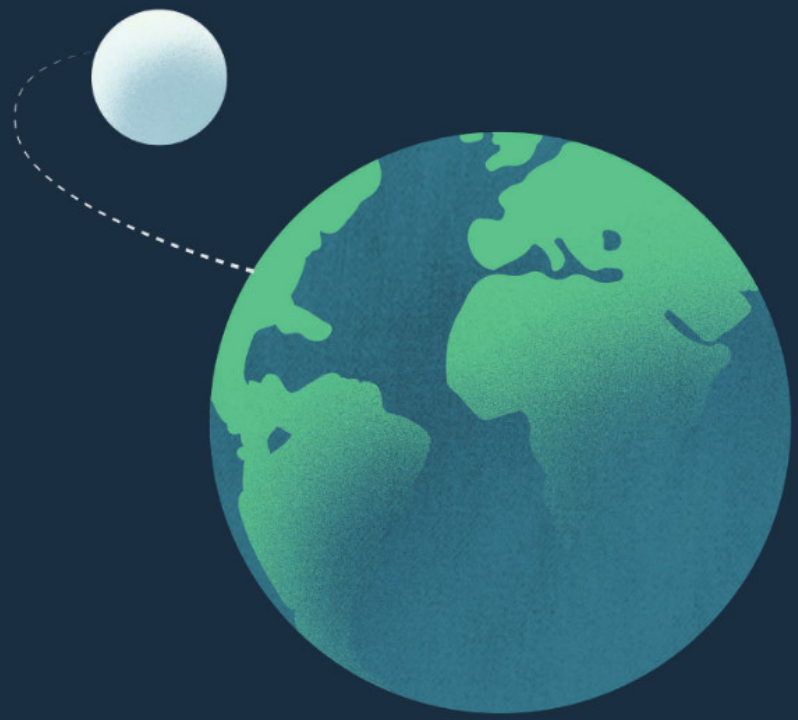
HOPA NEWS

Pharmacists Optimizing Cancer Care

VOLUME 13 | ISSUE 3



The Cancer Moonshot Initiative

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HOPA Hematology/Oncology Pharmacy Association

VOLUME 13 | ISSUE 3

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Pharmacists Optimizing Cancer Care

COLUMNS

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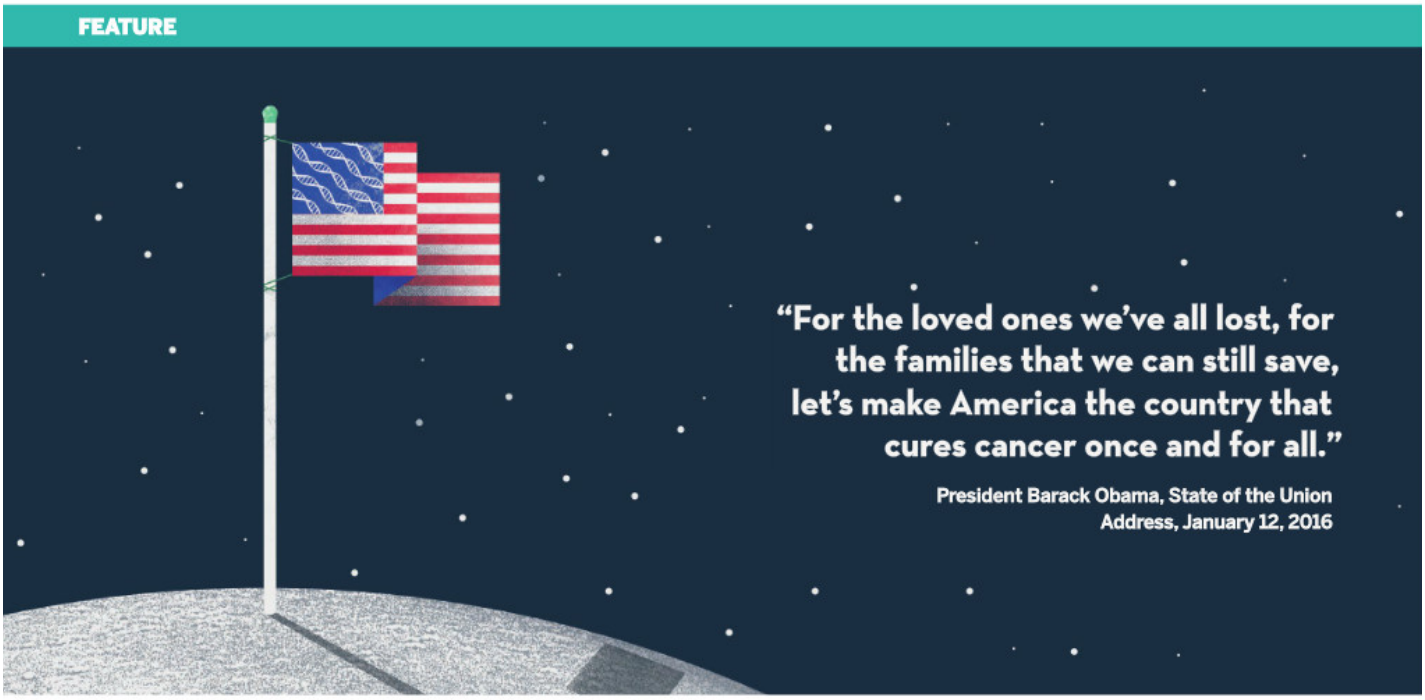
FEATURE



The Cancer Moonshot Initiative

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In 2016, during his State of the Union Address, President Barack Obama appointed Vice President Joe Biden to lead the Cancer Moonshot Initiative.[1] It is so named as a "call to humankind to be bold and do big things" in reference to President Kennedy's call to land on the moon.[2] The goal of this initiative is to "eliminate cancer as we know it" and identify new ways to prevent, diagnose, and treat this disease.[1] The Moonshot aims to accelerate research efforts and break down barriers to progress by enhancing access to data and fostering collaborations among key players. By bringing together researchers, doctors, philanthropies, patients and patient advocates, and biotechnology and pharmaceutical companies, the initiative aims to double the rate of progress toward a cure for cancer.

The Cancer Moonshot Initiative Task Force consists of heads of executive branch departments, agencies, and offices.[3] This initiative was funded by 1 billion federal dollars to spur momentum for this project with the promise of continued funding. The Task Force serves in an advisory role and will concentrate on maximizing federal investments, targeted incentives, private sector efforts from industry and philanthropy, patient engagement initiatives, and other mechanisms to support cancer research and expedite progress in treatment and care. The Task Force is working with departments and agencies focused on basic, translational, and clinical research; therapy development; regulation of medical products; and medical care related to cancer.

Some key functions of this task force include[3]

- accelerating our understanding of cancer and its prevention, early detection, treatment, and cure
- improving patient access and care
- supporting greater access to new research, data, and computational abilities
- encouraging the development of cancer treatments
- identifying and addressing any unnecessary regulatory barriers and considering ways to expedite administrative reforms
- ensuring optimal investment of federal resources
- identifying opportunities to develop public-private partnerships and increasing coordination of the federal government's efforts with the private sector as appropriate.

Following the announcement of the President's Moonshot Initiative, the Cancer Moonshot 2020 Program was created under the leadership of Dr. Patrick Soon-Shiong as a comprehensive collaborative cancer enterprise with the focus of developing combination immunotherapy as the next generation standard of care in treating cancer patients.[4] This national coalition consists of individuals from large pharmaceutical, biotech, major payer, and *Fortune* 500 companies; academia; and community oncology to work toward one common goal: to initiate randomized Phase 2 trials and enroll 20,000 patients at all stages of disease who have 20 different tumor types. These data will be utilized to create Phase 3 trials and the development of an effective vaccine-based immunotherapy treatment to combat cancer by 2020.

Vice President Joe Biden spoke at the most recent American Society of Clinical Oncology (ASCO) meeting on June 6 in Chicago, encouraging attendees and members to work together on this initiative.[5] He emphasized that there should be a team approach to

fast-track cancer research efforts and eliminate blockades to progress by promoting data sharing and facilitating collaborations to advance cancer prevention, treatment, and care. No one individual can do this on his or her own. Information and progress must be shared to achieve the goal of reaching a decade of progress in only 5 years. During this speech he introduced a new project called the Genomic Data Commons (GDC), which is a public database for clinical genomic data administered by the National Cancer Institute (NCI) to facilitate sharing among cancer researchers.[6]

Vice President Biden's complete speech can be viewed on ASCO on demand at ASCO.org.

