

ONCOLYTICS Today

EMPOWERING THE MEDICALLY INTEGRATED ONCOLOGY PHARMACY PRACTICE | SPRING 2020

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NCODA Cost Avoidance and Waste Tracker

The NCODA Cost Avoidance and Waste Tracker is an online tool created to help practices document the great work they are doing saving money for patients and showcasing the waste produced by outside vendors.

How it works:

Cost Avoidance: Whenever you perform an intervention for a patient that helps prevent an unnecessary Rx from being given to a patient, *record the savings.*

Waste: Whenever a patient brings in medication that was not used at all, *record the information.*

How to use the data:

Share the information with your administration, payers, employers, etc., to showcase the benefits of your practice over alternative services.

HELP US CREATE CHANGE AND ACCOUNTABILITY FOR HEALTHCARE SPENDING NATIONWIDE!

Cost Avoidance & Waste Reported To Date by NCODA Members

Cost Avoidance

\$4,343,560

Waste

\$5,373,312

To learn more about the tracker tool, please visit www.ncoda.org/CAWT

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NCODA's 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.



2020: NEW YEAR, NEW DECADE, NEW CHALLENGES FOR NCODA

It's 2020 – the start of a new year and a new decade. NCODA staff and members remain highly engaged and are working on multiple projects designed to improve the ability of oncology practices to provide more effective, cost-efficient oral chemotherapy care.

The highlight of his past year has to be the decision by the American Society of Clinical Oncology (ASCO) to incorporate the NCODA Quality Standards into their Quality Oncology Practice Initiative accreditation process.

This acknowledgement by ASCO of the value of NCODA's influence on oral chemotherapy treatment is symbolic of all the hard work and professionalism put in by the organization's upper management and all its members.

Congratulations are in order to – well, all of us!

The 2019 Spring Forum and Fall Summit were well-attended by members and corporate sponsors, focusing on important clinical developments in oncology, as well as presentations on operational issues designed to aid all practices in the provision of these very specialized oral chemotherapy agents.

Coming up soon will be the 2020 Spring Forum on March 18-20. This year's Forum will be held in Dallas, Texas, at the downtown Fairmont Hotel, featuring our host practice, Texas Oncology.

I hope everyone will make an effort

to be part of this exciting event, which will feature several nationally-known speakers, as well as breakout sessions focused on important practice operational issues. Plus, a record number of CE hours are scheduled to be offered.

Last summer, NCODA hosted the first annual Oncology Institute in Chicago.

Based on recommendations from our corporate sponsors, NCODA put on a very dynamic educational event with an excellent exchange of information and ideas between pharmaceutical industry and oncology practitioners.

Our sponsors insist that we continue this annual event, so the second Oncology Institute will be held this summer in Detroit. More information on the event is discussed in this issue on *Oncolytics Today*.

There are currently more than 1,800 members of NCODA representing more than 450 practices in both the United States and several foreign countries.

Yet our membership, unlike some organizations, has not remained passive; there has been a groundswell of volunteers for the many important projects NCODA manages.

There will be a big push this year to get Treatment Support Kits out to practices at an affordable price to assist patients in managing their oral oncolytic treatment.

There is a team working with the Hematology/Oncology Pharmacy Association (HOPA), the Oncology

Nursing Society (ONS) and the Association of Community Cancer Centers (ACCC) to begin writing patient education sheets for injectable oncology medications in the same format as the Oral Chemotherapy Education sheets.

That's because despite the fact that the word "oral" is right in the middle of the NCODA name, many practitioners have requested that NCODA and its partner groups provide this same beneficial teaching document for all chemotherapy agents.

Meanwhile, the Positive Quality Interventions document library continues to grow, with new information being provided for many new agents soon after they come on the market.

In the months to come, even more work will need to be done by NCODA committees. With just a small investment in time, you and your fellow staff members would be welcome additions to any of the NCODA committees.

The motto "Passion for Patients" defines who we are as members of NCODA, and that is due to the energy and commitment of all NCODA members with the valuable support of our corporate sponsors.

Please join me in actively working with NCODA to make our patients' cancer treatment experience as successful as possible!



James R. Schwartz, RPh
NCODA President, 2019-2020



James Schwartz



A record number of healthcare professionals turned out for the 2019 NCODA Fall Summit in Orlando, Florida.

PHOTOS BY ANDREW CLARK

By Robert Orzechowski

By every metric, the NCODA Fall Summit in Orlando, Florida, was another resounding success.

It was attended by a record setting number of participants, and the diversity, number and quality of attendees, presenters and programs received exceptional reviews in our post-event survey.

The Summit – Building a Patient-Centered Medically Integrated Oncology Pharmacy Community – offered more than 25 clinical, nursing, pharmacy

AN OPPORTUNITY TO LEARN, GROW AND NETWORK

RECORD NUMBER OF PARTICIPANTS TURN OUT FOR NCODA FALL SUMMIT

technician, operations and business presentations.

Each session was designed to reinforce NCODA's goal of supporting quality patient

care, while at the same time providing attendees with the resources to pursue that goal.

Altogether, the Fall Summit offered 16 sessions for continuing education (CE) credits for nurses, physicians, pharmacists and technicians, the most credits NCODA has offered at a meeting to date.

The programs focused on a wide variety of issues and topics important to our members and stakeholders, including:

- In-depth examinations of the Direct and Indirect Reimbursement fees and Co-Pay Accumulator applications;
- Workshops focused on



Lucio Gordan, MD, President and Managing Physician for Florida Cancer Specialists, speaks at the Fall Summit Welcome Reception.

Positive Quality Interventions, Treatment Support Kits, Oral Chemotherapy Education sheets, Cost Avoidance and Waste Tracker tool and Financial Assistance;

- Discussion of program implementation; and
- Announcement of the new ASCO/NCODA Patient-Centered Standards for Medically Integrated Dispensing.

Pre-conference sessions were geared toward professionals new to Medically Integrated Dispensing, as well as to distinct stakeholders such as nurses and technicians.

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The Summit offered many opportunities to renew old friendships and make new acquaintances during numerous networking breaks.



Poster exhibitor Irene Okeke, PharmD, discusses her poster with Russ Amy, Reimbursement Account Manager at Pharmacyclics during the Fall Summit.

FALL SUMMIT

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As always, numerous networking opportunities were provided during breakout workshops, receptions and open networking sessions.

NCODA also announced several new initiatives, including its exciting collaboration with ASCO for patient-centered quality standards, the tremendous growth of the Professional Student Organization program and the launch of the Oncology Institute, a new event focused on bringing healthcare professionals and pharmaceutical industry leaders together.



Above: Florence Osisanya, PharmD, a pharmacist at Joliet Oncology Hematology Associates, spoke on a panel about putting Positive Quality Interventions into action.



Left: Roy Paulson, MD, president and chairman of the board for Texas Oncology, spoke on enhancing patient access / how to minimize financial toxicity.

Also on display during the Summit were more than 35 posters detailing the latest issues in oncology care and research.

Alexandria Jarvais, a pharmacy student at the University of Rhode Island, presented a poster on the industry's lack of knowledge regarding exemptions on opioid limits for patients undergoing acute cancer-related pain. Jarvais said the event gave her

an opportunity to showcase her research with pharmacists from across the country.

The Fall Summit also featured exhibits by representatives of the pharmaceutical, group purchasing organization and healthcare industry.

"I've been in the industry for 17 years and I think this conference is top notch," Cindy Pope, a territory manager with Rigel Pharmaceuticals. "The collaboration with our pharmaceutical partners has been great and the topics are very useful because with oral oncolytics everything is changing."

In the past year, NCO-DA has continued to grow its membership as many new practices, partners and collaborators embraced our mission.

We look forward to further growth as we bring value to our membership and strive to improve patient care.

▲ **Robert Orzechowski**, MBA, SPHR, SHRM-SCPF, is COO for Lancaster Cancer Center, LTD, in Lancaster, Pennsylvania, and a member of the NCODA Executive Council.



Cara Mathews, MD, Women and Infants Hospital, and Chris Schumpp, PharmD, University of Illinois Cancer Center, spoke on the value of Treatment Support Kits and Oral Chemotherapy Education sheets.

