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GOING BEYOND THE FIRST FILL
How adopting the medically integrated pharmacy model led to improved treatment outcomes, greater patient satisfaction and better economics for five NCODA practices.

RECORD ATTENDANCE
Large turnout, powerful speakers energize NCODA’s 2019 Spring Forum in Denver.

EVEREST ON ONE LUNG
Sean Swarner conquered terminal cancer twice before conquering Mount Everest.

WALKING IN THEIR SHOES
Kirollos Hanna reveals how his journey with aplastic anemia enabled him to become a better oncology clinician.

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Our focus is to advance the value of dispensing practices for oncology physicians. We will provide leadership, expertise, quality standards, and sharing of best practices with all members. We will deliver positive outcomes through collaboration with all stakeholders involved in the care of oncology patients.
Welcome to Oncolytics Today, NCODAs first publication.

Wow, 2019 already! Where has NCODA been and where will NCODA be going?

We are now heading into our fifth year of existence as an organization, the first and only organization to focus exclusively on the management of cancer patients and their oral therapies at the dispensing level within oncology practices.

How did it all start? In 2014, Michael Reff, our Executive Director and Founder, saw a need and had a vision. The oral oncolytic pipeline was beginning to explode, but no one was focusing on the problems patients had simply obtaining their oral cancer medications. Prior authorizations, insurance plans, PBMs, costs, legislative issues and access further muddied the waters. Michael experienced these issues firsthand as a dispensary pharmacist at Hematology Oncology Associates of Central New York.

At the time I was in the process of setting up an in-office dispensary at New York Oncology Hematology in early 2015, so I contacted Mike and Jonas Congelli, my Albany College of Pharmacy alums, and asked them if I could pay them a visit.

I was immensely impressed by their dispensary setup – which was located right where patients walked in and checked out – as well as their medically integrated pharmacy staff, which included a full-time nurse and technician working directly with Mike to take care of the patients.

What I did not anticipate was Mike and Jonas sitting down and convincing me to become part of the organization they were planning. On my ride home that evening, I kept thinking, “What a great idea!” There is a huge void in patient care here and who else is more able to address it than the pharmacists and clinical staff in the practice who collaborate with providers as part of the care team.

After that, things started happening fast. More oncology pharmacy experts joined the team as board members and worked on several important starter projects. Linda Frisk completed the early work on the NCODA Quality Standards. Pharma support became critical to the growth of NCODA and our first corporate sponsor Tesaro led the charge. Concepts started becoming actual projects.

But, yikes! We all had day jobs! Mike soon realized he could not run NCODA as a part-time venture. By assuming the role of Executive Director, he has been able to focus on bringing our grassroots organization to national prominence.

What’s next? In addition to Oncolytics Today, NCODA will continue to forge ahead with initiatives that focus on patients’ access and meeting patients’ needs.

The collaborative effort with HOPA, ACCC and ONS that has produced the Oral Chemotherapy Education Sheets will continue as more and more oral agents are approved by the FDA.

More Positive Quality Interventions (PQIs) need to follow to ensure we are using these new agents safely and appropriately.

Monthly webinars continue to be a valuable resource for our members, offering new clinical information, legislative updates and patient advocacy information.

We will continue to collaborate with ASCO, PhARMA, "Be The Match," Syracuse University and pharmacy schools on initiatives that drive better outcomes for our patients.

We also are looking ahead to the 2019 Fall Summit Oct. 24 to 26 in Orlando, Florida.

We continue to partner with our corporate sponsors who have been with NCODA since the beginning, supporting us and our patients in accessing their life-altering therapies.

As we look back on 2018, we have seen NCODA grow to 350-plus member practices across the Medically Integrated Dispensing landscape. Our professional membership continues to expand and has reached 1,200-plus pharmacists, technicians, nurses, physicians, practice administrators.

And 2019 promises to be another year of continued growth and expansion in to new areas such as urology as well as the further development of the Oncology Pharmacy Technician Association (OPTA).

I want to thank Executive Council members Bob (“Bob O”) Orzechowski, Yen Nguyen, Jim Schwartz, Neil Nebughr, Jan Montgomery, Linda Frisk, Austin Cox, Ray Bailey and Mary Anderson for continuing to offer their wisdom, knowledge and experience to us and for continuing to help lead the way for the future of NCODA.
The theme for NCODA’s 2019 Spring Forum in Denver – Supporting the Integrated Patient Care Team with Oral Oncolytic Management – guided the development of its more than 27 clinical, nursing, pharmacy technician, business and special presentations delivered by 46 speakers and panelists.

The agenda was designed to equip attendees with the fundamentals and resources to advance effective practices and patient care.

By every measure, this year’s forum was a success. A record number of more than 400 participants attended the event. The diversity, number and quality of programs received exceptional reviews in our post-event survey.

Each session was designed to reinforce NCODA’s goal of supporting improved patient care while simultaneously providing valuable resources to pursue this goal. As with previous events, many sessions offered continuing education credits.

The forum also featured two keynote speakers:

**Georgia Congressman Earl “Buddy” Carter**, a pharmacist, energized attendees and encouraged advocacy for patients. It was clear that he “gets it” when it comes to the medically integrated dispensary goals of “right drug, right place, right time”.

**Sean Swarner**, cancer survivor and author of “Keep Climbing,” shared his journey and battle with cancer, culminating with his summitting of Mount Everest. Swarner is a truly special individual who captured our hearts and whose book is a true inspiration to the human spirit. He reminded us of why we should never lose our passion for patients.

The forum included resource workshops on such NCODA initiatives as Positive Quality Interventions, Treatment Support Kits, Oral Chemotherapy Education Sheets, Cost Avoidance/Waste Tracker Tools and Financial Assistance.

Twenty-eight excellent posters were
also presented.

As in previous NCODA events, the agenda allowed for numerous opportunities to network and share knowledge with peers from across the nation during breakout workshops, receptions and open networking Friday evening.

NCODA also announced several new and enhanced initiatives, including committees for publications, an adherence tool, quality standards in partnership with ONS and ASCO, credentialing, nursing and a new association, the Oncology Pharmacy Tech Association (OPTA).

In the past year, NCODA has more than doubled its membership from 400 to 1,000-plus as many new practices, partners and collaborators joined the organization and embraced our mission. We look forward to more growth in both numbers and diversity as we work to bring value to our membership and improve patient care.

We are excited for the future as we continue to execute on NCODA’s mission. We hope to see you at the NCODA 2019 Fall Summit, Oct. 24 to 26 in Orlando, Florida. We’re already working on the agenda and welcome your ideas and support.
Forum attendees learning contracting terms, processes and effective practices with oral oncology contracting.

Juliana Hawkins MHA, CPC-A, of Graves Gilbert Clinic, takes notes during a forum general session.

Forum speaker Dr. Merrill Norton, PharmD, DPh, ICCDPD, of the University of Georgia, addressed issues of opioid use disorders and resources related to medical cannabinoids for chronic pain patients.

Seanna Miller, NCGDA Student Chapter member of South University School of Pharmacy, reflects on her experience of attending the forum.
The NCODA Treatment Support Kit initiative is a collaboration of more than a dozen clinical experts.

The goal of the initiative is to develop the industry standard in support kits and kit recommendations for oral chemotherapy medications and to provide patients and caregivers with resources that make sense for adherence and adverse event management during treatment with these medications.

Our priority is to equip healthcare professionals and patients with the educational information and products that will be needed during the course of treatment.

The feedback NCODA received from member practices was that there was a need for a new all-in-one kit to help best address patient needs throughout treatment.

The TSK initiative rapidly progressed in 2018. A diverse committee of community and health-system experts was formed.

Throughout the first half of 2018, the TSK committee created a master online database of kit recommendations for more than 70 oral oncology medications. These recommendations include both products and patient education for each individualized kit.

Once the master database was created, a capecitabine TSK beta test was initiated. The beta test kit was developed in two different versions:

**BOX DELIVERABLE**
- Intro & description of kit
- Patient survey
- OCE sheet
- Treatment calendar/journal
- Loperamide (2mgx24 ct)
- Flexitol cream (12.5% urea)
- Flexitol heel balm (25% urea)

**BAG DELIVERABLE**
- Intro & description of kit
- Patient survey
- OCE sheet
- Treatment calendar/journal
- Loperamide (2mgx24 ct)
- Flexitol cream (12.5% urea)
- Flexitol heel balm (25% urea)
- AM/PM pill container
- Digital thermometer
- Lip balm

Twenty-four total community and health-system practices participated in the capecitabine TSK beta test and 240 kits were distributed.

Each practice received five bags and five boxes to dispense to patients who were receiving treatment with capecitabine.

Patient and practice surveys are still being received, compiled and analyzed. The subjective feedback from providers has been very positive; they are excited to see what is coming next!

We theorize that the Treatment Support Kits will reach more patients across the country, allowing for patients to remedy potential adverse events, tolerate therapy better and adhere to their treatment regimen.

This should ultimately lead to improved outcomes as patients are able to stay on therapy longer (**see above TSK Feedback Loop**).

We are currently working on future beta test TSKs. More information will be coming soon, so stay tuned.

If you and your practice are interested in participating in the next round of beta testing, contact Stephen Ziter at stephen.ziter@ncoda.org.

**NCODA Project Manager Stephen Ziter, right, interviews clinical pharmacist Chris Schumpp, PharmD, of the University of Illinois Cancer Center about his experience with NCODA’s capecitabine Treatment Support Kit Beta Test.**
SHARING BEST PRACTICES THROUGH PQI

HOW NCODA’S POSITIVE QUALITY INTERVENTION INITIATIVE HELPS OPTIMIZE PATIENT CARE AND SAFETY

ON BEHALF OF THE NCODA PQI COMMITTEE

Neal Dave, PharmD
Kirolos Hanna, PharmD, BCPS, BCPP
Julianne Orr, PharmD, BCOP

With the consistent approval of oral oncolytics on the market, access to care, adherence and side-effect management continue to be areas of concern for oncology pharmacists.

In an effort to help streamline and operationalize oral oncolytic management, NCODA created Positive Quality Interventions (PQIs) to provide concise and detailed information on quality standards and best practices to optimize patient care and safety.

A PQI should always meet either one or more of the following objectives: minimize and manage toxicities associated with treatment, provide efficient dispensing guidelines, and help identify and recommend changes in therapy.

Every PQI is developed in the best interest of the patient, with an emphasis on drug information and appropriate therapy management.

PQIs are available on NCODA’s website (www.ncoda.org/pqi/) with the intention of sharing pertinent clinical interventions with oncology practices across the country.
THE PQI PROCESS
Authors of PQIs are selected through various avenues, including peer recommendations and volunteerism.

Authors typically are practicing pharmacists in hematology/oncology. They are encouraged to provide information utilizing primary literature, package inserts and practice experience.

Pharmacy residents also are invited to author PQIs; however, they require a preceptor or faculty member as a co-author. It is important to note that a PQI consists of multiple sections (see sidebar).

The first draft of a PQI is requested within five weeks of the invitation to publish and acceptance of authorship.

However, NCODA understands the demands of clinical practice and is flexible in working with authors on the timeline. Upon receipt of the first draft, the PQI Committee reviews the material and provides feedback.

The author then has three weeks to update the PQI and resubmit to the committee. Upon review and acceptance, the PQI is published online at NCODA.org.

NCODA reserves the right to modify, deny or remove PQIs at any point in time.

PQIs in action
A PQI is a versatile document that can be implemented in numerous ways depending on the needs of a practice.

Some utilize PQIs as an official care plan to help with third-party accreditation requirements.