Pharmacists have the potential to be involved in the Cancer Moonshot Initiative through many different avenues. HOPA President Sarah Scarpace Peters attended the Cancer Moonshot Summit on June 29 in Washington, DC, which was assembled by the Vice President. HOPA members were encouraged to watch the live broadcast as well as post comments on the HOPA Central discussion board. ●●

Additional ways to get involved can be found at www.whitehouse.gov/cancermoonshot.

- **Share your story with the Vice President.**
- **Make a commitment to help.**
- **Share your Moonshot ideas.**
- **Be a part of the National Cancer Moonshot Summit.**

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Personal Impact *and* Growth Reflection

Motivation to Fight

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As oncology pharmacists, we all carry an unofficial list of memorable patients. Some leave this world before we are ready to say goodbye, and others defy the odds with no logical scientific explanation. Evidence-based guidelines and protocols provide the framework of our treatment plans, but as the great physician Sir William Osler once said, "The good physician treats the disease; the great physician treats the patient who has the disease." Each patient has an intricate and unique web of internal and external factors that will influence his or her treatment outcome. Today, I tell the story of one of my patients, David, whose admirable fight and motivation reinforced the need to focus on the individual.

I first met David about 1.5 years ago. He was a 39-year-old teacher with a loving wife and two beautiful children who had brought his family to America for a better life. The diagnosis of metastatic urothelial carcinoma hit hard. He was decades younger than the average patient with this condition, but his disease was aggressive and his prognosis poor. Many of our patients with this disease are in their 70s with different goals and priorities than someone half their age. As our team discussed his prognosis and treatment options with him, I couldn't help picturing myself in his shoes. To me, it seemed unfair that he had to face such a challenging journey at his age. However, David was selfless, and his focus was on his family. He made it clear: "I want to fight, Doc." As we would soon discover, this declaration became a recurring theme throughout his treatment. David was a spiritual man, and at 5'2" and 65 kg, I couldn't help envisioning the epic battle of David and Goliath that we were about to fight.

Following completion of his first chemotherapy regimen, David became hospitalized around the time of the winter holidays. As David required 6 liters of supplemental oxygen and multiple blood transfusions each week, we once again discussed the goals of therapy and encouraged hospice care. David's response was, "I want to keep fighting, Doc."

We had many difficult conversations with David and his wife, but this conversation was one of the hardest. In fact, it was one of the most challenging of my career. It was in this conversation that we learned the full gravity of the situation. If David passed away, his family would be deported back to their home country—one without opportunity and freedom as we know it. Obtaining a green card for his wife was underway, but the process is slow. He was motivated to keep fighting because he refused to leave this world without first providing stability for his family. We were running out of options and time, but we were overcome with compassion and couldn't give up. The family's future was in our hands.

> **"Understanding the true 'why' behind their decision is one of the most important variables in the equation and will allow us to provide care on a deeper level."**

David soon began a second-line regimen. Two doses into therapy, David became extremely fatigued, and his condition was deteriorating. Once again, we heard his familiar words, "I want to keep fighting, Doc." Through third-line therapy, his disease kept progressing, but he continued to stay motivated. With cancer patients, we often discuss treatments that extend survival and palliative care options. Patients often say their goal is to live longer to spend time with their family, and I believe this is where we need to stop and listen. Understanding the true "why" behind their decision is one of the most important variables in the equation and will allow us to provide care on a deeper level. Does an elderly patient simply want to spend time fishing on the lake with his grandson? Or is it more complex with a family's well-being at stake? David's situation reminded me that to truly care for our patients and their families, we must understand their desires and motivations.

David's motivation was now apparent, and following progression on third-line therapy, we heard him say again, "I want to keep fighting, Doc." Fourth-line therapy commenced and, after months of anxiously awaiting, his wife received her green card. The clinic was full of cheers and tears. He did it; he achieved his goal.

Just this week, David's restaging scans have showed progression. True to character, David said, "I want to keep fighting, Doc." We will soon begin a new chemotherapy regimen, but David's time on earth is limited. Perhaps he will be with us only for another month or two. Then again, I was proven wrong when those thoughts came to mind 8 months ago, and I hope to be proven wrong again.

Whether their goal is being comfortable or ensuring a better future for their family, our patients often thank us for helping them fulfill their last wishes. We credit our hard work, training, and knowledge, but it is patients like David who deserve much of the credit. These inspiring patients remind us that we don't treat just the disease, but also the patient suffering from it. Although they may not always win the battle, their unique stories and motivation to fight inspire us to be better oncology pharmacists. ●●

Advice for Staying Up to Date with the Literature

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Perhaps one of the most important skills you learn during residency is how to effectively teach yourself. This is especially important when you consider how rapidly the field of hematology/oncology pharmacy changes, with new drugs constantly being approved by the U.S. Food and Drug Administration, novel classes of agents being evaluated in the drug development pipeline, and the results of clinical trials being published. Knowing the data, learning how to interpret that information, and applying it to your patient population are essential skills of the clinical pharmacist.

So what advice would two young practitioners offer to students and residents pursuing a career in hematology/oncology pharmacy that would help them stay up to date on the literature? A good place to start is to ask your preceptors and mentors how they continually educate themselves. These seasoned practitioners have devised methods over the years to ensure that they are informed about the most recent events in their areas of practice, and each preceptor undoubtedly has different methods and resources to achieve this. They have established a good system for focusing on the key concepts, while also weeding out unnecessary ancillary information. Learn from your preceptors, and then tailor their advice to best suit your needs.

Preceptors are helpful in pointing you in the right direction in terms of resources you should utilize. For example, you can sign up to receive e-mails about the table of contents from the most recent issues of high-impact journals such as the *New England Journal of Medicine* and the American Society of Clinical Oncology's *Journal of Clinical Oncology*. Create a free account on these journals' websites and specify which alerts you'd like to receive (for example, with the *New England Journal of Medicine*, you can sign up for specialty updates in Hematology/Oncology and Infectious Disease).

Another good website to receive updates from is Clinical Care Options (sign up for oncology-related news at www.clinicaloptions.com). From solid tumor to hematological malignancies to supportive care, this resource provides a nice overview of a variety of topics in oncology. Additionally, PracticeUpdate Oncology (www.practiceupdate.com/explore) highlights news from several journals, with links to these highlighted trials. This website also has useful webinars and interviews with leading practitioners who offer insight into results from recent clinical trials and potential implications for clinical practice.

"A good place to start is to ask your preceptors and mentors how they continually educate themselves."

If you are looking for a valuable resource for hematology and bone marrow transplantation, sign up for e-mail alerts from *Blood*, which has a great series of review articles—"How I Treat"—that are written by prominent practitioners in that area. From recommendations for treating relapsed multiple myeloma to comparing tyrosine kinase inhibitors in chronic myeloid leukemia to discussing respiratory viral infections in transplant, these articles are useful reviews that incorporate both evidence-based medicine and considerations for clinical practice when there are limited data available to guide you.

In addition to the e-table of contents and alerts from these journals, listservs also are a great resource for keeping yourself in the loop! The HOPA listserv and HOPA Central feature discussions about issues in clinical practice, such as strategies for mediating drug shortages and use of biosimilars among different institutions. There are different communities on the HOPA Central website you can join to be involved in more focused discussions. HOPA Central also has a direct link to *HOPA News*, which offers a wealth of important practice-related information. It's a good idea to join listservs from organizations that focus on specialties that you're particularly interested in. For example, the American Society for Blood and Marrow Transplantation features a pharmacy listserv similar to that of HOPA: pharmacists can submit questions and request feedback from members of several different institutions, share ideas, and discuss prominent issues.