MICHELLE McCORKLE: ONCOLOGY NURSING SOCIETY

How did you become involved with NCODA and what prompted you to join its Executive Advisory Board?

I was fortunate to meet Mike Reff at an ONS Congress when NCODA was just being formed. We had the opportunity to talk about professional societies and I was able to share my insight based on the work I was doing at ONS. I was impressed with Mike's passion toward patient centered care.

It wasn't long after that when Mike reached out to me with an innovative collaborative project idea that eventually became the Oral Chemotherapy Education (OCE) sheet initiative.

I continue to be impressed with NCODA's efforts at convening key stakeholders, including the formation of an interprofessional advisory board for NCODA. I was honored to be invited onto the advisory board to represent ONS and the voice of oncology nursing in 2017.

Tell us a little about your business and clinical expertise.

My professional career has always been in oncology, starting right out of nursing school as a new graduate nurse at Presbyterian University Hospital in Pittsburgh, Pennsylvania. I worked in the inpatient hematology/oncology setting in clinical nursing roles and upon attaining my MSN as an Oncology Clinical Nurse Specialist, I joined the Oncology Nursing Society (ONS) in 1995 as the Assistant Director of Education.

Working at ONS has been professionally rewarding as I have gained many new skills that I might not have learned had I stayed in the inpatient setting. From the business perspective, I began ONS's first for-profit subsidiary, Oncology Education Services, Inc. (OES), a medical education company targeting oncology nurses. While this entity is no longer in existence, I learned many skills that have come in handy in today's

cancer care world including business proposal writing and collaboration.

Since that time, I moved into a variety of different executive leadership roles at ONS.

At the end of the day, NCODA is primarily focused on improving patient care. What are some of the key concerns that oral oncologic patients face, and what can be done to relieve their burden?

Management of patients on oral therapies requires careful monitoring using telehealth strategies and trained nursing staff. Documentation is essential and may require novel approaches to following patients at home. Current Electronic Health Records are not best equipped to handle the needs of clinicians and patients.

New roles have been emerging including oncology navigators and oral adherence nurses. It will be important to create evidence-based resources to assist in the delivery of quality care. Safe handling in the home and skilled nursing facilities is key to maintaining the safety of patients, families and staff.

Interprofessional communication is key to safe administration, follow up and lab testing, and adherence for optimal cancer outcomes.

How do you see NCODA and your organization collaborating to improve patient care in the future?

At an organizational level, ONS values collaborations and partnerships with others in the cancer community. Healthcare has become more complex than ever and interprofessional collaboration is required to improve patient care and enhance the delivery of quality cancer care.

I had the opportunity to attend one of the nursing breakout sessions at the recent 2019 NCODA Fall Summit in October and was impressed with the level of engagement from those in attendance. It was great to speak with some of the



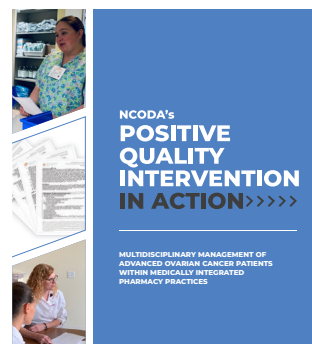
Michele R. McCorkle, MSN, RN, is the Chief Strategy Officer for the Oncology Nursing Society (ONS), leading a portfolio that includes strategic planning with the ONS Board of Directors, Global, and the ONS Center for Advocacy and Health Policy, Business Development and Partnerships. She is completing her third year in the Doctor of Nursing Practice Health Systems Executive Leadership (HSEL) program at the University of Pittsburgh School of Nursing.

nursing attendees to hear how they are using ONS and NCODA resources in their practice.

It is very clear that oncology nurses are an important part of the interprofessional team within medically integrated dispensing pharmacies. ONS looks forward to our continued working relationship with NCODA in the years to come.

"It is very clear that oncology nurses are an important part of the interprofessional team within medically integrated dispensing pharmacies. ONS looks forward to our continued working relationship with NCODA in the years to come."

NCODA INITIATIVE IMPROVES TREATMENT OF OVARIAN CANCER



By Matthew Schulz, PharmD

NCODA recently developed several initiatives to improve the current state of affairs in advanced ovarian cancer.

The disparities that exist in the delivery of care for advanced ovarian cancer patients are depicted by two alarming facts:

▲ Genetic testing rates hover around 50%.¹

▲ Only 49% of patients received maintenance therapy in second line or greater therapy.²

Current rates warrant improved methods to enable healthcare professionals to identify eligible patients and offer PARP-Inhibitors at the appropriate time.

NCODA's Positive Quality Intervention (PQI) on this topic – www.ncoda.org/ovarian-cancer-parp-inhibitor-eligibility – provides practical guidance and empowers professionals to take a more proactive approach with specific strategies to identify, offer and manage patients eligible for maintenance therapy with a PARP-Inhibitor.

The PQI highlights how these principles are implemented within six leading oncology organizations, each of which values the consistent guidance information found within the document. A copy of that article is available at www.ncoda.org/wp-content/uploads/2019/11/NCODA-PQI-in-Action-PARP-I-Ovarian-copy.pdf.

Finally, the 2019 NCODA Fall Summit in Orlando, Florida, featured an esteemed panel of providers as well as an ovarian cancer patient. This expert group

HOW TO GET INVOLVED

▲ PQI in Action articles are available at www.ncoda.org/pqi-in-action.

▲ For more information on PQI in Action, contact Matthew.Schulz@ncoda.org.

presented real-world perspective and recommended strategies for improving ovarian cancer treatment to all meeting participants.

Key takeaways from the presentation included:

Educating all patients about their anticipated therapy journey, including the role of maintenance treatment;

Ensure all patients are referred to a genetic counselor for evaluation;

Utilizing clinical, evidence-based EMR pathways, regimens, treatment plans or patient management software when available;

Scheduling appropriate timing of follow-up visits, imaging scans and next lines of therapy following initial diagnosis and treatment within the EMR; and

Manually tracking typical anticipated treatment milestones, such as final cycle of chemotherapy, surgery and appropriate time to maintenance therapy to serve as an essential patient safeguard. Utilizing the PQI on PARP Inhibitor Eligibility, the entire MIP team consistently checks the EMR to ensure these appointments and calls are made accordingly.

We encourage all NCODA members to carefully review the strategies presented in these initiatives and, thereby, implement improved methods to ensure more ovarian cancer patients will receive

and potentially benefit from therapy.

An Electronic Medical Record (EMR) educational resource is also available to access specific step-by-step instructions tailored to individual EMR systems. With these unique resources, NCODA members are empowered to conduct a chart review and identify eligible patients who may benefit from additional therapy.

NCODA will continue to partner with leading oncology groups to address significant issues in all the various types of cancer. Through the PQI in Action initiative, NCODA highlights organizations with effective practices that improve the lives of cancer patients.

If you are interested in partnering on this initiative – which may simultaneously serve as clinical quality improvement project for your organization – contact us today to share your story and help improve cancer care worldwide.

▲ **Matthew Schulz**, PharmD, is the manager of Clinical Initiatives at NCODA and is based out of Englewood, Colorado.

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MEDICALLY INTEGRATED PHARMACY: A TRULY INTEGRAL PART OF THE ONCOLOGY CARE MODEL



By Kashyap Patel, MD

Adopting a medically integrated pharmacy (MIP) strategy has helped Carolina Blood and Cancer Care Associates (CBCCA), an oncology practice located in rural South Carolina, address the needs of cancer patients in underserved areas of the state.

CBCCA's patient population includes a disproportionately large percentage of Medicare/Medicaid patients. With such a vulnerable population, the importance of its transformation was even more critical.

Despite its relatively small clinic size, CBCCA made significant progress in a very short span of time.

The catalyst for this transformation was the 2016 decision by the Center for Medicare & Medicaid Services (CMS) to launch a new voluntary Oncology Care Model (OCM) to improve the efficacy and efficiency of specialty care.

The program aims to provide higher quality and more coordinated oncology care at the same or lower cost to Medicare than traditional fee-for-service model. The OCM program ties payments to provider performance based on meeting specified quality metrics and practice reforms.