Others use them as a resource for training new team members or as a reference when a new product is prescribed.

In 2018, NCODA reached out to practices to examine how PQIs are being implemented at different medically integrated dispensing sites.

At Utah Cancer Specialists, Danielle Ercanbrack, CPhT, noted PQIs have become a resource used daily within the medically integrated team.

“All of our pharmacy technicians have the PQIs book marked on our internet browsers for quick access,” Ercanbrack said. “If we receive a prescription with a high alert of a side-effect of diarrhea, dry skin or dry mouth, then we can access the corresponding PQI for that drug and communicate directly with the oncologists to prescribe a recommended medication to ease those side effects. We then include the secondary prescription with the patient’s original prescription.

“If the PQI recommends pairing a cream with a drug, then we make a note for new-start patients to also include the cream with their prescription, at no charge, and we make the patients aware upon picking up their prescription. Our patients appreciate this extra level of service.”

Jeff Audet, RPh, of New England Cancer Specialists, uses PQIs as a resource for drug management.

“PQIs are a great resource for when talking with patients for side effects and dose adjustment recommendations,” Audet said. Fellow pharmacist Steven D’Amato, BSPHARM, agreed.

“Implementing the utilization of the PQIs within our Medically Integrated Dispensing team is an added resource that allows the pharmacists to provide better comprehensive service to our patients at New England Cancer Specialists,” D’Amato said.

The use of PQIs continues to grow at community oncology clinics throughout the country, providing relevant information to both patients and providers. The NCODA PQI initiative will continue to create concise and informative guidelines for oral oncolytics in the coming years.

HOW NCODA’S POSITIVE QUALITY INTERVENTION DOCUMENTS ARE ORGANIZED
PQIs are organized in the following manner:

▲ Title: PQI titles should be clear and provide a broad overview of the proposed interventions. For example, “Management of Abemaciclib Associated Diarrhea.”

▲ Description: Expands on the title and expands on the practice gap being addressed.

▲ Background: Provides a detailed description of the issue being addressed. This may include the mechanism of action of a specific drug or class, an explanation of certain adverse drug reactions, the incidence of the event, exacerbating factors and any other relevant information.

▲ PQI Process: Focuses on the “meat of the matter,” this section highlights specific recommendations for the clinician to optimize patient care. It should expand beyond the package insert and utilize evidence-based practices and up-to-date literature. For example, “Obtain monthly CBC/CMP”; “Ensure baseline EKG has been ordered,” etc.

▲ Patient-Centered Activities: Provides recommendations and education that should be addressed with patients. This ensures patients have educational material (OCE* Sheets), supportive care medications, and are familiar with side effect management and monitoring.

* Complete Blood Count/Complete Metabolic Panel
† Electrocardiogram
‡ Oral Chemotherapy Education

SUMMER 2019

ONCOLYTIKS TODAY | 11
NCODA created Regional Leaders to connect with membership on a local level.

Regional Leaders meet monthly to discuss how to engage our community and ensure that every member has a voice and opportunity to contribute to NCODA’s mission.

NCODA is growing each day, as our Regional Leaders reach out to individuals and practices that want to connect with our members about the Medically Integrated Pharmacy concept.

Through our Regional Leaders, NCODA builds an engaged oncology healthcare community and informs membership of both national and regional NCODA-related topics, issues, initiatives and meetings.

Regional Leaders are also able to help navigate for NCODA members and answer their questions.

Contact your NCODA Regional Leader today at www.ncoda.org/regional-leaders.

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Having cancer or caring for someone with cancer can be overwhelming; add to that the complex treatment regimens and vast number of side effects that come along with treatment, and it's enough to make your head spin.

Yet finding reliable and understandable information about the medicines that a patient may be prescribed while fighting cancer should not be a difficult process.

To help simplify the vast amount of complex information patients receive about their therapy, NCODA is collaborating with the Hematology/Oncology Pharmacy Association (HOPA), the Oncology Nursing Society (ONS) and the Association of Community Cancer Centers (ACCC) to produce drug-specific Oral Chemotherapy Education (OCE) sheets.

The OCE sheets contain accurate, easy-to-understand information. Each drug-specific OCE sheet lists the drug name; FDA-approved uses; dose and schedule; storage and handling; body fluid and waste handling procedures; drug and food interactions; side effects; pregnancy, sexual activity, and contraception recommendations; methods to obtain medication; and additional resource instructions.

The OCE sheets aim to be as informative as possible, while still being a concise resource for patients to utilize. For this to be the case, the OCE sheets discuss side effects reported in 30% or greater of patients and any black box warnings. To ensure the sheets are easy to understand for all patients, the goal is for them to be at an 8th grade reading level or lower.

Each OCE sheet undergoes an extensive initial review to ensure that the document contains accurate and patient-friendly educational information. This process includes all four guiding organizations – NCODA, HOPA, ONS and ACCC. Additionally, OCE sheets are reviewed quarterly by different NCODA committee members to ensure any necessary updates are made.

Once published, the sheets then undergo constant further review to ensure that they contain the most accurate, up-to-date information. To that end, NCODA has organized the OCE Committee. The committee is responsible for ensuring information contained on the sheets is accurate and current.

The committee has three tiers of involvement: steering, foundational and support.

The steering tier is responsible for the initial reviews of new OCE sheets and quarterly audit reviews. Members of this tier also join in on NCODA committee calls and track changes to prescribing information in real time.

The foundational tier is responsible for quarterly audit reviews and additional OCE committee initiatives as needed.

The support tier is responsible for joining in on calls and helping as needed with NCODA OCE committee initiatives.

The committee also constantly creates new initiatives, such as oncology treatment term reference sheets and side-effect management documents.

All OCE sheets can be found online at oralchemoedsheets.com.

The site has grown to become enormously popular and now generates more than 16,000 views per month.

The OCE Committee is always looking for new members with innovative ideas to help deliver accurate yet understandable information to patients. To get involved, contact Britny Rogala at brtny_rogala@uri.edu or Marie Sirek at msirek@billingsclinic.org.

Britny Rogala is a Clinical Assistant Professor in the Department of Pharmacy Practice at University of Rhode Island College of Pharmacy and Clinical Oncology Pharmacist at Women and Infants Hospital in Providence, R.I.; Marie Sirek is a Clinical Pharmacy Specialist in Oral Oncology at Billings Clinic in Billings, Montana; Brady Quinn is a 2019 PharmD candidate at the University of Rhode Island College of Pharmacy, Kingston, R.I.
Patients with cancer and other high-cost diseases face many physical, emotional and financial challenges. Many are at high risk for hospital readmission because they can’t afford the medications they need. Cancer hospitals and community practices are not in a financial position to simply provide these costly medications at no charge. Yet, from the standpoint of population health, we have a responsibility to ensure that patients comply with their medication therapies.

Help is available for uninsured or under-insured patients who can’t afford their medications. Medication Assistance Programs, or MAPs, are designed to help those patients obtain their medications at little to no cost.

It has been shown that patients on MAP support are more likely to adhere to their medications. Removing cost barriers can help with the successful implementation of the disease care plan, as well as support the financial health of the institution.

In 2010, the Department of Pharmacy Services of the Smilow Cancer Hospital at Yale New Haven Health launched a MAP program aimed at helping cancer patients with high out-of-pocket costs obtain their medications and ensure continuation of their cancer treatment.

The program relies on a collaborative and interdisciplinary approach to coordinate enrollment for patients in pharmaceutical manufacturer- and foundation-funded medication assistance programs.

Many drug companies offer medication assistance programs that provide free drugs to patients who lack insurance coverage for treatment.

Co-payment foundations are available to help insured patients who find themselves unable to pay the out-of-pocket copay requirements of their insurances.

While the guidelines and eligibility may vary from one company to another, most programs work in a similar fashion. Information regarding the patient’s medical insurance status, income level and treatment information is needed.

Companies also require documentation from the provider, which confirms medical necessity for their chemotherapy regimen.

The Yale New Haven Health MAP program has grown steadily over the past eight years. In fiscal year 2018, it supported more than 2,700 patients, providing in excess of $12 million in direct patient financial support.

The success of this program has allowed our pharmacy to expand this service to other high-cost diseases such as solid organ transplant, immunology, multiple sclerosis and pediatrics.

Additionally, a new web based software was recently launched to better help identify patients in need of MAP support. Our pharmacy currently has a team of nine MAP coordinators who collaborate across the health system.

The program focuses on drug replacement and co-pay assistance for high-cost therapies. Recently, the program expanded to capture reimbursement for high-cost injectable and infusion chemotherapy medications that are often wasted due to changes in patient status.

We encourage NCODA members to develop MAPs that support the NCODA standards of quality, safety and medically integrated pharmacy services. The MAP should ensure that all patients have access to prescribed medications regardless of their financial status, insurance or ability to pay.

In times of increasing health care costs, decreasing financial barriers can help to achieve the best patient outcomes. MAP directly supports Yale New Haven Health’s vision of “enhancing the lives of those we serve by providing access to integrated, high-value, patient-centered care.”
Management options for relapsed or refractory multiple myeloma in patients previously treated with at least two therapies including lenalidomide (Revlimid) and a proteasome inhibitor

By Wayne Ormsby, MD

Treatment of multiple myeloma continues to advance rapidly. New multiple myeloma-directed therapies, as well as new combinations of previously available treatments, have resulted in steady improvement in outcomes and options for patients and their medical oncologists.

Despite current treatment advances, multiple myeloma remains an incurable hematologic malignancy. Almost all multiple myeloma patients will eventually develop relapsed or refractory disease. This brief review aims to provide updated information for patients, physicians, and other health care providers for the challenging scenario when multiple myeloma has become refractory despite at least two prior regimens including lenalidomide (Revlimid) and a proteasome inhibitor (double refractory disease).

An appropriate clinical trial should always be considered as the first option for multiple myeloma patients with double refractory disease, but not every patient qualifies, has access to, or is interested in clinical trial participation.

Since 2017, two triplet regimens have been FDA-approved for multiple myeloma patients with double refractory disease.

DARATUMUMAB (DARZALEX), POMALIDOMIDE (POMALYST), AND DEXAMETHASONE

In June 2017, the combination of daratumumab, pomalidomide and dexamethasone was approved by the FDA in patients with multiple myeloma who have progressed despite at least two prior therapies including lenalidomide and a proteasome inhibitor based upon the results of the phase I (MMY 1001, EQUULEUS) study.

On average patients in the study had received four prior treatments. The average age was 64 years. Sixty-four percent of patients were refractory to both bortezomib (Velcade) and lenalidomide. Adverse side effects were manageable. The most frequent adverse side effects (occurring in greater than 20% of patients) were infusion reactions, diarrhea, nausea, vomiting, fatigue, pyrexia, upper respiratory tract infections, muscle spasms, cough, and dyspnea. Grade 3/4 adverse side effects were reported in 49% of patients.

Overall response was 59%. Very good partial response (VGPR) was noted in 28% of patients were refractory to both bortezomib (Velcade) and lenalidomide.

Adverse side effects were manageable. The most frequent adverse side effects (occurring in greater than 20% of patients) were infusion reactions, diarrhea, nausea, vomiting, fatigue, pyrexia, upper respiratory tract infections, muscle spasms, cough, and dyspnea. Grade 3/4 adverse side effects were reported in 49% of patients.

Overall response was 59%. Very good partial response (VGPR) was noted in 28% with a complete response (CR) in 6% and a stringent complete response (sCR) in 6% of patients. The median duration of response was 13.6 months. Response in general was rapid with a median time to response of 1 month (range 0.9 to 2.8 months).