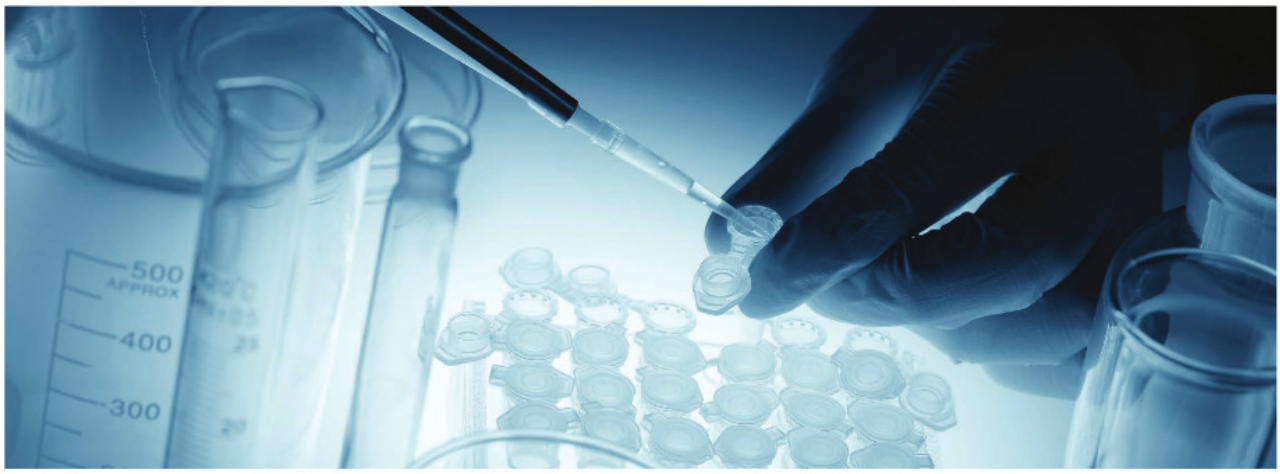
With all of the information currently available and constant changes in the hematology/oncology pharmacy world, keeping on top of the most important concepts can seem overwhelming. That's why it's essential to have a good system for saving and organizing this information so that you can refer back to it. We recommend creating folders broadly based on different disease states to keep yourself organized. For example, have a file for "hematological malignancies", then separate that into subfolders for acute myeloid leukemia, acute lymphoid leukemia, chronic myeloid leukemia, chronic lymphoid leukemia, etc. Within your transplant folder, you might create folders on different preparative regimens, the role of transplant in multiple myeloma or Hodgkin lymphoma, and graft versus host disease (GVHD), with important trials saved in each of these subfolders. Whenever your preceptors e-mail you pertinent articles, they may highlight key concepts in the body of the e-mail that you should be aware of and pay attention to, such as how the trials impacted practice, considerations about the patient populations, and limitations of the trials. It's a good idea to save this correspondence, too, whether by saving it in a Word document or forwarding it to another e-mail address.

(Unless you continue to practice at the same institution after you complete residency, you'll likely lose access to your work e-mail account, and saving articles and e-mails as you go is much easier than trying to save everything toward the end of residency.)

In addition to saving primary literature and review articles, we recommend you ask preceptors and co-residents to send you electronic versions of the presentations they have developed. (Think Oncology Forum presentations, for example.) These can be useful resources, especially because they contain citations of landmark trials that you can go back to and study. Keep your system of organization as simple as possible so you can easily locate articles when you need them. Remember, part of your role as a pharmacist is educating other members of the healthcare team, and the faster you can pull the articles you need and share them, the better! Building a thorough reference library for yourself should be an essential goal of your residency training.

Finally, in keeping with the specific, measurable goals you establish for yourself throughout your training, it's very important to consistently set aside a specific amount of time each week (at least 1–2 hours) to solely focus on reading oncology-related literature. This should be in addition to all of the reading you do to prepare for topic discussions and presentations. As one of our mentors advised us, the single most important task you can do to advance your knowledge as a practitioner in oncology is read, read, read! With all of the other responsibilities of residency and pharmacy training, devoting time to reading can easily get pushed to the end of your to-do list, and that's why we strongly encourage you to protect your reading time. Otherwise, the articles quickly pile up, and you may end up missing important information. Even reading one clinical trial or review article in-depth, or reading the abstracts of a few published trials each week, goes a long way to advancing your knowledge. By following all of these steps, you'll have a solid framework for educating yourself throughout your career!

"Remember, part of your role as a pharmacist is educating other members of the healthcare team, and the faster you can pull the articles you need and share them, the better!"



Cytokine Release Syndrome in Patients Receiving Blinatumomab or Chimeric Antigen Receptor T Cells for Acute Lymphoblastic Leukemia

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The U.S. Food and Drug Administration (FDA) approval of blinatumomab (Blincyto®) in December 2014 marked the arrival of immunotherapy for relapsed/refractory B-cell acute lymphoblastic leukemia (RR B-ALL). Since then, other immunotherapy strategies have emerged, particularly the development of chimeric antigen receptor (CAR) T-cell clinical trials at some U.S. cancer centers. Blinatumomab is a bispecific T-cell engager antibody fragment that binds CD19 on B cells and CD3 on T cells, forming an immunologic synapse resulting in B-cell lysis.[1] CAR T cells are virally engineered autologous T cells expressing a CD19 receptor that are capable of *in vivo* expansion resulting in T-cell activation and tumor lysis.[2-4] Both of these CD19 targeted immunotherapies display impressive efficacy in RR B-ALL, yet present new challenges in supportive care with unique adverse events (AEs) not observed with cytotoxic chemotherapy. Both blinatumomab and CAR T cells can cause cytokine release syndrome (CRS), a potentially life-threatening inflammatory AE that pharmacists must be familiar with to optimize supportive care and maximize patient outcomes with these new immunotherapies.

CRS following blinatumomab or CAR T cells is characterized by symptoms of excessive inflammation secondary to release of numerous pro-inflammatory cytokines following T-cell activation and expansion. The implicated cytokines include IL-10, IL-6, IL-2, IFN-γ, and TNF-α, yet the magnitude of elevation shows significant interpatient variability.[5] Severe febrile episodes (often > 40 °C) are common, presenting a challenge to delineate CRS versus infection. Patients may also experience myalgia, headaches, gastrointestinal distress, and fatigue. More severe sequelae include respiratory failure, neurologic toxicity (e.g., delirium, tremor, and seizures), cardiovascular compromise, tumor lysis syndrome, and disseminated intravascular coagulopathy. Using the FDA-approved dosing, blinatumomab has a reported CRS incidence of 11% for all grades and occurs only during the first cycle of treatment (usually within week 1), with symptoms correlating with T-cell expansion. CRS intensity correlates with disease burden (i.e., marrow blast count); as such, various attempts to reduce CRS have emerged throughout clinical trial experience with blinatumomab, including dexamethasone pretreatment and administration of leukoreducing chemotherapy.[6,7] The FDA-approved labeling for blinatumomab requires two interventions to reduce CRS: a step-wise dosing approach of 9 mcg/day on days 1–7 followed by 28 mcg/day on days 8–28 of cycle 1, as well as dexamethasone pretreatment. Dexamethasone 20 mg IV is administered 1 hour prior to starting the cycle 1 day 1 infusion, as well as with the day 8 dose escalation during cycle 1, prior to day 1 starts for subsequent cycles, and anytime the infusion is interrupted for 4 hours or more. Pharmacists are instrumental in limiting the risk of CRS by ensuring appropriate dexamethasone premedication and providing nursing education to never flush the line containing blinatumomab, as this can increase risk of CRS by giving a sudden bolus of drug to the patient.[1]

Treatment of CRS relies on toxicity grading using the National Cancer Institute Common Terminology Criteria for Adverse Events for CRS. Grade 1 CRS consists of symptoms that are not life threatening, such as fever and constitutional symptoms, which require only

symptomatic management with antipyretics and analgesics.[8] A full infectious workup, including blood cultures and appropriate imaging, followed by prompt initiation of empiric antibiotics is recommended, especially in the setting of concurrent neutropenia due to limited ability to separate CRS from infection. Grade 2 CRS is characterized by symptoms requiring moderate intensity interventions, including hypotension requiring fluid resuscitation or one low-dose pressor, hypoxia requiring the addition of up to 40% oxygen, or the presence of a specific grade 2 organ toxicity. Patients with grade 3 CRS require more than one pressor or high titration of a single pressor (i.e., ≥ 20 mcg/kg/min norepinephrine) for hypotension and must have an oxygen requirement of ≥ 40% or a specific grade 3 organ toxicity. Blinatumomab has a short half life of approximately 2 hours, which grants tight control of drug levels throughout the treatment course. In the setting of grade 3 CRS, the infusion should be discontinued and may be restarted at 9 mcg/day once symptoms resolve.[1] Dexamethasone is crucial in attenuating the excessive inflammatory cascade during blinatumomab-related CRS, yet the optimal regimen remains to be determined. One published recommendation includes a tapered regimen of dexamethasone 24 mg IV divided every 8 hours on day 1, 16 mg divided every 12 hours on day 2, followed by 8 mg daily on days 3 and 4, but the rapidity of the taper depends on the patient's clinical status.[9] Because blinatumomab relies on T-cell activation for efficacy, there is a theoretical concern that dexamethasone might impair efficacy. Low doses of dexamethasone suppress cytokine release without impairing *in vitro* cytotoxic effect,[10] and receipt of dexamethasone did not impair outcomes in a large phase 2 study[11]; nevertheless the absence of randomized data warrants judicious use of dexamethasone. The IL-6 receptor antagonist tocilizumab (Actemra®) is rarely needed for blinatumomab-related CRS, in contrast to CRS following CAR T cells (as discussed below). However, a case of steroid-refractory blinatumomab-related CRS complicated by macrophage activation syndrome that was responsive to tocilizumab has been reported.[12] Grade 4 CRS is characterized by life-threatening symptoms or ventilator-dependent respiratory failure, for which permanent discontinuation of blinatumomab is recommended along with the aforementioned supportive care strategies.[1]