CBCCA's transformation was multi-fold and occurred from top to bottom staff-wise. The roadmap it followed was certified by the National Center for Quality Assurance (NCQA) and ac-

credited as a Patient Centered Specialty Practice (PCSP).

The transformation strategy focused on patient navigation, same day services, 24/7 access, National Comprehensive Cancer Network guidelines, quality reporting, an Institute of Medicine plan and expanded access/weekend hours.

Looking at the importance of orally administered drugs, CBCCA adopted MIP as an additional strategy to control drug costs by closely monitoring side effects and limiting supply to a maximum of 30 days to reduce waste.

All of these steps had an end-goal of improving the population health of patients with multiple co-morbidities in the area CBCCA serves.

This article will primarily focus on the success in accelerating MIP to maximum efficiency and contributing to reducing total cost of care, while maintaining patient experience in the highest tier.

WHY CBCCA DECIDED TO START MIP

A reduction in the number of chemotherapeutic infusions as well as novel therapy delivery systems (Rituxan Hycelela, s/q Herceptin Hylecta and Velcade) led to a decline in non-drug infusion related revenues. This shifting paradigm likely will lead to a reduction in chair time requirements.

The net results of the changing landscape of treatment for cancer patients will be less infusion staffing requirements and redistribution of staff in other areas.

One of the solutions is to become

an early adopter in the oral dispensing space and create better patient care. By initiating MIP, we felt that we could provide better care, initiate a new revenue stream, improve patient experience, reduce cost of care and redeploy existing experienced staff.

To better control drug cost, we began dispensing after being selected for OCM.

Traditional PBMs send a 30-to-90 day supply, frequently resulting in waste due to either disease progression or side effects.

For patient attribution, the day a patient receives medicine triggers a six-month episode in OCM. With medically integrated dispensing, we were able to streamline Monthly Enhanced Oncology Services billing by reducing attribution errors.

As a result, MIP is an important tool for providers participating in value-based care initiatives, resulting in cost savings, improved efficiencies in delivery of high-value care through better compliance, and adherence.

BENEFITS OF MIP

Benefits of MIP in community cancer clinics are manifold:

The practice becomes a one-stop shop for all treatment related to cancer: By adding a medically integrated pharmacy, oncology clinics can provide the full range of treatment options at one site.

Whether patients receive intravenous therapy or need to fill a prescription for

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STARTING AN MIP

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self-injectable or oral medications, they would be able to access therapy as and when they need from a team of health professionals they have known and trusted throughout their cancer treatment journey.

Whether single or multi-agent therapy, oral or injectable, patients will have convenience and flexibility, along with the ability to undergo pre-authorization.

Improved patient satisfaction and better patient experience: When drugs are dispensed from oncology clinics, the practice's clinical staff can address any and all issues or concerns, including compliance issues and side-effects, adding a holistic view of patient care.

Patients can begin taking oral medications or learn how to self-inject medications under the supervision of health care providers. These providers have full knowledge of other co-morbidities as well as drug-drug or drug-food interactions.

Because these clinicians have knowledge of the full treatment program, many subsequent anxieties and concerns can be addressed on-site.

If a clinician needs to adjust a medication or dosage, it can easily be done in the office rather than going back-and-forth with a mail-order or external pharmacy that has no knowledge of the complexities of oncology care.

When patients are dealing with serious cancers, having all their medical needs met under one roof can reduce stress when it is needed most.

In the end, medically integrated pharmacy can help position oncology practices to better provide high-quality, potentially lower cost care, increasing the value proposition for both patients and payers.

Further, MIP can improve the patient experience by ensuring patients are not forced to use a specialty pharmacy over the convenience of their community provider.

Most importantly, if payers are going to hold providers accountable for value and care quality metrics, providers must be able to fill prescriptions so that they can assume full accountability for quality and cost management.

Improved patient care and compliance: In the era of Value Based Care (VBC), patient experience is very important. Offering oral and self-injectable medications at a practice helps increase patient satisfaction and enhances the level of care and adherence that can be attained.

One of the fundamental tenets of VBC is shared decision making and care coordination. With in-office dispensing, the goals of care coordination can be achieved with greater efficiency, incorporating all factors including co-morbidities and medication reconciliation, leading to fulfillment of compliance and enhanced patient care.

New revenue stream: Now more than ever, oncologists can add medically integrated pharmacy model as an avenue to tap into new revenue streams while offering better care for their patients. There may not be a better time for oncology practices to consider adding MIP to their operations.

As with any new business venture, starting MIP program requires investing in the resources needed to succeed. However, the additional revenue stream is an added benefit to any practice as they can now realize savings opportunities.

Patient assistance and support programs: An MIP allows the practice's staff to help patients with concerns about cost, coverage and patient assistance, bringing the pharmacy closer to the patient, and the physician closer to the pharmacy.

With robust patient assistance programs and foundations supporting underinsured and uninsured patients, as well as special programs sponsored by pharmaceutical manufacturers for commercially insured patients, oncology practices can help alleviate financial toxicity concerns and improve quality of care and compliance.

Increased clinic efficiency: With MIP, patient medication coverage, pre-authorization, and step therapy requirements can be explored at the time of medication filling.

It also enables pharmacy staff from the physician's office to reach out to the appropriate payer department to complete required documents like physician notes, pathology, and scan reports to obtain medication approval, versus a third-party prescription fill, which has the potential to result in waiting several weeks before medication can be obtained, also causing additional time spent by the clinic staff.

Value Based Care and Alternate Payment Models: The trend of switching physician payments from volume to value requires that physicians and providers become indirect stakeholders in spending.

Medically integrated pharmacy allows physicians to fill prescriptions for a limited time initially to explore patient compliance as well as tolerance.

When a prescription is filled via a third-party mail-order pharmacy, medication is usually sent for 90 days. If a patient cannot tolerate the medication, progresses on medications, or needs dose alterations, a very expensive drug supply would then be discarded, resulting in increased spending on medications.

MIP allows physicians to control the spending on medication resulting in savings for the system as well as complying with the theme of the VBC.

Medically integrated pharmacy is not a choice anymore; it is a case of business compulsion.

▲ Authors of this paper include **Kashyap Patel**, MD, ABO-IM, BCMAS, CEO of Carolina Blood and Cancer Care Associates in Rock Hill, South Carolina. Others contributing to this paper included **Hirangi Mukhi**, BS; **Resha Kodali**, BS; **Riley Fortner**, BS; **Lauren Travis**, BS; **Taylor Barnes**, BS; **Taylor Lavender**, BS, PA-C; **Dhwani Mehta**, MS, RD, BCMAS; and **Maharshi Patel**, BS, MBA.

CANCER DIAGNOSIS, COUPLE'S VISION CREATES THE CHARITABLE PHARMCY

By Rebecca Van Keulen

When my husband's doctor called with the MRI results and used the word "oncologist," I don't remember hearing much of anything else.

Jonathan and I were 29 at the time with two small children. We were terrified by his cancer diagnosis and ill-equipped for what was to come next.

I still recall weeping on the floor of our closet after receiving that call.

Six years later, it's hard to believe the journey we underwent.

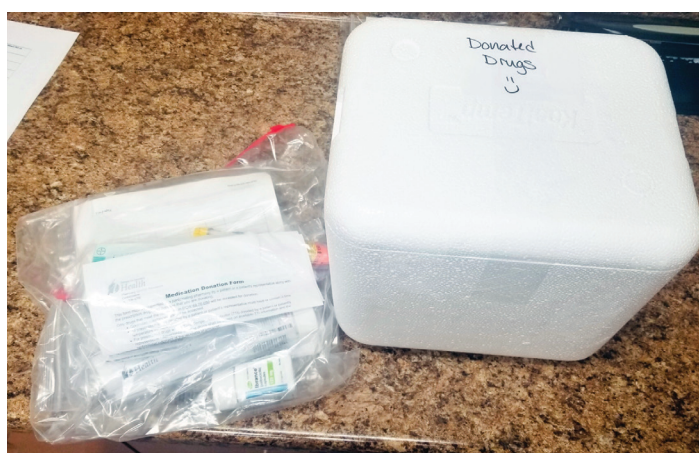
I am an interior designer by trade, yet despite my lack of medical training, I have gained the expertise of a patient's perspective. I now know:



Rebecca Van Keulen

- How to survive financially after losing the family's single source of income,
- How to help young children process the fact that their parent is going to die (Jonathan lost his battle with cancer in April 2016),
- What it is to need an \$8,000 drug that the insurance company won't approve for reimbursement, and
- What it's like to be told to throw thousands of dollars of unused drugs away – in one sense, that was the hardest lesson of all.

