal articles, oncology pharmacy research, and all that occupies so much of your time. That you went to the park and enjoyed a picnic with the cherished people in your life, saw a baseball game, watched the fireworks, hugged your kids, petted your animals, slapped on sunscreen and enjoyed some time outside of work. And right now, pat yourself on the back for doing a great job (you really do deserve it). Remember: if you do not re-energize and recharge your batteries, you cannot keep being the incredible HOPA members that you are! ●●

HOPA
Hematology/Oncology
Pharmacy Association

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RECOGNIZE OUTSTANDING HOPA Members

The HOPA Member Awards program gives members an opportunity to recognize their HOPA colleagues who have shown outstanding achievement in their field. Awards will be presented at HOPA's 2019 Annual Conference. In order to be considered for an award, applications must be submitted by **Monday, October 1, 2018.**

Award of Excellence

This award recognizes a HOPA member who has made a significant, sustained contribution to or provided excellent leadership in developing or supporting hematology/oncology pharmacy.

New Practitioner Award

This award recognizes a HOPA member early in his or her career who has made a significant contribution to developing or supporting clinical hematology/oncology pharmacy services.

Hematology/Oncology Technician Award

This award recognizes a HOPA tecÚician member who demonstrates excellence in his or her work and a commitment to hematology/oncology pharmacy practice in an organized healthcare setting.

Patient Advocacy Award

This award recognizes a HOPA member who demonstrates leadership and collaboration while advocating for outstanding patient care.

Oncology Pharmacy Practice Literature Award

This award recognizes an article, other than scientific research, that contributes to the betterment of the hematology/oncology pharmacy profession and describes innovations in community, hospital, or healthcare system hematology/oncology pharmacy practices.

Basic Science and Clinical Research Literature Award

This award recognizes a scientific article describing hematology/oncology basic science research, translational research, or clinical trials evaluating drug efficacy or safety.

Learn more and nominate a colleague at hoparx.org/membership.