CRS is a common and clinically significant AE following CAR T cells, with a variable onset following infusion and a reported all-grades incidence as high as 100% in ALL.[13,14] Despite increases in numerous cytokines, the key mediator of CRS following CAR T cells appears to be IL-6, an acute-phase reactant producing both anti- and pro-inflammatory effects, dependent on the level and signaling pathway involved. IL-6 is normally produced in response to infection, trauma, or immunological challenge, and contributes to a clinical syndrome mirroring sepsis.[8] C-reactive protein (CRP) and ferritin frequently are measured following CAR T-cell infusions and are associated with CRS.[15] CRP originates from the liver as an acute phase reactant and can be used as a surrogate marker for IL-6, given IL-6 monitoring can be a challenge with limited assay availability and slow turnaround time.[16] Significant ferritin elevations (sometimes > 300,000 ng/m), may occur in the setting of CRS, mimicking hemophagocytic lymphohistiocytosis with associated hepatosplenomegaly and hypofibrinogenemia.

CLINICAL PEARLS (continued)

As with blinatumomab, the severity of CRS following CAR T cells is related to disease burden prior to treatment, in addition to possible associations with the dose of T cells infused and the schedule of cell infusion (100% of target dose infused on day 1 versus administered over 3 days).[8,17] The presence of any grade of CRS following CAR T cells correlates with antitumor effect; however, it is unclear if patients experiencing severe CRS demonstrate greater antitumor efficacy than those with lower grade CRS.[16] Grade 3 CRS following CAR T cells (or grade 2 CRS in an older patient with comorbidities) is managed with the IL-6 receptor antagonist tocilizumab at 8 mg/kg IV administered over 1 hour.[16] Targeting IL-6 has become the most common management strategy for moderate to severe CRS following CAR T cells due to early clinical experience, rapid onset of efficacy, favorable tolerability, and lack of apparent detrimental effect on antitumor efficacy (although this remains experimental and expert opinion in the absence of randomized data).[16] Following tocilizumab, clinical improvement can occur quickly (within a few hours), yet some patients with suboptimal response may require an additional dose of tocilizumab within several hours of the first dose.[18] The IL-6 antagonist siltuximab, administered over 1 hour at 11 mg/kg, also is an option for CRS refractory to tocilizumab, but the benefit of this addition remains unclear.[16,18] A hallmark of CAR T-cell CRS management has been to limit use of corticosteroids in the first-line setting given the potential to dampen CAR T-cell efficacy due to the T-cell lymphotoxic effect of steroids. On the contrary, recent data suggest up to 2 mg/kg/day of methylprednisolone given at the peak of CRS for short intervals is unlikely to impair CAR T-cell efficacy, yet more clinical experience is needed to make a definitive statement regarding the effects of steroids on CAR T-cell efficacy.[16] Dexamethasone may be preferred over methylprednisolone in the setting of neurologic toxicity given its greater blood-brain barrier penetration.[16]

CRS is a complicated and unique toxicity following blinatumomab and CAR T cells, which are two major therapeutic advances in the management of RR B-ALL. Grade 1–2 CRS is typically managed with supportive care, with a low threshold to administer dexamethasone in the case of progressive CRS with blinatumomab. Minimal published experience exists for tocilizumab in blinatumomab-related CRS, and thus should be reserved for steroid-refractory CRS. The cornerstone of CRS management following CAR T cells is tocilizumab. Our practice is to deliver tocilizumab within 15 minutes of order entry, with a low threshold to repeat dosing in the setting of suboptimal response. Siltuximab and ultimately high-dose corticosteroids are options for tocilizumab-refractory CRS following CAR T cells. Further research is needed to determine the effects of high-dose steroids on the clinical efficacy of CAR T cells. Pharmacists working in centers using blinatumomab and investigational CAR T cells must understand the intricacies of this unique AE and be prepared to recommend supportive care despite limited clinical experience to maximize patient outcomes with these novel therapeutic agents.

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Protecting Access to Treatment: Opioid Therapy for Cancer-Related Pain

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Drug overdose deaths are at an all-time high with a large number of those deaths attributable to opioids, including both prescription opioid pain relievers and "street" drugs such as illicit fentanyl and heroin. The Centers for Disease Control and Prevention (CDC) has estimated that 78 people die each day from an opioid overdose in America and that between 2000 and 2014, nearly half a million Americans perished from opioid abuse.[1] Heroin initiation and dependence has been rapidly increasing in recent years, and many users report initial use of prescription opioids for nonmedical reasons prior to heroin use.[2] Analysis of prescribing patterns for opioids indicate an increase in prescriptions for opioid pain medications without a reported increase in patients reporting pain, which has likely perpetuated these issues.[1]

To combat the "opioid epidemic," many federal agencies are expanding efforts to reduce opioid misuse and abuse. Efforts currently being investigated and implemented include expansion of educational efforts, increased availability and improved access to naloxone, expansion of resources for addiction treatment of incarcerated individuals, increased access to drug disposal sites, new evidence-based opioid and heroin treatment programs, and strengthened prescription drug monitoring programs (PDMPs).[3] Many states are working to revise and strengthen their own laws regarding prescription opioids. Measures being implemented include limits on quantities of prescribed opioids and increased requirements regarding PDMPs, as well as and provider and patient education.[3]

Though this is certainly a complex topic and efforts to curb opioid abuse are largely needed, it is unclear what impact increased regulations may have on cancer patients and survivors suffering from moderate-to-severe pain. It also has been unproven that treatment of cancer-related pain with opioid medications has worsened the problem of opioid overdoses. In May 2016, the American Society of Clinical Oncology (ASCO) issued a policy statement putting forward several principles to balance access for appropriate patients and curbing misuse of prescription opioids.[3] The full statement can be accessed at www.asco.org/advocacy-policy/policies-positions-guidance/policy-statements.

Highlighted in the statement is that cancer patients should be considered a special patient population and should likely be excluded from much of the impending legislation and regulations. Pain has been reported as one of the most feared consequences following a cancer diagnosis and may impact quality of life, physical functioning, psychological well-being, and even survival. Opioid therapy has been the gold standard for treatment of moderate-to-severe cancer-related pain, and guidelines for cancer pain management support opioid use in appropriate patients.[4] Many barriers already exist for effective pain management in cancer patients, and more restrictions may only compound the issue. Though many regulations already have excluded patients undergoing active cancer treatment, there is ongoing concern that the needs of cancer survivors, or those not undergoing active treatment but still with active cancer, may not be fully met.

HOPA has identified pain management as an issue of importance to monitor as part of its Health Policy Agenda to ensure patients have access to essential pain medications. A policy statement issued in 2014 provides recommendations to help achieve this goal while avoiding opioid abuse and misuse.[6] Pharmacists are well suited to provide comprehensive education regarding opioid regimens and assuage patient fears related to addiction and side effects. We also can serve as a resource to provide education regarding safe manipulation, storage, and disposal of medications. We can assist providers with selecting appropriate regimens for patients based on individual factors and suggest tools for assessing adherence, such as pain diaries and pill counts.[5] All fellow pharmacists also are encouraged to stay abreast of ongoing regulatory efforts and legislation, both nationally and at the state level. Ultimately, a balance must be found to address the ongoing problem of opioid abuse and misuse while still allowing access to essential medications for patients with cancer-related pain being treated in accordance with best clinical practices.