Medical waste in this country is significantly under-researched, largely because it's impossible to quantify how many prescriptions are flushed down toilets or thrown away in the trash each year. Research by Roosevelt University¹



Above and left are some of the drugs donated to The Charitable Pharmacy Group. Rebecca Van Keulen and her late husband, Jonathan, founded the non-profit in 2016. The charity accepts and distributes medication to patients in need in Washington state.

revealed that up to \$5.4 billion in unused, unexpired drugs were wasted during the study period.

Lack of affordability only exacerbates the problem. A Kaiser Family Foundation 2019 Tracking Poll on Prescription Drugs reported that three of 10 adults did not take their medications as prescribed in the past year due to cost.²

Jonathan and I learned about medical waste the hard way when he was switched to a very expensive drug in the middle of his treatment. To make matters worse, he could no longer use the expensive drug (Granix) we already

had in our possession. We offered to return it, but were told a prescription cannot be accepted back once it leaves the pharmacy.

Yet the idea of trashing \$30,000 in medication was unfathomable to us.

We contacted a family friend who is an attorney to see if there was legal precedent for medication donation. He discovered that the idea had been evolving nationwide since 1997.

Georgia, for instance, initially allowed drug donations to nursing homes. And other states permitted drug donations to

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CHARITABLE PHARMACY

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prisons. The ball really started rolling in 2005, when Iowa passed legislation allowing the public to donate unused medicine for re-dispensation to the general public. A few other states later followed suit.

Unfortunately, our home state of Washington was not one of them.

We were unwilling to accept this situation and worked for months with our state legislators to change it. Finally, in late March 2016, Washington passed legislation allowing drug donation and re-dispensing to the general public.

Jonathan passed away one week later.

Yet my late husband and I still achieved our vision. Soon afterwards, The Charitable Pharmacy Group non-profit was launched and a medication repository system was started. The pilot program began with only five pharmacies, minimal marketing and only three oncology practices as word-of-mouth partners.

Two years later, we have \$500,000 in medication inventory and have re-dispensed more than \$300,000 in free medication.

Physicians call us when they are un-

able to obtain insurance reimbursement for medications needed by their patients. I get as excited as the patients do when I find the medication they need is in stock, which is an increasing occurrence.

The charity also benefits the families who provide the donations.

“We’ve gotten so many notes on the donation forms (saying that donating the medicine) makes the family feel better,” said Amanda Goyke PharmD, The Charitable Pharmacy Group Vice President, and owner of our pilot program partner, Owl Pharmacy. “Their loved one can’t use the medication anymore, but maybe someone else’s can, and maybe this drug will make the difference for them.”

Safety is the program’s number one priority. We only accept sealed medications. We do not accept narcotics, and all medication must be at least six months from expiring. Donors are required to sign a Washington State Department of Health waiver stating the medication has been stored properly, and all donations must be returned to a licensed pharmacist for inspection.

While we recognize that donated medication comes without a 100% safety guarantee, the fact remains that all un-

opened medication is originally sourced from a pharmacy. Had such a donation program been available during Jonathan’s battle, it would have been in my family’s best interest to take that risk.

Today, many states have some version of drug donation programs in place. Please ask your state legislators where they stand on the issue and support expansion of these important programs.

▲ **Rebecca Van Keulen** is executive director of The Charitable Pharmacy group and president and co-founder of Cancer Can’t. Both non-profits serve cancer patients in Washington state.

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The Financial Assistance Tool is a readily available resource for oncology healthcare professionals to use when assisting patients struggling to pay for cancer treatment. Many types and levels of assistance are available.

The NCODA Financial Assistance Tool provides up-to-date and comprehensive financial resource information about dozens of chemotherapy and anti-cancer treatment options.

This tool is available in a convenient online format and as a downloadable Excel spreadsheet on the NCODA website in the *Member Resources* tab.

START UTILIZING THE FINANCIAL ASSISTANCE TOOL TODAY!

Learn more at www.ncoda.org/financial-assistance

DRUG DONATION PROGRAMS PROVIDE A WAY TO HELP CONNECT PATIENTS IN NEED WITH UNUSED PRESCRIPTION MEDICATION

By Kathy Oubre, MS

The United States wastes \$5 billion worth of drugs, according to Sirum¹, a non-profit organization that helps collect and redistribute surplus medications from pharmacies and healthcare facilities to low-income individuals.

Across the country, drug donation programs have quietly emerged as a practical channel to connect patients in need of assistance with unused prescription medications. As of 2018, 38 states and Guam have enacted laws for donation and reuse².



Kathy Oubre

Unfortunately, many programs remain non-operational or underutilized. In states where drug donation programs have demonstrated success, the benefits of the program are

enjoyed by a variety of stakeholders, generating significant cost savings to program donors, healthcare providers and – most importantly – patients needing assistance.

Since these laws are all state-regulated, they differ by the types of drugs accepted, who can donate drugs, where the donations are collected and what happens to the drugs after collection.

For example, Colorado and Florida are two of 13 states that only accept and distribute unused cancer-related prescription drugs. Alternatively, Georgia and Iowa take all prescriptions and over-the-counter medications as long as they are in sealed packaging. Iowa has one of the largest drug recycling programs. Since 2007, it has saved \$17.7 million and provided 9.1 million units of free

drugs and supplies to patients².

In general rules and guidelines are universal when it comes to medication donation³, including:

- Pills in opened or partially used packages are not accepted;
- Old drugs are not accepted. Expiration dates must be visible and often at least six months later than the date of donation;
- Donated drugs must be delivered to a specific type of medical or pharmacy facility. Some may require donor waivers;
- Financial compensation as payment to the donor is usually prohibited, although donations may be tax-deductible; and
- No acceptance of controlled substances.

Although many states have passed laws establishing these programs, almost half of those states – including my own (Louisiana), don't have “operational programs.”

To have an operational program, a state must have participating pharmacies, charitable clinics and/or hospitals collecting and redistributing donated drugs to eligible patients.

The largest single obstacle often appears to be funding. As many states continue to face tough budget decisions, funding for these donation programs is often difficult to find. And when funds are available, patients and donors need to be protected. Most states include legislation that grants liability immunity for donors and program administrators.

Drug donation programs are designed to provide short-term assistance to low-income and under- or uninsured patients. These programs are not intended to provide medication assistance in lieu of state or federal programs, but they do serve patients who need short-term assistance, such as an insured, low-income patient who cannot afford a drug copay, an individual waiting to receive Medicaid benefits or a senior who has

reached the Medicare coverage gap.

Although some states allow the drug donation program to dispense directly to the patient in need, many programs are licensed in their state as a wholesale distributor. As distributors, the drug donation programs supply medical facilities, such as free medical clinics or federally qualified health centers, with donated medications that will be dispensed to patients in need.

Once the donated medications are received by the medical facility, the medications are dispensed to the patient in its donated format.

Drug donation programs with a history of success often use state assistance to underwrite operating costs. As a result, almost all state regulations for drug donation programs stipulate that only state residents are eligible to accept the donated drugs. Most states also specify the donated drugs must be dispensed to low-income patients lacking prescription drug coverage.

Ultimately, drug donation programs provide feasible solutions to drug waste and lack of access to care, which remain two major public health challenges.

▲ **Kathy Oubre, MS**, is Chief Operations Officer at Pontchartrain Cancer Center in Covington, Louisiana.

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BIRTH OF AN ORAL ONCOLYTIC

THE QUEST FOR A NEW CANCER DRUG IS NOT FOR THE FAINT OF HEART

By Brett Williams, PhD

With 10 new FDA approvals in the second half of 2019 alone, the toolbox of oral oncolytics is continuously expanding.