ELOTUZUMAB (EMPLICITI), POMALIDOMIDE (POMALYST), AND DEXAMETHASONE

In November 2018, the FDA approved a second triplet for multiple myeloma patients with double refractory disease based upon the results of the ELOQUENT-3 trial. The ELOQUENT-3 trial was a Phase 2 open label trial, which enrolled 117 patients in North America, Australia, Japan and Europe. Patients were randomly assigned to receive treatment with elotuzumab, pomalidomide and dexamethasone, or pomalidomide and dexamethasone.

Toxicity was manageable. Grade 3 or 4 adverse events were reported in 57% of the elotuzumab, pomalidomide, dexamethasone patients and 60% of the patients receiving pomalidomide and dexamethasone. Infections of any grade were common in both groups (65%). Grade 3 or 4 infections occurred in 13% of the elotuzumab arm and 22% of the control arm.

Treatment was discontinued secondary to toxicity in 18% versus 24%. The most common cause for early discontinuation was infection (7% versus 5%). Significant infusion reactions were reported in 5% of the elotuzumab group.

Overall response was reported in 53% of the elotuzumab treated patients versus 26% of the control group. Progression-free survival was markedly improved at 10.3 months versus 4.7 months. Greater than 20% of the elotuzumab arm achieved a greater than VGPR. Median time to response was 2.0 months.

Dr. Wayne Ormsby is board certified in internal medicine, hematology and medical oncology. He currently practices at Utah Cancer Specialists in Bountiful, Utah.

REFERENCES:
NEW DRUG APPROVALS

NEW INDICATIONS FOR TWO ORAL DRUGS APPROVED BY FDA IN 1Q19

**CABOZANTINIB (Cabometyx®)**

On Jan. 14, the U.S. Food & Drug Administration (FDA) approved cabozantinib (Cabometyx®) for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. Cabozantinib inhibits tyrosine kinases, including vascular endothelial growth factor receptors 1, 2, and 3, MET, and AXL, which are implicated in the progression of HCC. HCC death rates have been rising faster than any other cancers in the U.S. and outcomes have remained poor.

The CELESTIAL trial is a randomized (2:1), double-blind, phase 3 trial that evaluated cabozantinib 60 mg orally once daily as compared with placebo in previously treated patients with advanced HCC until disease progression or unacceptable toxicity. The primary efficacy measure was overall survival (OS); additional outcome measures were progression-free survival (PFS) and overall response rate (ORR), as assessed by investigators per RECIST 1.1. Median OS was 10.2 months for patients receiving cabozantinib and 8 months for those receiving placebo (HR 0.76; 95% CI: 0.63, 0.92; p=0.0049). Median PFS was 5.2 months and 1.9 months in the cabozantinib and placebo arms, respectively (HR 0.44; 95% CI: 0.36, 0.52; p<0.001). ORR was 4% (95% CI: 2.3, 6.0) in the cabozantinib arm and 0.4% (95% CI: 0.0, 2.3) in the placebo arm. The most common high-grade events were palmar-plantar erythrodysesthesia (17% with cabozantinib vs. 0% with placebo), hypertension (16% vs. 2%), increased aspartate aminotransferase level (12% vs. 7%), fatigue (10% vs. 4%), and diarrhea (10% vs. 2%).

The recommended cabozantinib dose for HCC is 60 mg orally, once daily at least one hour before or two hours after eating.

**TRIFLURIDINE/TIPIRACIL (Lonsurf®)**

On Feb. 22, the FDA approved trifluridine/tipiracil (Lonsurf®) for adults with metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, platinum agent, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy. Trifluridine/tipiracil is a fixed combination of a nucleoside metabolic inhibitor (trifluridine) and a thymidine phosphorylase inhibitor (tipiracil) that ultimately interferes with DNA synthesis and inhibits cell proliferation.

The TAGS trial is an international, randomized, double-blind, placebo-controlled trial that evaluated trifluridine/tipiracil 35 mg/m² twice daily on days 1-5 and days 8-12 every 28 days plus best supportive care or placebo plus best supportive care in patients with metastatic gastric and GEJ adenocarcinoma. The primary efficacy endpoint was OS; additional outcomes included PFS and ORR (as assessed by RECIST 1.1), tolerability, and safety. Median OS was 5.7 months for the trifluridine/tipiracil group and 3.6 months in the placebo group (HR 0.69 [95% CI 0.56-0.85], one-sided p=0.00029, two-sided p=0.00058). Median PFS was two months in the trifluridine/tipiracil group and 1.8 months in the placebo group. (HR 0.57 [95% CI 0.47–0.70]; two-sided p<0.0001). ORR were noted in 13 (4%...
The National Community Oncology Dispensing Association, Inc., (NCODA) Executive Council is pleased to announce that Mario Lacouture, MD, has joined the Treatment Support Program as Director of the Medical Advisory Board.

“The work that NCODA is doing with the Treatment Support Program is something that I fully support,” Dr. Lacouture said. “What better way to help patients than by providing them with the information and products they need to maintain their quality of life and health throughout their treatment course.”

Dr. Lacouture is a board-certified dermatologist at Memorial Sloan Kettering Cancer Center in New York City, where he serves as Director of the Oncodermatology Program.

Lacouture’s clinical career has focused on the recognition and management of side effects resulting from cancer treatments, affecting the skin, hair and nails of cancer patients and survivors.

“It is a great day for NCODA,” said Michael Reff, NCODA Founder and Executive Director.

In his role as Director of the Medical Advisory Board, Lacouture will be providing expertise and guidance to the program committee. Lacouture’s expert opinion will help the committee determine which products and educational materials to include in each patient support kit. Lacouture started work with the program in March.

NCODA NEWS
NEW DRUG APPROVALS
CONTINUED FROM PREVIOUS PAGE

[95% CI 2–8] of 290 patients in the trifluridine/tipiracil group and three (2% [95% CI<1–6]) of 145 in the placebo group (p=0.28). The most common Grade 3 or worse adverse events were neutropenia (34%), anemia (19%), and leukopenia (9%). Other common adverse events include nausea, decreased appetite, thrombocytopenia, vomiting and diarrhea.

The recommended dose and schedule of trifluridine/tipiracil is 35 mg/m2/dose orally twice daily with food on Days 1 through 5 and Days 8 through 12 of each 28-day cycle.

REFERENCES

Dr. Mario Lacouture

The mission of NCODA's Treatment Support Program is to provide patients and caregivers with resources that make sense for adherence and adverse effect management during treatment with anti-cancer medications.

The priority is to equip healthcare professionals and patients with educational information and products that will be needed during the course of treatment. NCODA’s Treatment Support Kits are a fundamental component of the program.

TSK committee co-chairs Chris Kepinski, PharmD, Southern Oncology Specialists, North Carolina, and Jamie Fritz, PharmD, Compass Oncology, Washington, said Lacouture will be a great asset to the program.

“Having an expert on the team who has seen firsthand how adverse effects of cancer treatments impact patient adherence is extremely important,” Kepinski said.

For more information about NCODA's Treatment Support Program, visit: www.ncoda.org/treatment-support-kits.
Alongside the development of tyrosine kinase inhibitors (TKIs) comes improved understanding of drug transporters.¹

Transporters, which are membrane proteins, can lead to drug interactions and increased toxicity or reduced efficacy of TKIs or concomitant drugs.

Conversely, transporters can be leveraged to improve efficacy of chemotherapy and overcome multi drug resistance (MDR) and could potentially be therapeutic targets themselves.¹

The two major super-families of membrane transporters are the ATP binding cassette (ABC) family and the solute carrier (SLC) family. Efflux, influx, or bidirectional transporters move xenobiotics, such as drugs; and endogenous substances, such as amino acids, across the cell membrane.¹²³

ABC transporters are mainly active transporters which use energy from ATP hydrolysis to transport substances across the membrane.¹

SLCs are either facilitative transporters, which move substrates across the membrane down the gradient, or secondary active transporters, which move substrates across the membrane against the gradient by coupling a downhill transport of another substrate.¹

Drug transporters involved in absorption, distribution, metabolism and excretion include P-gp, BCRP, OATP-1B1/1B3, OAT1/3, OCT1 and OCT2.¹²³

Membrane expression of transporters may become dysregulated in disease which can alter drug efficacy and detoxification.

For example, OATP1A2 protein expression can be 10-times greater in breast cancer. Usually confined to the liver, OATP1B1 may be over-expressed in various solid tumors. Breast cancer cell tumors display increased OATP2B1 expression with tumor grade, making it a possible marker of tumor progression. OATP2B1 over-expression could increase uptake of the substrate oestrone 3-sulfate into estrogen receptor positive breast tumor cells which enhances tumor proliferation and promotes tumorigenesis.²

Transporters in the intestines may bring drugs into the body thereby enhancing absorption or pump toxins out of the body. Hepatic transporters assist in the reabsorption of drugs or actively eliminate drugs for excretion in the urine. Transporters located within the blood brain barrier (BBB) potentially assist in bringing drugs into the brain or in keeping them out.³

OCT1, the major hepatic uptake transporter for xenobiotics, is a major contributor to the liver’s detoxification pathway. Oncology drugs transported by OCT1 include oxaliplatin and imatinib. Methotrexate, sorafenib and paclitaxel are substrates of the OAT transporters.¹²

Enzalutamide and its main active metabolite N-desmethyl enzalutamide inhibit drug transporters P-gp, BCRP and OATPs or induce drug transporters ABCB1, ABCG2 and UGTs. This may lead to altered pharmacokinetics of concomitant medications that are substrates for such transporters.

Enzalutamide demonstrated ability to enhance the efficacy of docetaxel through inhibition of P-gp, a transporter that forces docetaxel out of cancer cells.⁴ P-gp and BCRP may influence the brain penetration of erlotinib by reducing its ability to penetrate the BBB. Imatinib is a substrate for both P-gp and BCRP and gefitinib displayed active removal by BCRP.⁵

TKIs may be used to overcome MDR in cancer cells, thereby restoring chemosensitivity.⁵⁶ Gefitinib and imatinib may reverse BCRP and P-gp-mediated MDR. Data suggest that gefitinib

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A recently published article titled “Pharmacist-led patient education and adverse event management in patients with non-small cell lung cancer receiving afatinib in a community-based, real-world clinical setting” published in the “Journal of Oncology Pharmacy Practice” is co-authored by an NCODA member, Natasha Khrystolubova. The study examined the outcomes of a pharmacist-led patient education and proactive adverse event management program in patients with EGFR mutation-positive non-small cell lung cancer prescribed oral afatinib, in a community-based oncology setting. It was found that approximately 13% of the study sample discontinued the treatment due to afatinib-related adverse events. The article is available at https://journals.sagepub.com/doi/full/10.1177/1078155219833441.

The article “Digital pills may be on the horizon in cancer care” was published as a cover story in the journal “OncologyLive” in February 2019. In the article, Dr. Kirollos Hanna discusses about a major breakthrough technology, digital pills, and its potential importance in cancer care. Digital pills are being tested with oral anticancer medications with the aim to improve medication adherence and hence health outcomes. These pills, when ingested, transmit from inside the stomach to patient's portable devices. The software tracks patient's pills which aids in alerting the patient and providers when the appropriate dosage or medication is missed. The article is available at https://www.onclive.com/publications/oncology-live/2019/vol-20-no-5/digital-pills-may-be-on-the-horizon-in-cancer-care.