Other principles addressed in ASCO's policy statement[3] include

- **Education for providers—**Risk Evaluation and Mitigation Strategies (REMS) have been in place for certain opioid medications for approximately 2 years. In May 2016, the U.S. Food and Drug Administration (FDA) panel decided to broaden REMS programs to include immediate-release opioids and require mandatory provider education. Development of education related to REMS requirements falls to the manufacturer of the medication. ASCO advocates for provider choice in materials used for education. It endorses the use of materials that are evidence based and geared toward improving outcomes related to overdoses.
- **Education for patients—**ASCO endorses healthcare providers as being best suited to provide education about opioid therapy for patients. Education should be clear and comprehensive regarding benefits and risks of opioid therapy, with an emphasis placed on safe storage of medications. Misunderstandings regarding cancer pain can lead to suboptimal pain control, so it is essential that education for both providers and patients does occur to lead to better patient outcomes.
- **Prescription limits—**ASCO endorses existing exemptions for cancer patients in current regulations. It does not endorse placing limits on quantities prescribed to patients for cancer-related pain as they may limit access to needed medication. If limits are put in place, ASCO advocates for alternative means by which patients may be able to obtain additional medication, if needed.
- **PDMPs—**ASCO recognizes the benefits of PDMPs but also advocates for increased streamlining of the systems, ease of use, and real-time reporting. ASCO also advises caution with interpretation of data collected from PDMPs, given that some providers may have legitimate reasons to prescribe high quantities of opioids in the course of their practice, particularly in certain subspecialties.
- **Patient screening and assessment before and during opioid treatment—**ASCO does not endorse mandating specific requirements after initial patient screening and assessment. Specific practices should be left to the decision of the treating provider.
- **Abuse-deterrent formulations—**ASCO cautions that abuse-deterrent formulations may limit access for certain patients, given the high cost associated with manufacturing and obtaining these products. It recommends consideration of both abuse-deterrent and nonabuse-deterrent formulations for appropriate patients.
- **Treatment for misuse, abuse, or addiction—**ASCO offers full support of current efforts by Congress and the Administration to expand availability and coverage of medication-assisted treatment (MAT) for individuals with an opioid-related disorder.
- **Prescription "Take-Back" programs—**ASCO advocates for increased access to collection sites for unwanted or unused opioid medications. It also endorses changes to the Controlled Substances Act that would allow pharmacies to accept returned opioids and other controlled substances.
- **Wider availability of naloxone—**ASCO supports increased access to naloxone as a lifesaving medication for patients at risk of opioid overdose. It specifically comments on the need for caregiver education so caregivers can properly administer the medication and distinguish opioid overdose from symptoms of advancing disease.

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The Challenges of Drug Shortages

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Drug shortages have created significant challenges for oncology pharmacists over the past few years. In 2014, Fox and colleagues reported that the financial effect of drug shortages is estimated to be hundreds of millions of dollars annually for health systems across the United States.[1] At the time, the authors also reported more than 15 documented deaths from lack of available drugs or suitable alternatives.[1]

Unfortunately, manufacturing issues, allocations, and unavailability have become a reality in pharmacy practice. Dealing with these shortages continues to be a hot topic within institutions and has spurred much discussion in the oncology pharmacy community.

The American Society of Health-System Pharmacists (ASHP) defines a drug product shortage as a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent.[2] The U.S. Food and Drug Administration (FDA) defines a drug shortage as a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug are inadequate to meet the current or projected demand at the patient level. Some of the differences between the FDA and ASHP drug shortages websites are listed in **Table 1**.[3]

When a drug shortage occurs, it is important for pharmacies to develop action plans that clearly identify the drug shortage and the impact it will have on patients' treatments and the pharmacy operations. ASHP describes a process for decision making in the management of drug product shortages (**Figure 1**).[2]

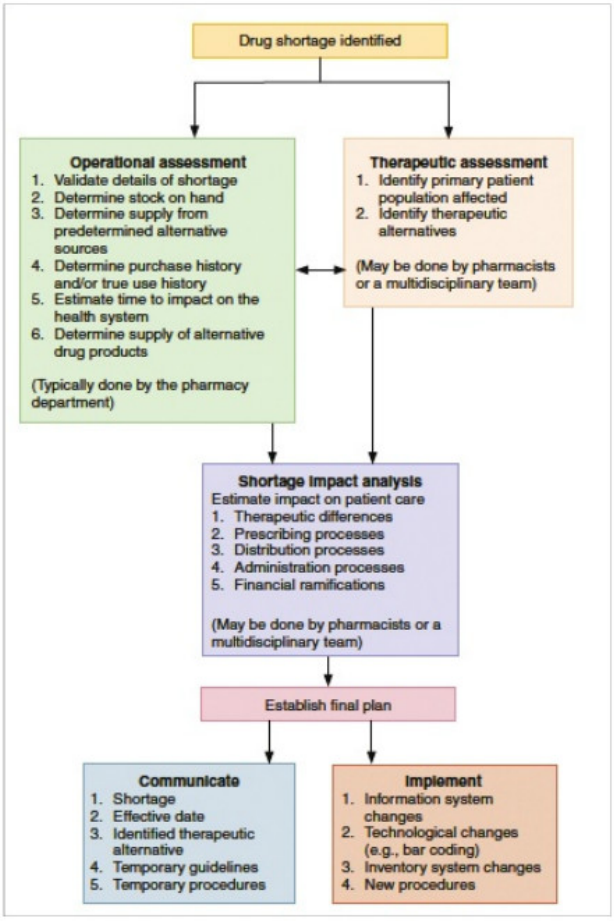
The ASHP decision-making process outlines a systematic approach to drug shortages. Initially, a thorough evaluation of the situation should be performed—including both an operational and a therapeutic assessment. Operationally, there should be a review of the details of the shortage (e.g., the reason for the shortage and when it will be resolved), stock on hand, and ability to obtain additional product.[2] Each institution should review usage and the supply of any alternative products that may be substituted. Parallel

Table 1: Contrasting the FDA and ASHP Drug Shortage Websites

Contrasting the FDA (CDER) and ASHP Drug Shortage Websites: What are the differences?		
	FDA	**ASHP**
Purpose	Provides information obtained from manufacturers about current shortages, estimated duration, and discontinuations and provides information about FDA's and other stakeholders' roles in addressing and preventing shortages	Notification of new shortages and status of ongoing shortages; drug shortage management resources
Audience	Public	Healthcare practitioners
Scope of shortage list	All drugs are listed that are confirmed to be a national shortage by FDA. A shortage is considered to be the period of time when the demand for the drug within the United States exceeds the supply of the drug. **Note:** A separate shortage webpage[i] for vaccines and some biologics is maintained by the Center for Biologics Evaluation and Research.	All drug and biologic shortages reported and confirmed with manufacturer that are national in impact. **Note:** ASHP frequently lists more shortages than FDA.
Source of shortage report	Manufacturers notify FDA of production disruption and voluntarily provided updates. Reports are also received from ASHP and from public via drugshortages@cder.fda.gov **Note:** Manufacturer-provided information represents shortage status at drug firm level	Voluntary reports from practitioners, patients, pharmaceutical industry representatives and others **Note 1:** Information is updated based on release dates from manufacturers. **Note 2:** Reports reflect status at healthcare provider level.
Criteria for inclusion on list	Manufacturers cannot meet current market demand for the drug based on information provided by manufacturers and market sales research	(1) Shortage is verified with manufacturers and (2) affects how pharmacy prepares or dispenses a product, or (3) requires use of alternative drugs, which may affect patient care
Criteria for resolving shortage	One or more manufacturers are in production and able to meet full market demand	All manufacturers of the drug restore all formulations and dosage sizes to full availability. **Note:** Product are listed despite partial or restricted availability as supply chain disruptions can result in intermittent shortages at the provider or patient level
Reason for shortage	Provided by manufacturers using reasons required by legislation.[ii] FDA encourages firms to provide additional information about reasons and other information which, if proprietary, is nondisclosable without the firms' permission.	Provided by manufacturer, if willing to disclose. **Note:** May differ from FDA's due to different sources of information and legislation requiring FDA to use specified reasons
Other information	Estimated duration, links to regulatory information such as recalls and Dear Healthcare Provider Letters	Estimated duration, list of available products, implications for patient care and safety, shortage management strategies, therapeutic alternatives

Developed by: Food and Drug Administration Drug Shortage Staff, American Society of Health-System Pharmacists, and the University of Utah Drug Information Service. August 2014

Figure 1: Process for Decision Making in the Management of Drug Product Shortages



to the operational assessment, practitioners must evaluate the broad patient population and individual patients affected by the shortage as well as possible therapeutic alternatives.[2]

Once both of these areas have been reviewed, the true impact on patient care can be assessed, and a plan can be created and implemented.[2] This plan may involve stratification of patients by curative versus palliative intent or other factors as well as identification of appropriate alternative therapies. All of this must be operationalized for the individual institution (i.e., changes to order sets and compounding guidelines).