These new approvals present patients and providers alike with new therapeutic options, but also bring the challenges of appropriately dispensing these agents and monitoring patient outcomes.

While many oncology providers are aware of the challenges and opportunities that come with each new chemotherapeutic, the tribulations of the discovery and development of these drugs may not be as familiar. Knowledge of the drug discovery process can bring providers and patients a valuable perspective on chemotherapeutics and their properties.

Put simply, drug discovery is not for the risk averse. The journey from concept through the clinic is long (10-15 years), fraught with high cost (\$1-3 billion) and low probability of success (12%).¹ Despite the odds, a number of molecules do successfully navigate the maze, earn FDA approval and make it to the patient's bedside.

REWARD EVEN IN FAILURE

For those that do not earn approval, there is still reward even in failure. While both costly and disheartening, the research behind a failed drug candidate still adds to the greater body of knowledge on disease biology and informs future drug discovery efforts.²

The birth of an oral oncolytic begins



PHOTO BY ANDREW CLARK

Brett Williams, a medicinal chemist at Goldfinch Bio in Cambridge, Massachusetts, gave a presentation on how oral oncolytics are created during the 2019 NCODA Fall Summit in Orlando, Florida.

with an intimate knowledge of cancer biology. Physicians, biologists, statistical geneticists and other scientists perform cutting-edge research to find new tactics to destroy malignancies. Their work ultimately culminates in a validated drug target. This is an enzyme or biological process – e.g. kinase, GPCR, ion channel, etc., that when modulated, results in cancer cell death.

Once the biological target is known, chemists and biochemists begin the search for small molecules that preferentially interact with the biological target.

Biochemists first develop robust and scalable assays to test the binding affinity or activity of small molecules. Then, libraries of up to several million compounds are tested for activity in a carefully engineered high-throughput screen (HTS).

SEARCHING FOR 'HITS'

Small molecules that are active in the HTS are called "hits." These hits need to be tested in orthogonal assays to con-

firm their observed activity in the HTS. Chemical inhibition of off-target biological processes can lead to dose-limiting toxicity, so selectivity of the hits is important and may be assessed early on in a drug discovery program.

Once the hit activity is confirmed, a medicinal chemistry campaign begins. The overall goal of the medicinal chemistry team is to turn these hits into a drug, which requires the interconnected efforts of many scientists including medicinal chemists, biochemists, biologists and pharmacologists.

THE HIT-TO-LEAD PHASE

The first phase of a medicinal chemistry campaign is called "hit-to-lead." Hits require optimization before they can be considered "drug-like." In the hit-to-lead phase, chemists synthesize analogs of the "hits," creating a series of compounds that are assessed in biological assays for their physicochemical properties (e.g solubility) to determine if

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the chemical matter has the potential to become a drug. If so, then the “hit” series will be labeled a “lead” series and move one step closer to the clinic; hence the name, hit-to-lead.

Once the team has turned hits into leads, a new phase begins – lead optimization (lead op). In lead op, attention turns from increasing potency and selectivity to crafting the chemical matter into a drug.

This process involves optimizing the *in vivo* exposure of the drug (determined in animal pharmacokinetic studies) and assessment of safety with *in vitro* safety assays. Some standard safety assays are cytochrome P450 inhibition or activation (a source of drug-drug interactions), inhibition of hERG (human Ether-a-go-go-Related Gene) activity, which can cause QT prolongation, and activity against a panel of targets and pathways that are known to cause adverse clinical events.

PRECLINICAL TOXICOLOGY STUDIES

The final hurdle for compounds to pass before they enter clinical trials are preclinical toxicology studies. This is an *in vivo* safety assessment in at least two animal species. In these studies, high doses of a small molecule (drug candidate) are given to the animals for an extended period of time (from days to

THE STEPS IN DEVELOPING AN ORAL ONCOLYTIC

I. TARGET ID

Biology and statistical genetic research identifies a target.

II. DRUG DISCOVERY

Chemist/biochemists find chemical matter, then optimizes it into a drug candidate.

III. PRE-CLINICAL DEVELOPMENT

Drug candidate is tested in two animal species for safety.

IV. CLINICAL DEVELOPMENT

- Phase I: Assess drug safety in humans, identify maximum tolerated dose (MTD).
- Phase II-III: Test for efficacy.

V. APPROVAL

(Phase IV): Drug is distributed to patients in need. Safety and efficacy are monitored in patients.

months), and a toxicologist examines the major toxic effects of the small molecule to determine a therapeutic index (efficacious dose/toxic dose).

If the toxicology report and therapeutic index are satisfactory, the small molecule is designated a development candidate (DC) and is ready for clinical trials.

When a development candidate enters the clinic, the baton is passed from the drug discovery team to the clinical team that designs and monitors the evaluation of its safety and efficacy in humans.

THE POINT OF NO RETURN

Extensive work persists throughout the preparation and duration of clinical trials, but it is important to note that the chemical structure cannot be changed once the compound enters the clinic.

The discovery of an oral oncolytic can be filled with scientific, practical and logistical challenges at nearly every phase. Teams of people in many different functions are required to confront and dismantle these hurdles in order to gain FDA approval.

The odds are low, and the timelines are long, but the battles are still hard-fought for the chance to provide new therapies for the oncology community.

▲ Brett Williams, PhD, is a medicinal chemist at Goldfinch Bio in Cambridge, Massachusetts.

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IMPLEMENTATION OF DRUG THERAPY MANAGEMENT PROGRAMS IN ONCOLOGY

By Ryan Titus, PharmD, BCOP, BCPS

No patient population has treatment regimens as dangerous and complicated as those being treated for cancer. Many immunobiologics and oral oncolytics have unique side effects and monitoring parameters.

Drug Therapy Management Programs (DTMP) are designed to optimize the efficacy and safety of drug therapies. Currently, DTMP's within oncology centers and clinics are an underutilized and poorly understood. NCODA is determined to be a leader in optimization of patient care; inclusive of DTMP implementation and practices.

There are two basic types of DTMP: Medication Therapy Management (MTM) and Collaborative Drug Therapy Management (CDTM).

MTM may be completed by medical providers, nurses or pharmacists. The MTM practitioner obtains all needed drug-related patient information, including vitals, laboratory values and previous medical histories.

This patient-specific comprehensive drug therapy analysis may include drug utilization review with goals of maximizing drug-related effectiveness, resolving drug-related adverse events and preventing potential drug-related problems.

Patient education is provided either face to face, via teleconference, or telephone consults. In addition, the patient is provided with an updated medication list including dosage, administration and indication.

CDTM, on the other hand, requires a written Collaborative Practice Agreement (CPA) between the physician and pharmacist that defines the scope of practice granted to the advanced practice



PHOTO BY ANDREW CLARK

Ryan Titus presented a session on implementing drug management programs during the 2019 NCODA Fall Summit in Orlando, Florida.

providers (APP).

The CPA may grant the pharmacist limited prescribing abilities for previously diagnosed medical conditions. In addition, practice allotments may include:

- ▲ Treatment protocol application;
- ▲ Dosage, frequency and/or administration route adjustments;
- ▲ Therapeutic interchanges;
- ▲ Direct patient consultation, education and monitoring;
- ▲ Authorization to write prescriptions for supportive care medications;
- ▲ Authorization for medication refills; and
- ▲ Permission to obtain vitals and order drug therapy related labs.

It's important to know what is permitted under your state's practice site

laws. Currently, there are 48 states which have CDTM legislation.¹ Many states, however, have divergent responsibilities and privileges granted to the DTMP practitioners. Washington State, for example, allows pharmacists to prescribe controlled substances, though most states do not.²

DOCUMENTATION OF DTMP EFFECTIVENESS

According to the 2017 survey of collaborative drug therapy management in U.S. hospitals, pharmacists reported practicing CDTM in 66% of respondents' hospitals.

The most prevalent CDTM activities reported included ordering laboratory and related tests (58.7% of hospitals), adjusting drug strength (57.9%), and changing the frequency of administration (53.8%).³

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MANAGEMENT PROGRAMS

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There are more than 100 published studies validating the clinical or economic benefits of DTMP, typically demonstrating improved patient outcomes relating to general family practice inclusive of diabetes, hypertension, anticoagulation and infectious diseases.⁴ Unfortunately, very few published reports exist specifically relating to the utilization of DTMPs within the oncology practice setting.