The article “Oral Anticancer Therapy: Management of Drug Interactions” was published on Feb. 12 in the “Journal of Oncology Practice” and co-authored by NCODA member Britny Rogala. As oral oncology therapies continue to become an increasingly important component to cancer therapy, drug-drug interactions must be carefully evaluated. The article discusses such interactions including effects on QTc prolongation, bleeding, CYP3A4 induction and inhibition and acid suppressing therapies. The authors provide evidence based management for the aforementioned drug interactions. The article is available at https://ascopubs.org/doi/pdfdirect/10.1200/JOP.18.00483.

Transporters can complicate drug therapy via drug interactions and MDR. However, with greater understanding, they can be used to our clinical advantage such as by targeting nutrient transporters to deny rapidly dividing cells from critical nutrients, ultimately leading to tumor cell death.³

Claudia S. Castro, PharmD, MS, BCOP, BCGP is a Clinical Pharmacist Specialist at Partners HealthCare Specialty Pharmacy in Massachusetts. She is also a member of the NCODA Editorial Board.

REFERENCES:
EVEREST ON ONE LUNG

Two-time cancer survivor proves that you can redefine what is possible by programming your brain

By Sean Swarner

Everest. The name alone invokes majesty, mystery, greatness, near impossible goals, but also misery and death.

Humans are not designed to survive in an altitude where jumbo jets level off and fly. At nearly six miles above sea level, it is one of the most inhospitable places and difficult challenges on the face of the earth.

Climbing into such thin air is a feat of near human impossibility. Climbers who stand on top of the windy, frigid summit of the world are surviving out of sheer will, determination, and mental toughness.

Yet here I was on the side of this behemoth attempting to make history and reach the summit with a swelling brain and half my lung capacity. Yep, I was trying to climb Mt. Everest with one lung.

I had just spent nearly a month and a half on the ice-covered mountain climbing up and down countless times to establish different camps and get my body used to the extreme altitude.

During that acclimatization period, my body had been manufacturing extra red blood cells and hemoglobin to be more efficient in this altitude, but something was incredibly wrong.

My brain was swelling, and I was suffering from high altitude cerebral edema (HACE). I was on the side of the largest mountain on the planet with one lung, and a swelling brain, trying to make history. I was wrapped up in my negative-40-degree sleeping bag in a tent at about 24,000 feet.

Just outside my makeshift shelter, I was tethered to some pickets hammered into the bulletproof ice that were holding me to the side of the mountain.

Below stretched an expansive 45-degree steep glacier that fell for nearly a mile, and I couldn’t even think without getting dizzy and suffering extreme anxiety and vertigo. I knew I was dying….again.

I had the amazing opportunity of speaking at the NCODA Spring Forum on Feb. 28. You may remember a guy who was a two-time terminal cancer survivor who climbed Everest with one lung? That’s me!

I was also given three months to live with the first cancer, and fourteen days with the second. I was in a medically-induced coma for a year, was read my last rites, and then climbed the highest mountain in the world.

SEVEN SUMMITS AND BEYOND

After Everest, I managed to summit the highest mountain on every continent (seven summits), complete the world’s most difficult race (the Ironman Triathlon in Hawaii) and ski to both the South and North Poles, completing the Adventure Grand Slam (seven summits and the two poles).

A lot of people call me crazy, but I’d rather look at it as being a very determined person who knows how to take
calculated risks. I also know how to program my brain to see opportunities, not obstacles.

Limitations are often an illusion and, like fears, are only in your mind. You have the power to determine what you let into your life experiences, how you react, and what you want, however if you don’t program your brain and your life, it will be programmed for you.

Every day I wake up is a blessing, because I know I have the opportunity to reinvent myself and accomplish tremendous things. You have the exact same opportunity when you wake up, when you choose to see not obstacles, but opportunities.

YOUR CLOSEST CONFIDANT

Who do you speak to most throughout the day? Your significant other? Someone at work? Your best friend? Think again … the number one person you have the most conversations with throughout the day is YOU.

How often is that self-talk negative? How often do you doubt yourself and your abilities? How often do you put yourself down? Would you want to be friends with someone who was that negative? Would you want to be around someone who’s constantly berating and degrading you? Then why on earth do you do it to yourself?

Start right now and pay attention to your internal dialogue and STOP the negative self-talk, right now.

Human beings are creatures of habit. We’re all guilty of getting into a routine throughout the day, because we have our normal, daily patterns.

More often than not, however, people have developed these routines unconsciously, and aren’t even aware of what they’re doing, because they just go through the motions. It’s become normal.

POSITIVE OR NEGATIVE: IT’S YOUR CHOICE

Here’s the thing – it’s just as easy to develop positive habits as it is negative ones. You simply make a decision, a choice. You consciously decide you want something different, something better, something more positive and constructive, not negative and destructive. You pay attention to your self-talk, you make conscious choices, and you decide you want to be more positive.

Going back to the self-talk, the internal dialogue, start paying attention to how you react when something happens to you.

In every situation, think about how you react: What’s your initial/core thought? Do you react negatively or positively? Do you see it as an obstacle, or an opportunity?

Begin paying attention to these core thoughts and your internal dialogue and make a conscious decision to be the type of person you want to be, reacting how you want to react.

In the next few issues of “Oncolytics Today,” I’m going to walk you through how to change your perspective and help you program your brain to want more, expect more… and get it.

By understanding your core values, you can consciously focus on your personal motivators and be the best version of yourself.

I want to help you understand and reach your untapped potential. We’re all capable of so much more. Aren’t you worth it?

Sean Swarner is a keynote speaker, adventurer, certified professional coach, author, and world-record holder. He can be reached at sean@cancerclimber.org.
GOING BEYOND THE FIRST FILL

HOW 5 NCODA PRACTICES WERE EMPOWERED TO TAKE THE NEXT STEP IN IMPROVING PATIENT CARE
There’s a moment in the life of nearly every oral oncology patient, a moment that can have a profound effect on their treatment outcome.

That moment occurs immediately after the “first fill” of their chemotherapy prescription by a local pharmacist. At that point, all future fills will follow one of two paths:

• The first requires a patient unfamiliar with their own situation and a phone representative unfamiliar with the patient to monitor and anticipate dosage, placing only minimal emphasis on related issues, such as adherence and financial toxicity.

• The second enables an integrated team of physicians, nurses, pharmacists, technicians and financial specialists intimately connected with the patient to manage prescriptions while reacting to dosage changes and side effects, placing only minimal emphasis on related issues, such as adherence and financial toxicity.

It’s no surprise that the second path leads to better outcomes for all involved, noted Michael Reff, Executive Director and Founder of NCODA.


It’s a win for the practice because they have better managed patients. It’s a win for the payer because they get superior drug utilization and less waste. Lastly, it’s a win for stakeholders like the pharmaceutical industry because they get better clinical results for their innovative products.”

Unfortunately the decision on whether an oral chemotherapy prescription will be filled by a mail-order pharmacy or a local pharmacy usually isn’t up to the patient; it’s up to their insurance carrier.

But most commercial payers – whether by contract, business structure or simply habit – require prescriptions to be managed by a mail-order pharmacy. In some cases, a mail-order pharmacy. In some cases, a mail-order pharmacy.

For more information, visit www.ncoda.org/wp-content/uploads/2018/06/positivequalityinterventions1.pdf

Foundational Elements Quality Standard: Outlines establishment of a mission statement, organizational chart, business plan, readiness tracker, operational elements, dispensing space, communication plan and standard operating procedures. For more information, visit www.ncoda.org/wp-content/uploads/2018/06/3foundationalelements1.pdf

Health Information Technology Quality Standard: Extrapolates data from prescriptions, first fill rates, first month discontinuation rates, reasons for discontinuations, adverse drug reactions, drug waste, cost avoidance and financial support tracking to achieve improved quality of patient care, including maximizing duration of therapy, dose intensity and adherence, while reducing adverse drug reactions and waste. For more information, visit www.ncoda.org/wp-content/uploads/2018/06/4healthinformationtechnology1.pdf

By Bill Wimbiscus
ONCOLYTICS TODAY EDITOR

NCODA QUALITY STANDARDS: A ROADMAP FOR SUCCESS

In collaboration with practices, payers and employer groups, NCODA has created the following patient-centered quality standards as a road map for success for practices establishing a Medically Integrated Pharmacy:

Patient-Center Quality Standard: Established to provide exceptional patient care, this standard focuses on maximizing patient convenience, providing timely access to treatment, monitoring patient adherence, ensuring financial support and delivering individualized patient education. For more information, visit www.ncoda.org/wp-content/uploads/2018/06/patientcenteredqualitystandards.pdf

Positive Quality Interventions (PQIs) Quality Standard: Utilizes the Electronic Medical Record, pharmacy software and other available resources to ensure patient safety, as well as advocate on the patient’s behalf regarding insurance benefit investigation, coverage determination including out-of-pocket expenses, and referral to patient assistance programs and foundations.

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pharmacy affiliated or even owned by the payer – and one that only can be reached by phone.

PHONE FRUSTRATIONS

Now talking, or trying to talk, to a customer service representative over the phone can be a frustrating experience. Anyone who owns a computer, appliance or an insurance policy has dealt with the frustration of navigating phone banks, call queues and hang-ups only to reach someone who either doesn’t understand their concerns or doesn’t have the authority to resolve them.

It was one such experience that convinced Reff that there had to be a better way to deliver desperately needed oral oncology to the practice’s patients.

“Back in 2013, we had a glioblastoma patient on radiation with Temodar. She’s in a wheelchair and it’s 4:30 Friday afternoon. She tries to get a refill, but the insurance company rep says we can’t do it here even though I have the prescription ready; she has to go through their mail-order pharmacy.

“But the mail order can’t get it to her until next Thursday at the earliest, and she’s due for radiation Monday. So her husband finally says, ‘How much is it to fill it here? I’ll pay for it.’ The insurance rep eventually agrees to let us fill it, but only for co-pay of $1,000, basically a penalty for filling out-of-network.

“The poor woman was already battling a terminal diagnosis, and to think that I had the drug and all they had to do was touch a couple of buttons on their end to make it better for her … it was crazy. After about 20 minutes of demanding, I finally talked to the rep’s supervisor. They eventually gave the patient an override, allowing us to fill her script without the penalties and a minimal copay.”

Reff’s experience is not unique. Talk to just about any oncology care provider across the country, and likely they’ll have encountered the same problem while trying to secure vital oral prescriptions for their patients.

GOING BEYOND THE FIRST FILL

That’s why NCODA established “Beyond the First Fill,” a benchmark initiative for positive patient care outcomes at the practice level based on NCODA Quality Standards (see sidebar, Page 23).

Beyond the First Fill encourages member practices to adopt NCODA Quality Standards and collaborate with payers and employer groups to authorize the practice’s own medically integrated pharmacy to dispense oral chemotherapy to their patients. In other words, prescriptions stay within the practice, rather being routed out to a mail-order pharmacy.

“Beyond the First Fill supports better patient care,” Reff said. “There is a
value proposition to keeping it in-house. It’s more convenient for the patient, their speed to therapy is quicker, follow-up is more efficient, adherence is enhanced and the economics are better for all concerned.”

Jonas Congelli, RPh, Director of Pharmacy Services at Hematology Oncology Associates of Central New York (HOACNY) in Syracuse, was an early advocate of what has come to be called the medically integrated team approach, also known as medically integrated pharmacy. He worked with Reff in 2013 to pioneer the concept after becoming exasperated with the existing dispensing system.

“It didn’t take very long to realize that the current system with Pharmacy Benefit Managers and mail-order pharmacies didn’t make sense for oncology,” Congelli said. “There’s so many things that go into the treatment of a patient with cancer; there’s just no way a mail order can react to them.”