One key factor is communication with all involved parties. Communication to physicians, nurses, pharmacists, pharmacy assistants, and purchasing agents should begin when the date the shortage takes effect is known. Alternative prescribing practices and temporary guidelines must be clearly outlined and passed along to the multidisciplinary team.

One recent shortage—bleomycin—has left practitioners scrambling for options and provides a real-world example of the ASHP decision-making process. Assessment of the situation reveals that the bleomycin shortage is a result of manufacturing issues.[4] Of three manufacturers, one has stopped making bleomycin completely, one has the product on back order because of a shortage of the active ingredient, and the third is on shortage due to increased demand and has placed the product on allocation. Anticipated resolution dates are September 2016 for one active manufacturer and the second quarter of 2017 for the other.[4]

Two major populations affected include testicular cancer and Hodgkin lymphoma patients. If clinicians cannot obtain enough bleomycin for all patients from usual suppliers or through allocation for specific patients, they will be forced to find a plan B. This leaves pharmacists and other providers to decide when it is appropriate to switch regimens entirely—such as choosing EP instead of BEP for testicular cancer patients. If this is not possible, stratifying patients—either by age, therapy intent, or other factors—has become necessary.

Alternatively, clinicians look to any available literature to guide treatment. In the case of bleomycin for Hodgkin lymphoma patients, several centers report using information from the RATHL study—presented by Johnson and colleagues at the 2015 13th International Conference on Malignant Lymphoma—to omit bleomycin after 2 cycles of ABVD if adequate response is seen on PET scans. Others are substituting brentuximab for bleomycin in ABVD. Two trials were presented at the same conference in 2015 that added brentuximab to AVD (one was sequential in elderly patients and one included brentuximab plus AVD with or without radiation). A phase 1 study that compared ABVD plus brentuximab or AVD plus brentuximab also was published in *Lancet Oncology*.[5] Though it was a small trial (51 patients), complete response rates in each arm were statistically equal (95% for ABVD group and 96% for AVD; 95% confidence interval 77.2–99.9 and 79.7–99.9, respectively).[5]

Regardless of the agent, strategies employed during this particular challenge can be translated to the larger problem of drug shortages. The management of drug shortages will continue to challenge oncology pharmacists on a daily basis. Implementing a drug shortage management strategy and ensuring communication to all affected individuals will help in effectively managing such shortages.

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Expanding Oncology Pharmacy on a Global Level

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In 2013, the Global Burden of Disease Center Collaboration reported 14.9 million cancer cases and 8.2 million deaths worldwide.[1] With the rise in overall cancer incidence and increased lifespan through improved prevention and treatment of communicable diseases, cancer poses a major threat to public health. Low- and lower-middle-income countries will feel this burden disproportionately because their health systems are not designed to treat complex and expensive disorders such as cancer.[1] There is a growing need for pharmacists worldwide,[2] but stable infrastructures, education, and resources are required for developing countries to address this need. Local pharmacists in all countries need to be motivated to ensure pharmacy involvement in the evolution of cancer prevention, treatment, and supportive care.

I am fortunate to have developed a partnership with a local pharmacy initiative through my participation in the University of California-San Francisco (UCSF) Global Health Clinical Scholars Program[3] as a PGY-2 oncology pharmacy resident. Through this experience, I learned about the challenges of global health and the continual need of pharmacist involvement to help solve these issues. The University of Namibia School of Pharmacy (UNAMSOP) was established in 2010 and is the first pharmacy training program in Namibia. Its vision is to build a sustainable workforce with the skills to increase access to and improve the use of essential medicines by having pharmacists at the forefront of patient care.[4] The role of pharmacy is currently in development, and clinical pharmacy expertise is limited to a few disease states. With the increased incidence of cancer, UNAMSOP and the local hospitals are invested in developing oncology pharmacy specialists as part of a multidisciplinary team. Therefore, my global health project was a clinical audit of the standard-of-care practices at the AB May Cancer Centre at the Windhoek Central Hospital (WCH) in Windhoek, Namibia. The purpose was to help UNAMSOP develop a clinical-based rotation for its postgraduate master's of pharmacy (MPharm) students to participate in clinical training in oncology.

Serving a population of 2.1 million,[5] Namibia now has three state hospitals and four private hospitals.[6] WCH is centrally located and is currently the only cancer center collecting data for the Namibia Cancer Registry.[6] As a result, almost all patients with cancer are assessed and treated at WCH. Within the past year, approximately 14,000 cancer patients were treated in the medical oncology unit.[6] Namibia is a lower-middle-income country, with access to cytotoxic chemotherapy agents and monoclonal antibodies to provide many patients with standard-of-care treatment. The most common malignancies treated at WCH's medical oncology unit are breast cancer, leukemia, and lymphoma. After patients are seen

Kathryn Yee, PharmD, (second from left) with intern pharmacists at their weekly case discussion at the main pharmacy of the Windhoek Central Hospital

The medical oncology infusion center at the AB May Cancer Centre at Windhoek Central Hospital

Dr. Yee (third from left) with the technologists who help facilitate laboratory and didactic courses at the University of Namibia School of Pharmacy

by a physician, a nurse will compound the prescribed treatment, including cytotoxic agents, on the countertop in the clinic. The role of the pharmacist is to dispense supportive care medications at the outpatient pharmacy. Because of workflow issues and limited personnel, the pharmacist compounds chemotherapy agents in the laminar flow hood for pediatric patients only. All of the healthcare staff understands the safety risk of not using the hood, but with the current workflow, there is a lack of appropriate training and staffing. It was encouraging to know the lead physician and nurse recognize the value of pharmacy and want the pharmacist to have greater involvement. With my review of current workflow in both the pharmacy and oncology clinic, I made suggestions for the development of an oncology rotation with the goals of having pharmacists round on the wards, help develop workflow models to integrate pharmacy, and improve the education of pharmacists in oncology. I gave didactic lectures on oncology and led small-group case discussions for current students. Although one of the major barriers to implementing this rotation is having the resources to provide a dedicated oncology pharmacist, I hope the small contribution I made will make a lasting difference for future pharmacists in Namibia.

Not only has this been a life-changing experience for me personally and professionally, but it also has confirmed my passion for providing health care on a global level. I learned that volunteering in medical missions or donating supplies may help address an immediate problem, but it does not create a stable system that gives low- and lower-middle-income countries the ability to provide for themselves. What I love about UNAMSOP is that the institution hired a group of individuals who understand the importance of training Namibian pharmacists and is passionate about promoting and creating a sustainable profession of pharmacy. This should be the ultimate goal of global health initiatives, and I am glad the Global Health Scholars Program and my experience in Namibia have taught me this distinction for impactful global health care.

Global health issues should be a topic covered in the education of future pharmacists around the world. Through global collaboration, information and ideas can be shared to expand the profession of pharmacy locally and internationally. We also should be open to practices we might learn through these collaborations. Pharmacists can look for institutions or organizations with global health programs established like UCSF, join organizations like the International Pharmaceutical Federation, or find nonprofit organizations. I am hopeful pharmacy involvement on a global level will expand, especially in the field of oncology, as there is a growing need. I hope I will be able to continue to be involved in global health, especially at UNAMSOP, throughout my career, and I am grateful for this wonderful opportunity.

“Not only has this been a life-changing experience for me personally and professionally, but it also has confirmed my passion for providing health care on a global level.”

Special thanks to Timothy Rennie, PhD MPharm; Dan Kibuule, MSc BPharm; Mwagana Mubita, MSc BPharm; Tina Brock, EdD MS BSPharm; Mimi Lo, PharmD; and Lauren Jonkman, PharmD MPH.

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Legislative News

Jordan Wildermuth, MSW, Health Policy & Advocacy Manager, HOPA

HOPA is working hard on Capitol Hill, both individually and with coalitions, to continue to move the needle forward on our health policy priorities. As we go to press, the Pharmacy and Medically Underserved Areas Enhancement Act has over 290 cosponsors in the House and over 50 cosponsors in the Senate. HOPA and the Patient Access to Pharmacist Care Coalition are continuing to push for a hearing on the bill in hopes of finding a potential vehicle to move the legislation across the finish line. The same scenario is playing out for the Cancer Drug Coverage Parity Act. There is bipartisan support in both chambers with over 120 cosponsors in the House and 20 cosponsors in the Senate. HOPA continues to work with the Patient Equal Access Coalition in visiting congressional offices to move this bill forward as well. The fate of both bills will be better realized when Congress comes back for the lame-duck session, but the amount of support for both pieces of legislation is tremendous and bodes well for their reintroduction in the 115th Congress if they do not move during this Congress. HOPA member actions have garnered several cosponsors and are still integral as we near crunch time.