REIMBURSEMENTS

Reimbursement for DTMP may include billing as a provider, Incident to Physician or facility charges. Physicians and mid-level providers can bill directly for their services rendered as Medicare Part B recognized providers.

A pharmacist may bill for MTM services via Medicare Part D through prescription drug plans within the community pharmacy setting. The patient eligibility criteria for Medicare Part D reimbursement includes:⁵

- ▲ Documentation of at least three chronic health conditions;
- ▲ That the patient is receiving multiple Part D medications; and
- ▲ The likelihood to incur Part D drug costs of \$4,044 or greater.

Unfortunately, MTM and CDTM services performed by nurses and pharmacists in hospital-based or physician offices are not recognized as a Medicare Part B benefit and cannot be billed to Medicare Part D. As a result, Incident to Physician Order or facility charges must be utilized to receive reimbursement within these practice settings.

Medicare Incident to Physician Order billing is an indirect billing mechanism where auxiliary personnel under their state scope of practice may provide patient care services under the direct supervision of a physician or other approved Medicare Part B provider.⁶ The service rendered is part of the physician's bill.

Incident to Physician Order billing requires the following:

The extremely positive outcomes helped reinforce the DTMP initiative and propelled its accessibility and utilization within the St. Lawrence Health System.

- ▲ The patient receive evaluation from provider prior to consultation;
- ▲ Consent from patient and an "incident to" order from the provider; and
- ▲ A physician or Medicare Part B-approved practitioner be on the premises, but not necessarily in the room, when "incident to" services are performed.

The supervising physician need not be the same physician or other practitioner whose professional service serves as a basis for the "incident to" service.

Hospital-based outpatient clinic revenue options for pharmacists and nurses include the Facility Fee. This indirect billing option pays the hospital the costs of using the facility to provide services to the beneficiary. This requires a facility charge form with payment correlating with the level of service rendered, as well as the "incident to" rule requirements as previously outlined.

DEVELOPING A DTMP

It is important to get your business and finance representatives involved early in the DTMP development and implementation process.

I currently practice within a hospital-based outpatient clinic. The best reimbursement model that worked for us was a facility charge.

Our charge form contains a list of activities that the DTMP practitioner completes; during the direct face-to-face patient consult, such as ordering

medication related labs, completing the chemotherapy teach, ordering supportive care medications or obtaining vitals and consents. The summation of the completed activities relates to the level of services rendered and reimbursement rates.

The implementation of DTMPs generally includes writing policy and procedures, obtaining customer buy-in and developing a business plan, as well as a pilot study and quality assurances.

It is imperative to utilize your practicing site's state laws when writing your DTMP policy and procedures. States and individual practice sites may differ in the professional duties allotted and requirements for certification.

For example, state CDTM accreditation requirements may include residency training, board certification by the board of specialties, clinical experience, medical malpractice insurance, credentialing and privileging, and ongoing assessment and peer review.

BARRIERS TO IMPLEMENTATION

Barriers to successful implementation of DTMPs include:

- ▲ Lack of medical provider buy-in;
- ▲ Fear and concern from other health professionals of job competition;
- ▲ Lack of confidence in pharmacist and nurses;
- ▲ Fear of the unknown; and
- ▲ Variable payment options from private, state and federal insurances.

Drug Therapy Management Programs are novel services that many consumers have never heard of. It's important to keep documentation of your DTMP consultation interventions and to report them to your practice site leadership.

COST BENEFITS

I completed a pilot study which demonstrated lower hospital health care costs per cancer patient in the DTMP group vs. control group (\$5,309 vs. \$7,478), $p = 0.0012$. In addition, I surveyed my practice site medical providers

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and DTMP patients.

The extremely positive outcomes helped reinforce the DTMP initiative and propelled its accessibility and utilization within the St. Lawrence Health System. The future implications of DTMP include improved medical management of patients, enhanced interprofessional collaboration and improved professional satisfaction.

I believe that the Medically Integrated Pharmacy/Dispensing model optimizes patient medical care by maximizing effectiveness, reducing adverse effects, improving adherence, increasing accessibility of services and augmenting medical provider efficiency.

▲ **Ryan Titus**, PharmD, BCOP, BCPS, is an Ambulatory Oncology Pharmacist with St. Lawrence Health System and an Assistant Professor at Clarkson University in Potsdam, New York.

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By Emily Uebbing

The NCODA Advanced Pharmacy Practice Experience introduced me to a whole new world, where pharmacists work in collaboration with other professionals to improve patient care around the world.

My time as an Advanced Pharmacy Practice Experience (APPE) student with NCODA helped me to begin to understand the



Emily Uebbing

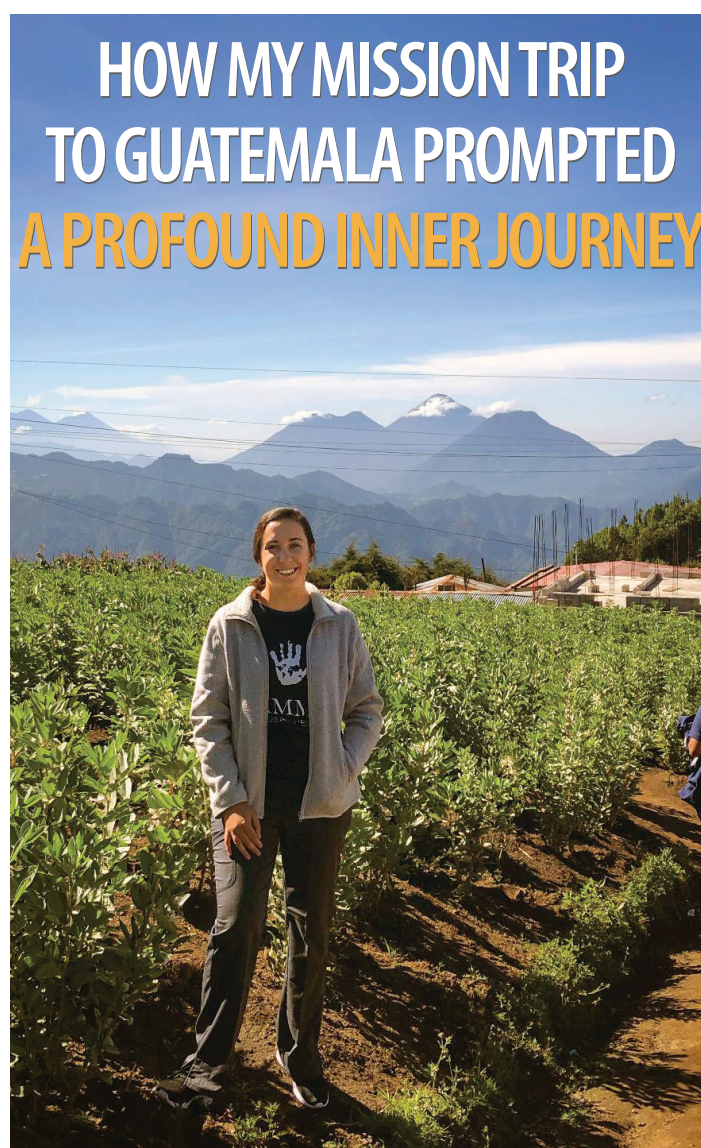
amount of coordination, teamwork and effort it takes to bring quality care to all

patients. But I did not appreciate the efforts that NCODA makes towards removing barriers to access of care until the last week of my rotation.

It was then that I traveled to Guatemala, where I served on a Timmy Global Health medical brigade with pre-medical students, nurses and physicians. We conducted five days of clinic in and around the city of Quetzaltenango.

Quetzaltenango (or Xela in Mayan) and the surrounding towns and villages are still deeply rooted in a Mayan culture that predates the Spanish conquest. The majority of people, even in the regional capital of Xela, continue to wear colorful traditional clothing in daily life and predominantly speak native languages.