The mail-order model’s slow reaction time causes a host of problems, Congelli noted. New prescriptions and dosage changes can’t get filled quickly enough. Patients end up waiting for vital therapy, sometimes receiving out-of-date fills, the wrong dosage or even the wrong medication, resulting in treatment complications, as well as unnecessary waste and expense.

The solution? Establish a more intimate relationship between provider, pharmacist, patient and payer, one that allows oral chemotherapy to be dispensed directly through the practice rather than a mail-order pharmacy.

Reff and Congelli addressed the front end of the relationship issue by establishing a trio of experts – a pharmacist, a pharmacy technician and a nurse – to help coordinate patient care throughout the practice. Keeping all aspects of treatment within the practice, they believed, would deliver better patient care, at a lower cost and with improved patient satisfaction.

The new system proved to be a hit from the start. Providers and patients appreciated the HOACNY’s streamlined, integrated approach to oral oncology therapy.

“Once it was in place, it quickly became very clear how powerful it was,” Anthony Scalzo, MD, President of HOACNY, said. “One sign of success was the benefit to the patient. There was no longer a question of a drug being available on time; if I changed a dose, there was never a lapse in treatment. Plus, our patients were better educated regarding their treatment and its possible side effects.

“From a business perspective, it was also good for the practice. We do make a margin on these medications, but part of it goes into overhead. At the same time we are providing a tremendous amount of care to patients.”
of expertise towards patient care and I think that’s a fair exchange.”

OVERCOMING THE PAYER HURDLE

Yet for all its initial accolades, the fledgling medically integrated team approach still faced one significant hurdle: the payers. That’s because nearly every commercial insurance carrier required oral chemotherapy to be filled by a mail-order pharmacy.

“We were initially a little naïve about the way the system truly operates and the hold that Pharmacy Benefit Managers and mail-orders have on it,” Congelli said. “What we found was that almost all the insurance companies had agreements with mail-order pharmacies, especially for expensive drugs. Within months of opening we realized we needed to do something about the inadequacies of that system.”

Yet when Congelli and Reff began pushing for a medically integrated team option with payers, they met resistance; that’s because nearly every commercial insurance carrier required oral chemotherapy to be filled by a mail-order pharmacy.

“Decreasing waste and avoiding cost is a one-two punch,” Reff explained. “You avoid cost by providing faster, more direct care for the patient. This, in turn provides better patient outcomes, and helps avoid high-cost events, such as emergency room visits and hospitalization.

“You eliminate waste by avoiding unnecessary prescriptions. Should the patient’s condition call for a higher or lower dosage or even a change in medication, a medically integrated pharmacy is able to respond immediately, keeping waste to a minimum or avoiding it altogether.”

SHOW AND TELL

But it wasn’t enough just to tell payers about waste and cost avoidance; Reff and Congelli quickly realized they needed a way to show it.

So in 2014 HOACNY’s new integrated team began actively documenting mail-order pharmacy waste, actually saving bottles of pills returned by patients because they were either an out-of-date or incorrect dosage, or, in some cases, even the wrong prescription.

“Over the years I couldn’t even tell you how much medicine we’ve ended up throwing away,” Congelli said. “It’s kind of sad; the payers have paid for it, but no one is going to use them. Payers think they’re getting a good rate up front, but they don’t see the waste on the back end.”

At the same time, the pair realized it was important to get patient feedback to document the effectiveness of the new system. So Reff created a method to generate direct and immediate response.

“I began handing out satisfaction surveys to our patients when they came to pick up their prescriptions,” Reff said. “They filled them out and handed them back in.”

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In this way, Reff was able to collect several hundred patient satisfaction surveys. The response: overwhelmingly positive.

Armed with both the survey data and a big bag of wasted prescriptions, Congelli and Reff were able to finally convince HOACNY’s largest regional insurance carrier and another smaller payer that medically integrated team approach provided better care at a lower cost and with greater patient satisfaction than the conventional mail order system.

FLORIDA FIRST

Yet years before HOACNY even began working on its new oral oncology concept, another group – Florida Cancer Specialists & Research Institute (FCS) – had already established its own “value based” model.

With 230 doctors at nearly 100 sites (including many clinical trial sites), FCS is the largest privately-held independent oncology practice in the United States. Ray Bailey, RPh, serves as Pharmacy Director.

“Our oral oncology pharmacy, Rx To Go, opened in 2008, so it’s been going for more than 10 years now,” Bailey said. “Back then there were maybe six or seven oral drugs. But then the whole landscape just exploded. We saw it coming, because we were participating in many of the clinical trials.”

Like the medically integrated pharmacy model, the FCS value-based protocol calls for an integrated team of doctors, nurses, pharmacists and technicians to coordinate patient care, as well as a squad of specialists working to help patients access financial assistance. Over the last decade, its superior value for oral chemotherapy patients has been proven time and time again.

Like HOACNY, FCS recognized from the start that the emerging oral therapies had an enormous price tag and a profound effect on the cost on insurance and a patient’s co-pay.

“Every patient has different insurance dynamics that affect whether or not they can afford their medicine,” Bailey explained. “And the industry constantly is trying to shift cost onto the patient.”

He’s quick to blame the Pharmacy Benefit Managers plan design for many of the faults in the conventional payer structure for oncology patients on oral regimens.

“We’ve been pushing back on PBMs for our patients the whole time,” Bailey noted. “They have for years designed and sold pharmacy benefits packages to their customers that benefit their own mail order pharmacies. Patients cannot choose to stay inside the practice and be cared for by our medically integrated pharmacy model in many cases.”

Still, unlike HOACNY, FCS had an easier time negotiating its value-based model into their contracts.

“We’re a large practice, so payers want to work with us to bend the cost curve of oncology care,” Bailey explained. “Our efforts to improve patient compliance and outcomes also offer the benefit of waste avoidance strategies and effectively managing patients in home inventory of expensive oral medications.”

FCS was able to negotiate contracts with Blue Cross Blue Shield Florida, United Healthcare and Cigna. Nearly 60 percent of its commercial patients now can take advantage of the group’s valued-based system.

“We go at risk for shared savings in these models,” Bailey noted. “We must be able to manage the oral regimens as we do the infusion regimens. Often oral and infusion drugs are combined in regimens adding to the complexity of patient management.”

FCS President and Managing Physician Lucio N. Gordan, MD, said Rx To Go has been a great asset for the practice, both from the perspective of patient care...
and the business overall.

“For the patient, it has helped deliver prescriptions on a timely basis,” Dr. Gordan said. “I don’t think there’s another pharmacy that can deliver faster than Rx To Go; it’s way ahead of the PBM approach. Plus our adherence program puts quality on the forefront.

“From a physician’s perspective, it can be challenging to keep up with all the literature, side effects and specific treatment plans of the new and ever-increasing oral therapies. No matter how much you study, there’s no way to absorb all the literature.

“Being able to work directly with our pharmacists is a tremendous help and important resource. For instance, after I prescribed a dose of a new oral this week, I got a call from our pharmacist suggesting that I should consider a different dose due to drug interaction. This is incredibly relevant and improves safety, adherence and outcomes.”

Finally, FCS’ value-based system also has been successful from a business perspective, Gordan noted. “It’s an important part of our business portfolio and has been financially positive,” he said. “But again, it’s truly more tied to improving patient outcomes.”

FCS’s oral chemotherapy standards proved to be a natural fit with those of NCODA; the practice has been an active member of the organization since 2015.

FIGHTING FOR ACCEPTANCE

In January 2015, New York Oncology Hematology (NYOH), a seven-site practice in the Albany area, became the next practice to adopt the medically integrated team model.

“I heard HOACNY was opening up a dispensing pharmacy,” recalled NYOH Area Manager

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of Pharmacy Services Nancy Egerton, PharmD, BCOP. “So when I was looking to set it up here in Albany, I called Jonas and Mike and asked them for a tour. They gave me a good bird’s-eye view of how they did things.”

Egerton said it was apparent from the start that the medically integrated team approach would get meds to patients quicker, improve patient education and reduce waste. But, again, the biggest challenge proved to be convincing the payers.

“We started filling and once we came up with a problem that we couldn’t fix, we contacted the insurance companies and tried to work it out,” Egerton said. “Some worked with us immediately, others waited.”

In the end, she was able to get clearance from six or seven payers – mostly regional HMOs – that covered about 60 percent of NYOH’s commercial patient base.

“The unfortunate part is our biggest commercial payer still has the restriction that we use their specialty pharmacy,” Egerton said. “We have certain scenarios where I still can’t go beyond the first fill.”

NYOH patients that are able to take advantage of the medically integrated dispensary model are ecstatic about the speed and convenience of the new system, especially its financial assistance component.

Jean Morris was diagnosed with metastatic breast cancer in April 2018. After undergoing radiation therapy, she was prescribed Ibrance, an oral drug that costs about $15,000 per month.

“When I heard the cost, I knew I couldn’t afford it,” said Morris. “NYOH making me aware that I qualified for assistance was a matter of life and death, because if I hadn’t qualified, I wouldn’t be taking it. It just blows me away because I didn’t even initiate (the assistance process).”

Prior Authorization Supervisor Gina Boilard provides financial counseling to NYOH patients. In 2018, Boilard and her team brought in more than $750,000 in copay grants.

“I get patients in tears, but I try to tell them they are in good hands,” Boilard said. “As long as their income guidelines are met, I can help them.”

EMBRACING INTEGRATION

Still, not all insurance carriers have to be convinced of the value of the medically integrated pharmacy model; some actually embrace its patient care and cost-savings benefits.

In 2016, for instance, Blue Cross Blue Shield of South Carolina approached South Carolina Oncology Associates (SCOA), the largest practice in the state, about participating in the Oncology Care Model initiative. The initiative, part of the Affordable Care Act, was specifically created to reduce the cost of cancer care.

Jan Montgomery, PharmD, SCOA’s Director of Pharmacy, was part of that process.

“The only way to affect the cost of care that we could see was to reduce hospitalizations and

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reduce the cost of chemotherapy,” Montgomery said. “You can keep people out of the hospital by bringing them into the clinic and treating them there. We knew we could do that, but we couldn't reduce the cost of IV drugs; there was no room to move. The only place we saw that we could really make a difference was on the oral side, which we were totally cut out of.

“We wanted orals included in the contract, so of course this was a point of discussion. But BCBS said they could not open their PBM network to us because of a contractual obligation. It took many back and forth meetings, along with our very eye-opening presentation to educate them about our abilities and to show that waste was a problem.”

Montgomery’s presentation included having payer representatives tour the practice and dispensary, plus giving them a look at her own “big bag of wasted drugs” returned by mail-order patients.

“We’re talking $30,000 worth of waste, and that was on just one patient,” Montgomery said.

The collaboration process ended up taking about a year and a half. In the meantime, SCOA brainstormed new ideas, such as “short scripting” as opposed to the 30- to 90-day fills that were being offered by many of the mail-orders.

“We'll dispense a two-week supply, and then give the patient a chance to come back in, see the doctor and get it filled again,” Montgomery explained. “We’ll do this four or five times until we get it right.”

Finally, after speaking with the carrier’s medical director, SCOA was given permission to dispense oral oncolytics to BCBS SC members.

“We stand tall with all the PBMs,” Montgomery said. “We’re here and we do it better. We give the warm and fuzzy: patient assistance, foundations, etc. We have everything to offer that a big PBM has, plus the electronic medical records, as well as the personal touch because we see the patient face-to-face.”

**SOMETIMES IT JUST TAKES A PHONE CALL**

Still, not all contract negotiations take months to accomplish.