On the regulatory side, there continues to be dialogue on the Centers for Medicare & Medicaid Services' Medicare Part B Drug Payment Model. The Senate Finance Committee convened a hearing in July to question CMS's chief medical officer on the specifics of the model. In addition, Congressman Larry Buschon, MD (R-IN), introduced a bill that would block implementation of the proposed rule. CMS has indicated that they will not publish a final rule until 2019, which is the latest it could publish by statute. Many opponents of the rule are viewing this as a win, but CMS is still reviewing the public comments that were received and has not indicated whether it will consider tabling the proposed model altogether. HOPA Past President Scott Soefje and representatives from the Oncology Nursing Society and Association of Community Cancer Centers met with CMS to discuss concerns with the proposed rule. The HOPA Board of Directors and Health Policy Committee also discussed the payment model with members of Congress during HOPA's Hill Day in April.

The Cancer Moonshot Initiative is continuing to unfold. HOPA President Sarah Scarpace Peters attended the Cancer Moonshot Summit in Washington, DC, on June 29, 2016. The summit brought together more than 300 stakeholders to generate ideas about how individuals and organizations can better engage in the Moonshot Initiative, and come up with ideas for new collaborations and actions.

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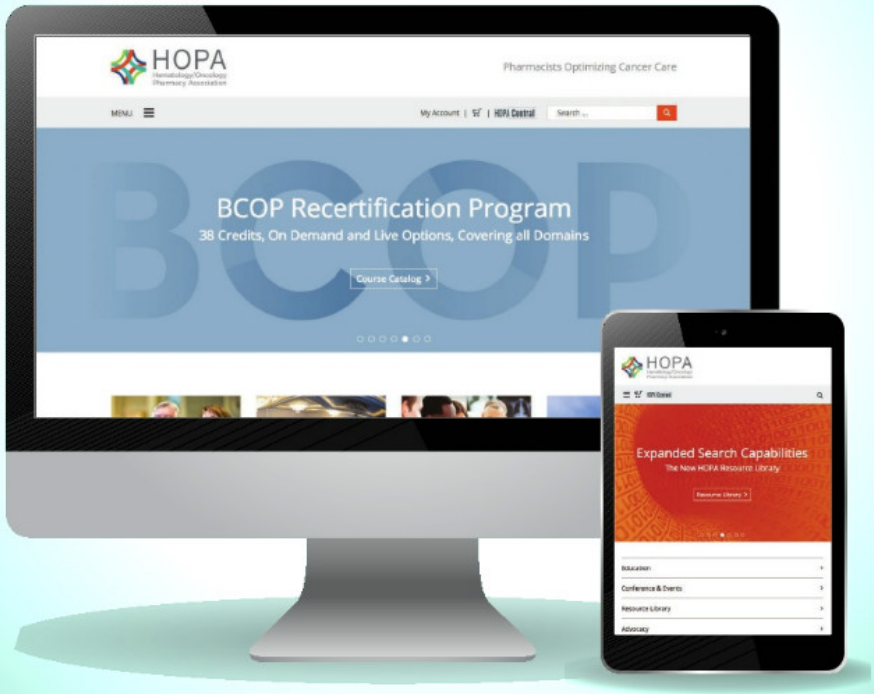

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Lisa M. Cordes, PharmD BCOP BCACP
Oncology Clinical Pharmacy Specialist
National Institutes of Health
Bethesda, MD

Featured in this article are excerpts from Dr. Burke's and Dr. Folan's research posters. Their posters, as well as those submitted by other residents and students, may be found on the HOPA website by selecting the "Education and Conference" tab, then "Conference Archives." Please note that access to these electronic posters is limited to registered attendees of the HOPA Annual Conference.

The HOPA Annual Conference consistently offers educational sessions to encourage sharing information and ideas among attendees, and the 12th Annual Meeting was in keeping with this tradition. One of the best opportunities for students, residents, and practitioners to disseminate and discuss research is through the poster presentation sessions. The research projects presented at the annual conference are assessed by a committee of HOPA members, and particularly impactful projects are recognized with awards in the categories of clinical/translational research or practice management. This year's award winners were Dr. Ellen Burke, PGY-2 oncology pharmacy resident at the University of Kansas Hospital (UKH), and Dr. Stephanie Folan, PGY-2 oncology pharmacy resident at the University of Texas MD Anderson Cancer Center.

Dr. Burke was recognized for her research in the area of practice management focusing on "Assessment of Cetuximab-Induced Infusion Reactions and Administration Re-Challenge at an Academic Medical Center." Although cetuximab is typically well-tolerated, the U.S. Food and Drug Administration-approved labeling includes a black-box warning for serious infusion reactions (IR). Clinical trials have reported a 15%–20% incidence for all grades of IR, and a 3%–5% incidence for grade 3/4. Retrospective studies have demonstrated a higher incidence of all grade IR and grade 3/4 IR in areas of the southeastern United States as well as Kansas and Missouri. Limited data are available regarding cetuximab rechallenge after an initial IR, and patients who experience an IR may be excluded from potentially beneficial therapy with cetuximab if the medication is discontinued. Patients at UKH are rechallenged on the same day as an initial IR using a slower infusion rate and administering additional premedications to help prevent an IR secondary to the rechallenge dose.

The primary objective of Dr. Burke's study was to determine the incidence, IR grade, timing, and completion of a rechallenge dose in patients who experienced an initial cetuximab IR. Secondary objectives included determining the incidence and IR grade that occurred with the administration of the first dose of cetuximab and identifying specific risk factors to further characterize patients who experienced an initial cetuximab IR. This retrospective, single-center study included patients with squamous cell carcinoma of the head and neck who were treated with cetuximab as monotherapy or in combination with chemotherapy between June 2008 and September 2015 at UKH or Westwood Cancer Center. Patients were excluded if they had previous exposure to cetuximab or received cetuximab outside of the UKH health system. IR were graded using the Common Terminology Criteria for Adverse Events (CTCAE v4.03).

Patients were categorized as either not experiencing an IR (NR = 132) or experiencing an IR (n = 33). Baseline patient characteristics of the two groups were similar. There was no statistically significant association between any of the patient-specific risk factors evaluated and the development of an initial IR. Risk factors assessed included receiving chemotherapy within the past 12 months, the treatment of the initial malignancy, single-agent chemotherapy, underlying respiratory disease, history of allergies, use of nonsedating allergy medication, and mean absolute neutrophil, lymphocyte, and eosinophil counts. Various combinations of premedications given prior to the initial IR also were assessed, and no statistical difference in the incidence of an initial IR was observed. Among patients who experienced an initial IR, none had a grade 1 IR, 87.9% had a grade 2 IR, 9.1% had a grade 3 IR, and 3% had a grade 4 IR. Approximately 88% of patients who experienced an initial IR were rechallenged, and all but one patient completed the rechallenge dose. Of those who were rechallenged, the majority (approximately 38%) received the rechallenge dose between 30–59 minutes after the initial dose.

This study found incidences of all grades of IR similar to those reported in clinical trials. However, this study demonstrated a much higher incidence of initial IR of grade 3/4 than that reported in clinical trials (12.1% versus 3%–5%). Dr. Burke's study demonstrated that the majority of patients were able to be quickly and successfully rechallenged after an initial IR, which demonstrates that the institution's current practice of same-day rechallenge is feasible and safe. Additional plans for this research include extending the study period to evaluate more patients.

Dr. Folan's research, "Clinical Outcomes Associated with Linezolid-Resistant *S. epidermidis* Bloodstream Isolates in Leukemia Patients Empirically Treated with Linezolid," was recognized with a Clinical/Translational Research Award. *Staphyloccocus epidermidis* is a common isolate in bloodstream infections among patients with hematologic malignancies. At the University of Texas MD Anderson Cancer Center, linezolid is used as empiric therapy in 85% of leukemia patients with febrile neutropenia. However, an estimated one-third of *S. epidermidis* bloodstream isolates in patients with leukemia at MD

Anderson are resistant to linezolid; the clinical significance of this finding was unknown. The objective of Dr. Folan's study was to assess short-term clinical outcomes in adult leukemia patients with linezolid-resistant *S. epidermidis* bloodstream infections treated empirically with linezolid. This retrospective, single-center cohort study included patients ≥18 years old with a primary diagnosis of leukemia who had at least one blood culture positive for *S. epidermidis* between June 2013 and July 2015 and for whom linezolid therapy was initiated within 1 day of the first positive blood culture.