The healthcare system in Guatemala is drastically under-resourced. Many pa-



APPE student and PharmD candidate Emily Uebbing spent five days working in clinic around the city of Quetzaltenango, Guatemala, as part of the Timmy Global Health medical brigade in the summer of 2019.

tients travel hours on foot to the hospital, clinic or doctor's office, only to be offered treatment that they can't afford.

My time with NCODA helped me to prepare for this experience. And while I knew I would work hard and utilize the clinical skills I learned in school and on rotation, I did not expect to learn a whole new set of skills. With NCODA, I gained a better understanding of empathy and humility, as well as a pro-

found new sense of identity.

In school, I learned about empathy and its importance in becoming a good clinician. But it wasn't until my time at NCODA that I began to truly understand the patient's point of view. And until I traveled to Guatemala, I didn't realize that learning about empathy and feeling empathy were two very different concepts.

Even though talking to the patients in Guatemala of-

ten required the assistance of one or two translators, I was able to hear their stories, understand their hardships and feel the overwhelming gratitude they had for our service. In this face-to-face setting, I couldn't help but empathize with their situation.

During the trip my job was to help manage the labeling, counting and checking of medications given to our patients. I felt that we were doing amazing work and I was impressed by how many patients we were able to help in our short time there.

Yet at the same time, it was also a humbling experience. While our brigade helped many Guatemalans, it was still only a tiny portion of those in need. A month of preparation and a week's hard work barely scratched the surface of the region's healthcare struggles.

My last lesson in Guatemala was one of identity. I learned that to truly experience empathy and humility, I first had to gain a sense of identity of myself, my colleagues and my patients. I learned each of us is on our own individual journey, and that it's impossible to truly help people without first understanding how they came to be, who they are now and where they want to go.

I believe this revelation – combined with my new sense of empathy and humility – will help me keep me centered on patient care as I move forward in my career.

▲ Emily Uebbing is a 2020 PharmD candidate at the University of Rhode Island. She completed her NCODA APPE rotation in 2019.

“As we move from a volume-based healthcare system, practices at all levels have to be able to transform themselves to provide what the value-based healthcare system requires. The oral oncolytic area of cancer therapy is exploding right now and these standards are a key element to ensure that all patients are getting the right drugs at the right time and not wasting exceedingly expensive drugs.”

Stephen Grubbs, MD,
Vice President of Clinical Affairs,
ASCO



“NCODA created quality standards six years ago and recognized the importance of better patient care for patients receiving oral therapies. The standards provide a management system to support the continuity of care that creates a win-win-win situation for everyone involved in the care of these patients. And ASCO brings these medically integrated dispensing standards to scale.”

Michael Reff, RPh, MBA,
Executive Director and Founder
NCODA



Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards

Melissa S. Dillmon, MD¹; Erin B. Kennedy, MHS²; Mary K. Anderson, BSN, RN, OCN³; Michael Brodersen, PharmD⁴; Howard Cohen, RPh, MS⁵; Steven L. D'Amato, BScPharm⁶; Patty Davis, BSN, RN, OCN⁷; Gury Doshi, MD⁸; Stuart Genschaw, MHA, MBA⁹; Issam Makhoul¹⁰; Wayne Ormsby, MD¹¹; Rajiv Panikkar, MD¹²; Eileen Peng, PharmD¹³; Luis E. Raez, MD¹⁴; Ellen A. Ronnen, MD¹³; Bill Wimbiscus¹⁵; and Michael Reff, RPh, MBA¹⁵

ABSTRACT

PURPOSE To provide standards for medically integrated dispensing of oral anticancer drugs and supportive care medications.

METHODS An Expert Panel was formed, and a systematic review of the literature on patient-centered best practices for the delivery of oral anticancer and supportive care drugs was performed to April 2019 using PubMed and Google Scholar. Available patient-centered standards, including one previously developed by the National Community Oncology Dispensing Association (NCODA), were considered for endorsement. Public comments were solicited and considered in preparation of the final manuscript.

RESULTS A high-quality systematic review that was current to May 2016 was adopted into the evidence base. Five additional primary studies of multifaceted interventions met the inclusion criteria. These studies generally included a multicomponent intervention, often led by an oncology pharmacist, and also included patient education and regular follow-up and monitoring. These interventions resulted in significant improvements to patient quality and safety and demonstrated improvements in adherence and other patient outcomes.

CONCLUSION The findings of the systematic review were consistent with the NCODA patient-centered standards for patient relationships and education, adherence, safety, collection of data, documentation, and other areas. NCODA standards were adopted and used as basis for these American Society of Clinical Oncology/NCODA standards. Additional information is available at www.asco.org/mid-standards.

INTRODUCTION

For the most part, antineoplastic drugs are delivered intravenously; however, the prescription of oral anticancer drugs is becoming more common, and many of the new antineoplastic agents currently in development are oral options.¹ Oral administration can be more convenient for patients because hospitalization is not required; however, it also presents unique challenges, with patients and caregivers being responsible for correct adherence to prescriptions that are self-administered in the home, as well as financial and other challenges.²

Typically, prescriptions for oral medications are submitted to centralized pharmacies and delivered to patients through mail order.³ While this model may offer an economy of scale, many practices have cited delays in receipt of mail order prescriptions due to processing and transit times.⁴ In addition, filling prescriptions through pharmacies that are located remotely from the clinical practice may result in fragmentation of care

provision, inadequate follow-up and monitoring of patients, and insufficient exploration of the possibilities for financial assistance for patients.⁵

More recently, to address these limitations, an increasing number of oral anticancer drug prescriptions are being filled under an alternative model called medically integrated dispensing (MID), wherein patients' prescriptions are processed and dispensed through a pharmacy located within the oncology clinic, rather than via mail order.

Proponents of MID cite the advantage of convenience for patients, because medications can be dispensed at the time of the clinic appointment. Cost savings to the system may also be realized; mail order pharmacies usually deliver prescriptions prior to the start of the next chemotherapy cycle and may not have the capacity to respond to changes in prescriptions in a timely way.

By contrast, in the MID model, the in-practice pharmacy can be immediately responsive to prescription holds or changes in dose, thereby avoiding unnecessary dispensing waste.⁶

Other advantages of MID include immediate verification of insurance coverage, support and assistance with investigation of options for financial assistance, ability to ensure that subsequent fills of the prescription beyond the first fill are completed and received on time by the patient, integration of patient information (e.g., laboratories, other medications) with prescription information, and pharmacist in-person verification of adherence with the patient. In addition, MID clinics generally provide more personalized individual follow-up with patients, resulting in higher adherence rates.³

As oral anticancer drugs have become more common, and MID has emerged as a delivery model, a need has been identified for quality standards for patient monitoring, education, and follow-up.⁷ This is important within the ambulatory care setting because studies have shown that there is a risk of patients discontinuing medication without consulting their physician,⁸ or otherwise not adhering to the prescription due to toxicity or for other reasons. Studies have shown that reduced adherence can decrease treatment efficacy and compromise the goals of treatment.⁹

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ASCO/NCODA STANDARDS

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Adoption of standards can help MID practices obtain optimal adherence and persistence rates, minimize the risk of toxicity with therapy, and positively affect patient health outcomes. In addition, there is an underlying need for clinics that are engaging in or planning to initiate MID to demonstrate that they are providing a high level of patient-centered care, to achieve recognition and reimbursement from health insurance payers.

In recognition of this need, the American Society of Clinical Oncology (ASCO) has partnered with the National Community Oncology Dispensing Association (NCODA) to create joint evidence-based standards for MID. NCODA is an organization that was established in 2014 by a group of community-based oncology pharmacists with the goal of facilitating and promoting the MID model to improve patient care and convenience. These joint ASCO/NCODA standards build on that work through a systematic review of the quality improvement interventions that have been studied for ambulatory patients receiving oral anticancer and supportive care drugs, and provide an environmental scan of existing standards, tools, and resources. A multidisciplinary Expert Panel further refined the standards. After a two-week open comment period, public feedback was reviewed and integrated.

These standards fill a gap, because we are currently not aware of existing evidence-based standards for the MID setting, and will provide a blueprint for safety and quality of care for outpatients who are prescribed oral oncology drugs in MID practices.