After hearing about NCODA’s successes in late 2015, Neil Nebughr, then-Director of Pharmaceutical Services at Utah Cancer Specialists (UCS) of Salt Lake City, started calling payers.

“Just being able to talk to our payers was phenomenal,” Nebughr, RPh, said, noting that his first call was an easy one.

“Regency Blue Cross Blue Shield told me we were in network and could keep all our scripts in-house,” Nebughr said.

The next two took a little more work. With one payer, UCS had to wait for the contract to open up. In the other, the practice had to agree to take less reimbursement to become a specialty pharmacy in the payer’s contract.

“But I thought it was worth it to be able to manage our patients in-house,” Nebughr said. “It really was a benefit to our patients and it definitely increased our volume. We had to pay more attention to our reimbursement rates, but it really wasn’t a huge change.”

**TIME TO TAKE THAT NEXT STEP?**

As NCODA continues to grow, Reff plans to emphasize the message of Beyond the First Fill to oncology practices that are committed to better patient care.

“Going Beyond the First Fill supports better patient care,” Reff explained. “Practices understand that when the script leaves their hands and goes to a mail order pharmacy, they’re losing control of caring for their patient.

“That’s why the medically integrated pharmacy is so important; as I said before, it’s a win-win-win proposition. But it doesn’t happen by itself. First there has to be a passion to make the change, a commitment. You have to put the energy into making it happen.”

NCODA established its patient-centered Quality Standards to help guide practices seeking to establish medically integrated pharmacies. Those standards – along with tools such as Cost Avoidance & Waste Tracker, Patient Satisfaction Surveys and Oral Chemotherapy Education Sheets – provide the groundwork for practices that are ready to move forward.

Since its inception, NCODA has helped eight practices collaborate with 16 payers and employers to go Beyond The First Fill. In the coming months, the organization will continue to actively work with other NCODA practices ready to take the next step toward improving patient care.
At Pfizer Oncology Together, patient support is at the core of everything we do. We help patients access their prescribed Pfizer Oncology medication, identify financial assistance options, and connect to resources for their day-to-day challenges. And as patients’ needs change, our dedicated Care Champions will continue to point them to relevant tools and information.

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Nursing is an Essential Part of Managing Oral Oncolytics

By Mary Anderson, RN, BSN, OCN & Elizabeth Bettencourt, RN, MSN, OCN

NCODA Nursing Committee

Nurses are on the front line in cancer care.

The traditional role of the nurse in the direct administration of chemotherapy provides an opportunity for the nurse to assess, diagnose, plan, intervene and evaluate (the Nursing Process) patient issues to ensure the patient receives the best quality of care.

The use of oral oncolytics is shifting this direct nursing role to indirect nursing care. It is projected that the use of oral chemotherapy will more than double in the next several years. One estimate puts 25 percent of anticancer agents in the research pipeline of anticancer agents in oral oncolytics. An assessment of the whole patient – including physical, behavioral, social, financial and learning needs – allows nurses to help ensure the best outcome for the patient.

Oncology nurses also continue to follow up with patients during the course of treatment, providing ongoing patient assessment, utilizing evidence-based interventions for side-effect management, and monitoring of adherence to the treatment regimen.

The oncology nurse acts as an advocate for the patient and the care team, becoming the eyes and ears for both. The result is the safe administration of oral chemotherapy and the best clinical outcome for the patient.

Nurses are an essential part of the integrative care team in oral oncolytic management. Nurses are instrumental in facilitating timely access to treatment through collaboration with providers, the dispensing pharmacy and financial advocates.

NCODA is pleased to announce the formation of its Nursing Committee, with more than 30 nurses from varying practice levels committed thus far. When nurses join the committee, a brief survey is completed to assess current work practices and identify challenges by answering questions pertaining to processes, access and acquisition, documentation, monitoring and continued follow up.

Based on recent survey results, the issues most frequently voiced include access and affordability, multiple patient tracking and patient adherence.

Most survey respondents report having some sort of process flow within their practice, but some have more defined policies and procedures than others. Also noted is a large variation in how nurses track patients on an ongoing basis, from EMR reports, calendars, spreadsheets and lists to no tracking tools used at all. Less than 50 percent of respondents have access to a standardized oral chemotherapy flow sheet for ongoing documentation.

Several initiatives are being considered to assist nurses in overcoming these challenges. These include providing resources to develop a standardized oral chemo process, and development of documentation tools and tracking resources.

The NCODA Nursing Committee looks forward to strengthening the partnership between NCODA and oncology nurses across the country. We, the Nursing Committee, would like to have all nurse members of NCODA join the committee to support nursing, provide a networking platform, share best practices and develop useful tools. The ultimate goal is to provide comprehensive and safe care for the patients we serve.

Mary K. Anderson, RN, BSN, OCN, is an oral oncology nurse navigator at Norton Cancer Institute in Kentucky; Elizabeth Bettencourt, RN, MSN, OCN, is an oral oncology nurse navigator at Palo Alto Medical Foundation in California.

REFERENCES:
Mission statement: The mission of SCI is to serve the people of central and southern Illinois by addressing their present and future cancer care needs through medical education, biomedical research, patient care and community service.

Address: 315 W. Carpenter St., Springfield, Ill.

Practice details: We have 26 providers in oncology, surgery, counseling and genetic counseling. Employees, including administrative, front desk staff, and medical personnel number approximately 60.

Qualifications/credentials: Quality Oncology Practice Initiative, National Accreditation Program for Breast Centers.

Services provided: Simmons Cancer Institute provides bone marrow biopsy, chemotherapy, as well as specialized programs including genetic counseling, psychology oncology, laboratory services, patient navigation, financial counseling and a side-by-side wellness program.

Pharmacy services: The SCI Infusion Center offers chemotherapy administration, IVIG, bladder instillations and other intravenous infusions including iron and electrolytes. In October 2018, the center launched a physician dispensary for oral chemotherapy.

Staff: Megan Adami, PharmD, Pharmacy Supervisor; Peggy Martin, Pharmacy Technician

How would you like to be more involved with NCODA? We would like to be involved in patient advocacy issues, positive quality interventions and information regarding the latest updates on standards of care.

What are some of the oncology challenges you now face or will face in the future? ASCO estimates that there will be a shortage of 5,000 oncologists by 2020. Many oncologists stay in larger cities or on the coasts, which is challenging for Central Illinois. We also face the challenge of tighter reimbursement margins for infusion therapies.

For more information about Simmons Cancer Institute, visit: www.ncoda.org/practice-in-focus.

Submitted by Megan Adami, PharmD, Pharmacy Supervisor at Simmons Cancer Institute at SIU Medicine.

BE OUR NEXT PRACTICE IN FOCUS
NCODA is committed to creating a collaborative community environment, providing a platform for practice members to share common experiences and help one another succeed. Practice in Focus connects practices to one another as we all strive to provide better care to patients.

The Practice in Focus application process is simple and takes approximately 20 minutes to complete. Once an application is submitted, NCODA will help develop an online profile for the respective practice.

Practice in Focus participants have the opportunity to talk about their practice each month during the NCODA National Monthly Webinar, an ideal way to highlight the work being done within their facility.

In order to be considered for selection:
• An application is completed and submitted by an NCODA member
• Applications are considered when one person from each facet of the practice/organization’s medically integrated team (i.e. doctor, nurse, pharmacist, pharmacy technician, financial counselor, etc.) is an NCODA member
• One or more members of your medically integrated team will present during the National Monthly Webinar as the featured practice

For an application, visit www.ncoda.org/practice-in-focus
WHAT A WASTE: LATEST MAIL-ORDER DELIVERY SHADES OF MIX-UPS PAST

Had a knock on my door the other day. It was a special delivery guy, holding a large cardboard box.

“For me?” I asked.

“For you,” he said. “Please sign.”

I was excited to open the box, even though I already knew what was inside. Two weeks earlier I had been hospitalized with a massive staph infection. The doctors blamed it on my five-year-old infusion port, which they promptly removed.

And now, after a nine-day stint in the hospital, I was back at home with a PICC line in my arm, pushing a syringe containing two grams of Cefazolin in 20 ml of sterile water every eight hours.

Like I said, I knew what was supposed to be in the box: six refrigerated syringes of Cefazolin, two 60-syringe boxes of saline, a new sterile dressing and other assorted paraphernalia.

Now, it was no skin off my teeth – I’d already paid $70 to the mail order – I’d already paid $70 to the mail order pharmacy dictated by my insurance plan.

So when a second bill for $304 for “Supplies” arrived in my mailbox a couple weeks later, I was a bit upset.

“Medicare doesn’t cover home health supplies, nor does your supplemental insurance,” explained the friendly phone rep in an accent from the other side of the planet.

“What about the supplies I didn’t need?” I asked, already knowing the answer.

Further discussion proved pointless, so I hung up on the friendly rep from the other side of the planet.

I ended up giving the saline and PICC supplies to my son-in-law, who is a traveling hospice nurse.

But the 15 unused and now unusable syringes of Cefazolin still sit in my refrigerator. I just can’t bear to throw them out.

What a waste.

Shades of October 2014, when I was on my second course of Velcade transfusions for multiple myeloma.

My first course, started in January, began well. Ten weeks in, and my numbers had dropped. But progress plateaued the second 10 weeks, and by the third my numbers were rising again.

In September, my oncologist decided an additional 15-week Velcade session was in order. This time, though, he added a second drug – Revlimid.

“It’s kind of expensive,” he noted. “Around $600.”

“Six hundred a bottle?” I asked.

“No, $600 a pill,” he said. “But at this point, your insurance should cover it.”

He was right. Chemo treatment had maxed out my commercial plan’s out-of-pocket months earlier. And since Illinois is an oral oncology parity law state, there’d be no co-pay.

I was prescribed the maximum 25 mg dosage for 14 days, followed by seven days rest, until the end of the year. The Revlimid proved wildly effective; from the start my numbers began dropping steadily.

Unfortunately so did my stamina. A few hours after taking the pill each evening, I’d get terrible chills.

My wife would help me upstairs into bed, where she’d cover me with blankets. I’d fall asleep shivering, only to wake up hours later drenched in sweat. By morning I’d feel reasonably well again, ready to tackle another day of treatment.

After finally talking to my doctor (I guess I figured chills and sweats were just part of the deal), he immediately cut my dosage back to 15 mg, and had the order called in to the mail-order pharmacy dictated by my insurance plan.

Unfortunately, by the time the 15 mg prescription was called in, the following week’s 25 mg prescription already had been processed.

A couple days later, the delivery guy dropped off the old prescription. The next day, he returned to drop off the new one.

That bottle of 25 mg pills, which back then cost somewhere north of $8,400 (now closer to $15,000), still sits up in my room. I just can’t bear to throw it out.

What a waste.

That waste, along with the terror of financial toxicity, are two of the big reasons I jumped at the opportunity to work with NCODA.

I’m not a doctor.

Or a nurse.

Or a technician.

I’m a patient. And from my perspective, NCODA members are on an important quest to improve patient care, alleviate patient stress, eliminate waste and avoid unnecessary cost concerning oral oncolytics.

And as a patient, I’m excited to have the opportunity to work with you on this mission.

Bill Wimbiscus

My personal experiences with oral oncology waste and the terror of financial toxicity were two of the big reasons I jumped at the chance to work with NCODA.