The primary endpoint was a composite of short-term outcomes on day 3 including persistent fever (> 38° C), persistent *S. epidermidis* bacteremia, intensive care unit admission, and death from any cause. Secondary endpoints evaluated were individual components of the primary outcome, time to blood culture clearance, and time to hospital discharge from initial positive culture (within 10 days). These outcomes were compared between patients with linezolid-resistant isolates versus those with linezolid-susceptible strains. Of the 82 patients included in the study, 33 (40%) had a linezolid-resistant isolate, a substantial increase from the institution-specific rate of 5.5% in 2009. Patients with linezolid-resistant *S. epidermidis* tended to have worse short-term clinical outcomes as defined by the investigators' composite endpoint compared to those with linezolid-sensitive organisms (60.7% versus 34.7%, $p = 0.022$). No differences existed between groups based on the individual components of the composite endpoint, with the exception of persistent bacteremia (36.4% versus 8.2%, $p = 0.009$). In addition, linezolid resistance was associated with a significantly longer median time to discharge. The study demonstrated that patients with a linezolid-resistant *S. epidermidis* bloodstream infection treated empirically with linezolid had significantly worse short-term clinical outcomes, primarily because of persistent bacteremia, as compared to patients with linezolid-susceptible isolates. Long-term morbidity is being assessed, and the results from Dr. Folan's study will be used to discuss comprehensive treatment for leukemia patients with febrile neutropenia and gram positive bacteremia in light of the current resistance rates and antimicrobial usage trends at the institution.

Board Update

HOPA's Seat "at the Table"

Sarah Scarpace Peters, PharmD MPH BCOP
HOPA President

Summer is usually a slow time for HOPA as members, staff, and elected leadership are away on vacation or working extra to cover a colleague who is. This was certainly not the case for HOPA in summer 2016! New committee members were selected and began their official 2016–2017 terms on June 1 and already have met several times. This is the usual cadence of HOPA in the summer; however, this year, we were "at the table" for some new and very important external collaborations.

Back in February, HOPA joined the Academy of Managed Care Pharmacy's Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) (see www.bbcic.org for more information); Ed Li was appointed as HOPA's Board Liaison. In May, the BBCIC requested that two additional HOPA members be appointed to serve on two research groups related to g-csf's and ESAs. After a call to the membership for volunteers, Gary Yee and Catherine Weber were selected and have begun their work. In July, BBCIC sought two more members to serve on the Planning Committee and Scientific Committee, and after a review of the literature and a scan of member profiles and applicants from the first call for volunteers, two former HOPA presidents—Phil Johnson and Jim Koeller—were asked to serve. The impact biosimilars have on the routine practice of oncology pharmacy has been a frequent topic of HOPA Central discussions, and HOPA is recognized by external groups as a key stakeholder in the ongoing practice and policy issues related to biosimilars.

HOPA also was represented at Centers for Medicare & Medicaid (CMS) Innovations meeting in May by HOPA Past President Scott Soefje, who provided comments and expressed oncology pharmacists' concerns regarding a new CMS-proposed rule regarding Medicare Part B reimbursement. Representatives from the Oncology Nursing Society (ONS) and the Association of Community Cancer Centers also were in attendance to show support for our shared concerns.

June kicked off with board members Susannah Koontz Webb and Heidi Finnes, Executive Director Suzanne Simons, and Director of Professional Relations Julie Ichiba attending the American Society of Clinical Oncology (ASCO) Annual Meeting to meet with ASCO and ONS leadership and continue to develop and expand HOPA's collaborations with our industry partners. We appreciate former president Donald Harvey connecting us with ASCO's CancerLinq program and look forward to formalizing our role in that project soon. We also are looking forward to a formal meeting with ASCO's new CEO, Cliff Hudis, in late November to further identify ways in which our organizations can work together.

Did you see the July 14 issue of the *Journal of Clinical Oncology*? Earlier this year, the Canadian Association of Pharmacy in Oncology (CAPhO) reached out to HOPA and the International Society of Oncology Pharmacy Practitioners (ISOPP) to co-author a letter to the editor in response to an important omission in ASCO's "intended audience" for its updated chemo-induced nausea and vomiting (CINV) guideline–the oncology pharmacist! CAPhO, HOPA (Past President Scott Soefje), and ISOPP (former HOPA president and ISOPP President, Moe Schwartz), co-authored the response. Our letter has been published (http://jco.ascopubs.org/content/early/2016/07/14/JCO.2016.68.4746), and ASCO's response will be included in the next issue (http://jco.ascopubs.org/content/early/2016/07/14/JCO.2016.68.6147).

HOPA has earned greater recognition from external groups and an increasing number of invitations to "sit at the table" on the national practice and policy stage.

Also in June, HOPA was among a select group of 350 invited to attend Vice President Joe Biden's Cancer Moonshot Summit in Washington, DC. HOPA's health policy advisor, Jeremy Scott from District Policy Group, and I went on HOPA's behalf and attended four separate small group sessions with White House staff to recommend ways in which the nation could "cure cancer once and for all" and specifically explain how oncology pharmacists support patients with cancer as a chronic disease. In addition to offering ideas to the Vice President, we networked with many other nonprofit and for-profit companies and have been contacted by some for additional collaborations in follow-up to the Moonshot Summit. In fact, HOPA was invited to participate in a conference co-chaired by ASCO and Discern Health on defining value and value-based metrics in cancer care.

Several HOPA members and I presented at the U.S. Food and Drug Administration (FDA) on August 22 at the invitation of the Office of Hematology and Oncology Products. The FDA is interested in the perspectives of oncology pharmacists in different practice settings on the utility and opportunity for improvement with the product label of oncology drugs.

Finally, one very important table that HOPA has sought a chair at has been granted. Since the spring of 2014, at the suggestion of then-secretary Daisy Yang, the president and executive director of HOPA have attended the quarterly meetings of the Joint Commission of Pharmacy Practitioners (JCPP) as guests with the intention of requesting membership in the JCPP. When we first began, JCPP was in the process of re-evaluating its membership structure and later had some hesitancy about the role of specialty organizations within the JCPP. On August 2, Suzanne Simons and I presented our case to the JCPP CEOs and the full JCPP audience; at the conclusion of that meeting, we received a verbal "you're in" from the JCPP chair. We expect to hear more details formally after the next meeting of the JCPP on November 29, as the group continues to define its new membership structure.

There are several other ongoing collaborations that we are involved in or will have future representation in—the ASHP/HOPA pharmacy technician standard, the National Comprehensive Cancer Network Biosimilar Summit, the Drinker-Biddle Client Advocacy Summit, and ISMP collaboration, among others. These efforts are layered on top of our already excellent continuing education programs, three live conferences, our inaugural offering of the BCOP Recertification Program, advocacy on our health policy agenda, continued work refining a new committee structure, and research agenda. As a member since 2005, it is so impressive to see our organization grow from a residency conference to a premier resource for oncology pharmacy education, and now layering on a more sophisticated advocacy agenda. HOPA has earned greater recognition from external groups and an increasing number of invitations to "sit at the table" on the national practice and policy stage. It is well-deserved recognition that demonstrates the evolving maturity of our organization and particularly the expertise of our members and dedication to cancer patients. Kudos to you! ●●

HOPA
Hematology/Oncology Pharmacy Association

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HOPA Recruit a Colleague Program

Help us strengthen the HOPA community!

- Provide greater recognition of the oncology pharmacy profession.
- Improve education and networking opportunities for all members.
- Enhance your colleagues' careers.

For every new member you recruit, you will receive 1 free month of membership and an entry into a drawing to win one of three prizes:

- Complimentary registration to the 2017 Annual Conference in Anaheim, CA
- A $250 travel grant for the 2017 Annual Conference in Anaheim, CA
- 1 free year of HOPA membership.

Deadline for this drawing is December 13, 2016.

Let's work together to advance the practice of hematology/oncology pharmacy! Looking for recruitment ideas? Visit hoparx.org.

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