Bill Wimbiscus is a journalist and cancer survivor who lives near Chicago.
OLANZAPINE: OFF-LABEL, AND IN THE GUIDELINES

By Rebecca Corvese

INTRODUCTION

For years, olanzapine has been used to help treat Chemotherapy-Induced Nausea and Vomiting (CINV) without an FDA-approved indication. However, olanzapine is recommended in numerous international guidelines and several clinical studies have shown its efficacy in treating CINV. Prevention of nausea and vomiting is one of the many uses of olanzapine, initially approved for schizophrenia and advertised as Zyprexa by Eli Lilly in 1996.1 Olanzapine has become part of a backwards system a number of drugs have fallen into, which is to be recommended in guidelines without an FDA-approved use for such treatment.

STUDIES

In a systematic review of the efficacy and safety of olanzapine in CINV prophylaxis, seven studies were reviewed. Endpoints included complete response, no vomiting and no use of breakthrough antiemetic medications, and complete control, no emetic episodes, no use of rescue medication, and no more than mild nausea. In these studies, olanzapine was given at doses of either 2.5 mg, 5 mg, or 10 mg orally (alone or in combination therapy) and was used to treat High or Moderate Emetic Risk chemotherapy in a variety of tumor types. The outcomes for High Emetic Risk chemotherapy for overall complete response and overall complete control were 87.9% (n = 58) and 82.5% (n = 40), respectfully. The outcomes for Moderate Emetic Risk chemotherapy for overall complete response was 76.2% (n = 84).2 Although this systematic review has its limitations, it is one of many studies that are identifying olanzapine as an effective and safe antiemetic.

GUIDELINES

Olanzapine can be found in both the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) Antiemesis Guidelines for Acute and Delayed Emesis Prevention for High and Moderate Emetic Risk Intravenous Chemotherapy. Both guidelines recommend the addition of olanzapine to a serotonin 3 receptor antagonist, dexamethasone, with or without a neurokinin 1 receptor antagonist as second line therapy. Olanzapine is also dually recommended for use in Breakthrough Treatment for CINV. Typically, when initiating breakthrough therapy, it is recommended to add a medication from a class not currently being taken, including the sole atypical antipsychotic endorsed, olanzapine. On a related note, the ASCO guidelines generally recommend the addition of olanzapine to a patient’s regimen if they have not yet tried it.3 The NCCN guidelines generally recommend olanzapine in patients that are not able to tolerate treatment with dexamethasone.4 The ASCO and NCCN guidelines on antiemesis also use overlapping studies for evidence of the mechanism of action of olanzapine.

ASSUMED MOA

Chemotherapy causes acute and delayed nausea and vomiting through the damaging of the enterochromaffin cells in the gastrointestinal tract. The damage results in the release of serotonin, substance P and dopamine neurotransmitters activating the vagal afferents by binding to the receptors 5-HT3 and NK-1, which then conduct the stimuli to the dorsal vagal complex, releasing the emetic response. Other neurotransmitter pathways are believed to be a part of the nausea and vomiting pathway. Olanzapine works against CINV via inhibition of serotonergic, dopaminergic, alpha-1 adrenergic, histaminic, and muscarinic receptors, inhibiting stimulation of the dorsal vagal complex and other possible pathways.5

MANAGEMENT FOR PATIENTS TAKING OLANZAPINE FOR CINV

Patients taking olanzapine for CINV should be instructed to take 10 mg on days 1 to 3 or 4 of chemotherapy without regard to meals. If patients are taking the orally-disintegrating tablet, proper education should be provided. Common adverse effects patients can experience include hypotension, drowsiness, weight gain and liver problems. Patients should take olanzapine at bedtime if olanzapine causes drowsiness. Serious adverse events include edema, hyperglycemia, stroke, lung and pancreas problems, and seizures. Patients should contact their prescribing physician if any serious events occur.6,7

WHAT YOU SHOULD KNOW

Patients may be hesitant to try an atypical antipsychotic as part of their CINV treatment due to the stigma against mental health medications. Healthcare providers need to be ready to support their recommendation given the abundant evidence for olanzapine in CINV and the placement for it in national and international guidelines. It should also be noted that there is some evidence that olanzapine causes depression, a common comorbidity in patients receiving chemotherapy. An 8-week, open label, flexible dose trial performed at Vanderbilt University Medical center showed a significant decrease in overall score of the Montgomery-Asberg Depression Rating Scale from baseline to end-point in patients with bipolar disorder.8 Overall, consideration of the patient’s wants and needs for their treatment should always be respected, as should over 10 years of evidence supporting olanzapine use in treating CINV.

REFERENCES

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SPECIALTY PHARMACY CREDENTIALING: BEING PREPARED BEFORE BEING REQUIRED

By Trey McNiel, PharmD
NCODA CREDENTIALING COMMITTEE

Since 2016, the number of pharmacies and Medically Integrated Pharmacies that have become credentialed with payers and Pharmacy Benefit Managers (PBMs) has skyrocketed.

This trend has emerged because many payers and PBMs now require that pharmacies dispensing oral oncolytics be credentialed in order to participate in their Specialty Pharmacy networks. Payers and PBMs initially limited access to these networks by requiring pharmacies to agree to lower rates of reimbursement.

Since then, the PBMs have demanded increasingly stringent requirements, including accreditation. Express Scripts was the first PBM on a national level to require at least one accreditation from a third-party accrediting body.

Other PBMs such as OptumRx, have initiated requirements for accreditations from multiple sources in order to stay in-network.

This trend is likely here to stay, and if your pharmacy has not yet been impacted by these requirements, it's only a question of time before you will need to go through the credentialing process. With that in mind, what can you do to prepare yourself for specialty credentialing prior to being required to do so?

ACCREDITATION

Utilizing your professional networks, proactively investigate pharmacy accreditation by identifying the most important payers/PBMs in your area and see which accreditation is required to participate in their specialty networks, if any.

Accreditation through Utilization Review Accreditation Commission (URAC), Accreditation Commission for Health Care (ACHC), The Joint Commission (TJC), Center for Pharmacy Practice Accreditation (CPPA) or any other accrediting body may seem like a daunting task, but ultimately the process is a good thing for both your pharmacy and your patients.

Most pharmacies already do a great job taking care of their patients. Going through the standards and requirements of the accrediting bodies forces the pharmacy to do a gap analysis and see how they could improve processes to comply if they were to proceed with accreditation.

The standards that these accrediting bodies utilize can be purchased for review, without actually going through the full accreditation process.

ACCESSING AVAILABLE RESOURCES

If there is one thing that unites community oncology almost as much as our passion for patients, it is the willingness of practices across the country to help each other when needed.

The NCODA Credentialing Committee plans to make tools available to you that may help when you are faced with the task of credentialing with a payer/PBM.

Utilize your Group Purchasing Organization to help and assist in the process. More than likely they have assisted other practices with credentialing, and have every desire to see your pharmacy succeed.

Many of your fellow NCODA practices have already been through the credentialing process, and are great resources. Utilize this network as much as possible, and they will guide you down the right path.

You and your practice are not alone in this, and with a little research you can find areas where your pharmacy may be lacking and correct them to be ready if a credentialing requirement comes your way.

There is no downside to proactively committing your pharmacy toward meeting the standards. In doing so, you will make your pharmacy more efficient and, in turn, take better care of your patients.

At the same time, the process also gets you prepared for potential credentialing in the future.

Trey McNiel is the Retail Pharmacy Supervisor at Georgia Cancer Specialists affiliated with Northside Hospital Cancer Institute in Atlanta, Ga. He can be reached via email at thomas.mcniel@gacancer.com.
By Josh Nubla, PharmD

CODA regularly seeks out fellow organizations that have similar patient care values. In this issue of Oncolytics Today, we welcome AnneMarie De Frein, Deputy Chief Pharmacist of the National Cancer Control Programme (NCCP).

The NCCP is an organization within the Health Service Executive (HSE) in Ireland. Its primary aims are to prevent cancer, treat cancer, and increase survival and quality of life for those who develop cancer by converting the knowledge gained through research, surveillance and outcome evaluation into strategies and actions.

De Frein’s work is primarily concerned with the treatment of patients using systemic therapy.

What are the main differences between oncology healthcare in the U.S. and Ireland?

AD: In Ireland, all residents are entitled to receive health care through the public healthcare system, which is managed by the HSE and funded by general taxation. Although a two-tier system exists with both public and private healthcare, the majority of patients are treated in the public healthcare system. For a patient to avail of a drug through the public health care system, it must have been approved for reimbursement by the HSE. Drugs are licensed by the European Medicines Agency and the company then makes an application to each country for reimbursement of that drug. There is a standard HSE reimbursement process in place; it is intended to arrive at decisions on the funding of drugs that are clinically appropriate, fair, consistent and sustainable. Once a drug is approved for reimbursement, any patient fitting the reimbursement criteria is entitled to be prescribed that drug.

Can you share some of the NCCP’s successes with us?

AD: In 2014, the NCCP carried out a baseline review of hospitals involved in the administration of systemic cancer therapy to assess the policies and practices in place from a patient safety and quality perspective. This Oncology Medication Safety Review Report set out proposed recommendations for future action to inform the development of national policies relating to safety and quality of systemic cancer therapy services. In the area of systemic therapy, the NCCP has done a lot of work in the development of national treatment regimens. These are approved through a robust methodology involving clinicians, pharmacists and other healthcare professionals as appropriate. This has standardized the regimens in use within hospitals and removed the need for each hospital to develop and approve treatment regimens locally. These will form the basis of the regimen library underpinning the NCCP National Cancer Information System project.

What projects are the NCCP currently working on?

AD: With the publication of the National Cancer Strategy 2017-2026, the NCCP has clearly identified a number of areas to focus its attention on for the coming years. One large project is the National Cancer Information System (NCIS), which is an eHealth program under the leadership of the NCCP. The goal of the NCIS program is to provide a patient-centric information system solution for Systemic Anti-Cancer Therapy (SACT) in Medical Oncology and Haemato-Oncology care services. Other projects involve establishment of a cancer prevention program, expansion of clinical practice guidelines and a workforce-planning framework for hospital pharmacists involved in cancer services.

One of NCCD’s main goals is to improve upon the sustainability of patient care at the point-of-care, especially within the field of oral oncolytics. Where does NCCP align with NCODA in this regard?

AD: The NCCP published an Oral Anti-Cancer Medicine Model of Care Recommendations Report earlier this year as the use of OAM had been identified as a critical area for patient safety in the 2014 review. The OAM report identified a number of means to improve services and these will be areas of focus for NCCP in coming years. The national treatment regimens also include OAM and are intended for use by all healthcare providers in primary and acute care settings. The NCCP continues to reorganize cancer services to achieve better outcomes for patients.

What other oncology issues do you see on the horizon?

AD: Outside of systemic therapy innovations, it must be acknowledged that the future will contain growing numbers of patients living with and beyond cancer diagnoses and treatment. Many patients may remain on longer term treatment and these will need to be supported in a manner that suits them. There will continue to be new and innovative treatments and the challenge will be in how to manage these with limited resources. In particular, growth in OAM is expected so there will be an increasing need for education programs for healthcare professionals in primary care to support patients.

Additional information about the NCCP, including reports and national treatment regimens, can be found at www.hse.ie/cancer. Email queries to oncologydrugs@cancercontrol.ie.

Josh Nubla is manager of Stakeholder Engagement and Operations at NCODA.
WALKING IN THE SHOES OF A PATIENT

HOW MY JOURNEY WITH APLASTIC ANEMIA ENABLED ME TO BECOME A BETTER ONCOLOGY CLINICIAN

By Kirollos Hanna, PharmD, BCPS, BCOP
NCODA PQI COMMITTEE EDITOR

Patients are the center of day-to-day oncology practice. As clinicians, we strive to provide the best care and continuously work to educate one another, collaborate on best practices, optimize safety and much more for our patients.

Over the past decade, the growth of oral oncolytics has allowed patients the convenience of receiving cancer care at home; however, several gaps in care have been identified with payers, dispensing pharmacies, and the lack of medically integrated dispensing systems. Having once been a patient, I have gained better insight in the needs of the patient that arise from such issues.

Cancer has emotional, physical and mental impacts on patients and their families. As a result, patients seek more than just care from their clinicians; they seek empathy, and this need is well-recognized in the medical community. Upon diagnosis, patients often are overburdened with information and questions as they seek out the best medical care.

My journey began in 2013, during my third-year term as a pharmacy student. I suddenly began to experience significant bruising and petechiae on my arms and legs. The symptoms continued over the course of two months. Not sure what to make of it, I decided to complete my final exams and see my primary care provider for a follow-up.

During my visit, my doctor suggested that I might be anemic and ordered lab work. Three hours following my appointment, I received a call to return to the emergency room. Lab tests had determined I was exhibiting severe pancytopenia. Upon arrival, I underwent a CT scan to rule out any cranial hemorrhage, followed by more lab work. After hours of anticipation, I was told there were no signs of leukemia but that there must be something “wrong” with my bone marrow. I was asked to spend the night in the hospital and have...
a bone marrow biopsy the next morning.

My diagnosis was severe aplastic anemia. My doctor informed me that I had six months to live if the condition was left untreated. My options were to undergo immunosuppressant therapy or a bone marrow transplant, pending donor availability.

Over the next 100 days, I underwent intensive chemotherapy with cyclophosphamide and lymphocyte immune globulin, a bone marrow transplant donated by my younger sister, and immunosuppressive therapy with cyclosporine.

Fast forward five years later. I am considered cured.

Having walked in the patient’s shoes, my passion for oncology pharmacy and my patients stems far beyond that of a clinician alone. Over the years, I have had the privilege to serve and build numerous relationships with patients, families and caregivers. Through this process I have gained a better understanding of their personal needs and concerns, which in turn has enabled me as a clinician.

Despite the convenience of oral chemotherapy at home, several gaps in care have been identified with payers, dispensing pharmacies and the lack of medically-integrated pharmacy systems.

Through NCODA, I have been equipped with numerous tools to address these gaps.

With NCODA’s value proposition, community oncology practices convey why it is vitally important for the patient’s treatment to remain with their oncologist beyond the first fill.

On a personal level, it was very important for me to have all my care under one umbrella to prevent the stress and time of dealing with various departments.

To date, although I live in a different state from my doctors, I travel to see them annually because of the positive impacts they had on my care.

Overall, NCODA’s mission of advancing the value of dispensing practices to optimize patient care has become a valuable resource in my day-to-day practice.

As an active member of the Positive Quality Interventions, Oral Chemotherapy Education, Publication and Treatment Support Kits committees, I have the privilege to work alongside clinicians from across the country and professional organizations including the Hematology/Oncology Pharmacy Association and the Oncology Nursing Society.

I am honored to be a member of NCODA.

**SEVEN REASONS TO JOIN NCODA**

1. Access to experts who have collaborated with payers to go *beyond the first fill*
2. Opportunities to learn from other practices who have successfully implemented a medically integrated pharmacy model
3. Updates on emerging trends in continuity of care, enhancing quality systems, and more
4. National support network of professionals who can provide experience, advice and collaboration
5. NCODA Tools – PQI, Treatment Support Kits, Cost Avoidance and Waste Tracker
6. Oral Chemotherapy Education, developed in collaboration with nationally recognized organizations HOPA, ACCC and ONS
7. Two annual learning and networking events – Spring Forum and Fall Summit
ADVOCACY MOST EFFECTIVE WHEN ALL STAKEHOLDERS ARE INVOLVED

By Kathy Oubre, MS
NCODA ADVOCACY COMMITTEE

Those of us who were born before the Y Generation grew up with a different philosophy regarding the role of patients and healthcare providers in cancer care.

There was an unspoken relationship in which patients presented with symptoms, the doctor made a diagnosis and recommended treatment, then the patient underwent treatment.

But medicine is changing. The phrase “participatory medicine” refers to the relationship in which patients and their loved ones actively work with their oncologists during every step of their cancer journey.

Advocacy is part of this relationship. If you’ve been online or read anything recently about cancer, you’ve probably heard the term “oncology advocate.” As patients continue to face rising drug costs, increased financial toxicity and increased cost-sharing from insurers, it is more important now than ever to become an advocate.

At Pontchartrain Cancer Center, we believe everyone should be part of this process.

Remember: you are not an island. Not only is it important for you to become an advocate, but advocacy is most effective when all stakeholders – patients, caregivers and staff – are involved.

We started by educating our staff, since they are the people behind our mission statement. It was important they understood constantly-changing market forces and how they affected a patient’s ability to receive potentially life-saving care in a timely manner, as well as their role in the process.

We quickly found staff wanted to know and do more, so we empowered them with the tools to do so. They now actively email their legislators when we come upon a proposal or bill that may adversely or positively affect the cancer patients we serve.

We have a group who works tirelessly to find much-needed grants/financial assistance. Ask any financial counselor, and they’ll recount a heartwarming experience of a patient crying on the phone when told money was secured for their treatment.

We also advocate through Pharmacy Benefit Managers (PBMs) by tracking the timeline from prescription submission to time of fill and any subsequent delays.

Interestingly, this information had more importance than we realized. In spring 2018, we submitted our PBM data to a healthcare reporter at The Times-Picayune in New Orleans. The reporter interviewed two of our patients and wrote an article that received an overwhelming response.

Consequently, I sent the article and our data to Sen. Bill Cassidy (R-La.). The senator distributed the story to some of his congressional colleagues and later met with both patients’ families.

Our advocacy group – Patients Conquering with Confidence – was founded in 2016. My advice is to start small and be ready to reframe expectations. We had only 10 people attend our first meeting (out of 40 invites and 30 RSVPs), but those 10 remain our most passionate and consistent advocates.

The group, which meets quarterly, has since grown to about 30. Some of the topics we discuss include Open Enrollment, PBMs and Meeting with Legislators 101.

One of our most interesting meetings occurred this past August. We invited one of Sen. Cassidy’s local staffers to discuss legislative issues with the group.

The meeting was supposed to last one hour. After 10 minutes, it quickly segued into issues (healthcare and not) that kept the advocates up at night. Three hours later, as I tried to turn off the lights and encourage people to leave, the staffer was handing out business cards and making appointments to meet with the advocates/constituents.

The next day I received a call from an advocate who felt it was our best meeting ever. Not because we solved any big issues or even made it through the presentation, but because for three hours, their concerns were heard.

As patients continue to face rising drug costs, increased financial toxicity and increased cost-sharing from insurers, it is now more important than ever to become an advocate.

Kathy Oubre is Chief Operations Officer at Pontchartrain Cancer Center in Covington, Louisiana.
By Katherine Clift, CPhT, AS
NCODA OPTA COMMITTEE

Theodore Geisel, better known as Dr. Seuss, played an integral part of my youth. His vibrant characters like Thing One and Thing Two, and even Thidwick the Big-Hearted Moose. There was Horton the Elephant, and the Cat in the Hat, his books are filled with creatures like that. His most prevalent theme was imagination, but taught us so many things, like self-actualization.

As an adult, his lessons I can’t forget and I apply his teaching as a Pharmacy Tech.

Please give me a second, a minute or two, and I shall explain this to you. It might start off a little bit nerdy, but I promise to try not to make it so wordy. I’ll try not to rhyme through this whole process, but I have been reading Dr. Seuss, and I feel a bit nervous.

Hum, where to start let me check, how about with what is a Pharmacy Tech?

Under the direct supervision of a licensed pharmacist or physician, a pharmacy technician is a health care provider who provides support and assistance to pharmacy and medical staff. They allow a streamlined work flow supporting the work of the pharmacist and physicians, while maintaining high-quality patient care.

Historically, the role of the pharmacy technician was to assist with some of the basic functions of pharmacy, such as data entry, prescription preparation, inventory control and patient assistance at check out.

However, in recent years pharmacies have started transforming their practices to provide more enhanced service and focus on a value-based patient care, making the pharmacy technician a more integral part of both the inpatient and outpatient oncology practice settings.

As valuable members of a medically integrated pharmacy team, technicians can be found performing roles in –

▲ Medication compounding: dispensing, distribution and drug preparation of sterile and non-sterile hazardous medications, documentation, pump management, inventory management.

▲ Patient care: patient interviews, medication histories, investigational drug management, risk evaluation and mitigation strategy (REMS) programs, monitoring and documenting adherence to treatment, medication patient outreach.

▲ Revenue cycle optimization: therapy authorization, patient assistance, waste management, revenue cycle management (RCM) and billing management.

▲ Supply chain management: purchasing, managing storage and drug inventory, drug shortage management.

▲ Technology and informatics: technology systems and equipment management, telepharmacy services.

▲ Quality improvement services: project management, compliance auditors, medication management.

Wow, look and see all the wonderful things we can do to provide patient care and support for you. Our day to day can be full of business, with the running around often causing dizziness.

On days when the coffee, and magic wands are all used up, you’re tired, grumpy and want to give up. Stop for a moment, take a deep breath, and insert a little Dr. Seuss into your practice:

• “I meant what I said and I said what I meant. An elephant’s faithful one-hundred percent!” – Dr. Seuss, “Horton Hatches the Egg”

• “Think left and think right and think low and think high. Oh the thinks you can think up if only you try!” – Dr. Seuss

• “The more that you read, the more things you will know. The more that you learn the more places you’ll go.” – Dr. Seuss, “I Can Read With My Eyes Shut!”

I know these are corny, so I just gave a few, but stop take a minute and think, how these lessons can apply to you.

Are we not like the Lorax who speaks for the trees, do we not speak up for our patient needs?

He spoke against the greedy Once-lers, who remind me of PBM administrators.

We hear the voices of our patient, no voice too big, too small, or too impatient.

We do the things we say we are going to do, because after all that’s important to you.

▲ Katherine Clift, CPhT, AS, is a member of NCODA’s Oncology Pharmacy Technician Association (OPTA) leadership team.

REFERENCES:
Oncology care has gone through many changes since the beginning of cancer research, but never so much as now; new drugs, care protocols and therapeutic regimens are emerging at an astonishing pace.

Yet while cancer research is a worthy endeavor and one that NCODA fully supports, NCODA has made the conscious effort to focus on cancer care, care that is best provided through a medically integrated team.

NCODA believes that team should consist of all those who interact with the patient, including but not limited to, physicians, pharmacists, nurses, technicians, patient advocates and financial navigators.

When team members are fully integrated and communicating, intervening and engaging with one other, they can exponentially improve a patient’s health and well-being.

NCODA strives to provide our members with all the necessary tools to facilitate the creation of medically integrated teams, teams that will provide the highest quality of care to their patients and, in turn, create NCODA centers of excellence.

NCODA’s ultimate goal is to build a patient-centered, medically integrated community whose focus is to innovate the continuity of cancer care, so every patient receives the maximum benefit from their cancer treatment.

As our association acronym may imply, community oncology was once our sole focus.

Yet as we continue to grow support throughout the oncology community, we also have developed a growing base of members from hospitals, health systems, academic centers and urology practices that greatly uphold our values and share the same obstacles as all oncology care centers.

Through Oncolytics Today, we will spotlight practices and members providing exceptional patient care through NCODA Quality Standards.

We hope you enjoy this first edition of Oncolytics Today and will share our goal of improving oncology care practices for the progress of better patient care.
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