METHODS

Standards Development Process

This standard addresses the following key question: What patient-centered interventions improve the quality and safety of MID of oral or other oncology drugs?

This standard was developed by a multidisciplinary Expert Panel that included individuals with expertise in medical oncology, pharmacy, nursing, and health care administration, including a patient representative and an ASCO staff member with health research methodology expertise. Members of the Expert Panel were nominated by the ASCO Quality Oncology Practice Initiative (QOPI) Certification Program Steering Group and the ASCO Clinical Practice Committee, or by NCODA leadership. Prior to issuing invitations to the entire Expert Panel, the nominations were reviewed by the panel co-chairs to ensure geographic diversity and sufficient expertise in relevant areas. Members of the Expert Panel were permitted to be using MID in their current practice. This was not considered to be a conflict of interest because the standard does not recommend for or against using MID, or promoting MID as a delivery model, nor recommend for or against the prescription of oral chemotherapy or supportive care drugs generally or

specifically. The Expert Panel met via teleconference and/or Webinar and corresponded through e-mail. Based on consideration of the evidence, the authors were asked to contribute to the development of the standard, provide critical review, and finalize the standard. The standard statements were sent for an open comment period of two weeks, allowing the public to review and comment on the draft document after submitting a confidentiality agreement. These comments were taken into consideration while finalizing the standard statements. The document was reviewed by the Quality of Care Council and ultimately approved by the ASCO Board of Directors. All funding for the administration of the project was provided by ASCO.

A preliminary environmental scan resulted in the identification of several existing standards by ASCO,^{10,11} NCODA,¹² and other organizations,¹³⁻¹⁶ or published in peer-reviewed journals.^{17,18} Of these documents, only the NCODA standard was specifically developed for the setting of MID in the context of the United States health care system; therefore, this document was retained for potential endorsement, pending the results of the systematic review. A preliminary scan for existing systematic reviews located a relevant systematic review that included studies of the quality and safety of oral dispensing interventions and was current to May 2016. This systematic review scored highly on the Assessment of Multiple Systematic Reviews tool¹⁹ and was included in the evidence base. To avoid duplicate included studies, the inclusion criteria for the systematic review were subsequently designed to look for primary studies published after May 2016. This systematic review included searches of PubMed; search terms were (antineoplastic agents/administration & dosage* and administration, oral [MeSH Terms]) or (adherence [title/abstract] administration, oral [MeSH Terms]) or (oral [Title/Abstract] and oncolytic) and Google Scholar (May 2016 to April 2019). Studies were considered eligible for inclusion if they included a patient population that was prescribed oral anticancer drugs or other cancer therapy-related drugs as outpatients and had an intervention and comparison group. Prospective or retrospective studies were eligible for inclusion. Eligible study outcomes were effects on patients, such as adherence and toxicity (rather than effects on the health system or processes).

Articles were excluded from the systematic review if they were (1) meeting abstracts; (2) editorials, commentaries, letters, news articles, case reports, narrative reviews; (3) studies published in a non-English language; or (4) studies that compared MID with other models of care delivery.

In the course of the evidence review, a concurrent informal environmental scan was conducted for tools and resources that could be helpful in the implementation of the standards. Those tools and resources were identified through the formal systematic review, as well as through searches of Web sites of relevant organizations that are involved with the dispensing of oral

anticancer drugs, such as NCODA, the Hematology Oncology Pharmacy Association, the Oncology Nursing Society, Cancer Care Ontario, and others, or any tools or resources mentioned in background materials or studies included in the evidence base. These could include checklists, algorithms, templates for patient education materials, or other resources. The Expert Panel considered these tools and chose to recommend some as potentially helpful for practices to implement.

The ASCO Expert Panel and standards staff will work with co-chairs to keep abreast of any substantive updates to this standard, and updates will be performed as needed. This is the most recent information as of the publication date.

Standards and Conflicts of Interest

The Expert Panel was assembled in accordance with ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines ("Policy," found at <http://www.asco.org/rwc>). All members of the Expert Panel completed ASCO's disclosure form, which requires disclosure of financial and other interests, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the standards. Categories for disclosure include employment; leadership; stock or other ownership; honoraria, consulting or advisory role; speakers' bureau; research funding; patents, royalties, other intellectual property; expert testimony; travel, accommodations, expenses; and other relationships. In accordance with the Policy, the majority of the members of the Expert Panel did not disclose any relationships constituting a conflict under the Policy.

RESULTS

Systematic Reviews

As outlined previously, an initial environmental scan located a high-quality systematic review that included studies of interventions that were designed to improve the quality and safety of care for patients receiving oral anticancer drugs.¹ The search strategy for this review was current to May 24, 2016. The results of that review are summarized subsequently within this section. Eligible studies were those that included patients who were receiving ambulatory care with traditional cytotoxic or targeted oral anticancer agents and where a prospective or retrospective comparison group was specified. Sixteen studies (3,612 patients) met the inclusion criteria,²⁰⁻³⁵ including seven randomized controlled trials^{20-23,25,27,29} and nine observational studies.^{24,26,28,30-35} Interventions were categorized according to the following domains: prescribing (*n* = 1), preparation/dispensing (*n* = 2), education (*n* = 11), administration (*n* = 5), monitoring (*n* = 14), and storage/disposal (*n* = 1), which were delivered for the most part by nurses and/or pharmacists, and consisted of algorithms for assessing toxic effects, tools to track adherence and provide reminders, and increased interactions beyond the clinic visit. Adherence and persistence were the most common primary outcomes found in the included stud-

ies. Other outcomes included safety/toxicity and the frequency of taking chemotherapy above the recommended dose. Zerillo et al¹ used the Revised Standards for Quality Improvement Reporting Excellence–SQUIRE2–reporting framework as a quality assessment tool and found that most items (eg, context, methods, results, funding source) were included for most studies.³⁶ Many of the interventions had multiple components, and most studies were published recently and had fewer than 100 patients. Seven studies reported statistically significant results,^{21,23,24,26,29,33,34} including:

- A multi-institution study of patients with chronic myelogenous leukemia found that an initial education session and follow-up as needed related to adverse effects, drug interactions, and adherence significantly increased the medication possession ratio.³¹
 - Adherence was significantly improved with a program that included contact by pharmacists and nurses on day 10 and 20 of treatment, and monthly thereafter.³³
 - Daily adherence was also significantly improved in a multiple-institution case-control study that provided an initial education session with a pharmacist and ongoing counseling.²⁴
- Other interventions that resulted in improvements in adherence included ongoing adverse events and adherence counseling,²⁶ pre-filled pillboxes,³⁰ and personalized feedback on adherence data;³² however, significance tests were not performed for these comparisons. There was no improvement in adherence found with monitoring using text messages.^{20-22,28}
- In terms of safety and toxicity, the following significant results were found in single-institution studies:
- A reduction in toxic effects, improvement in quality of life, and reduced inpatient hospitalization with "patient education and phone calls by nurses using toxicity algorithms within the first week of treatment and ongoing thereafter"²⁹
 - A cohort study reported lower toxicity scores with a nurse-led telephone intervention.³⁴
 - In a case-control study, pharmacist education regarding adverse events and ongoing adherence counseling resulted in increased detection of drug-related errors, and adherence (medication possession ratio > 90%).²⁶

Other interventions that demonstrated improvements in single institution studies included "initial education and phone call assessment with drug diaries, to e-health reminders and assessments with as-needed triage to a clinician"; however, significant tests were not performed for these comparisons.¹

A study that addressed cost savings did not report out-of-pocket costs for patients.³³ Zerillo et al¹ provided limited conclusions based on their review, including a recommendation that initial education and telephone monitoring within the first few weeks of treatment would be beneficial. They consider technological interventions to be an active area of investigation.¹

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PATIENT-CENTERED QUALITY STANDARDS

Based on consensus-based standards statements previously developed by NCO-DA and supported by the evidence for a multicomponent approach to MID, these ASCO/NCODA standards provide statements that are intended to optimize the quality and safety of dispensing of oral anticancer drugs and other cancer therapy–related drugs in the MID setting. In addition, to assist practices that may be considering the adoption of an MID model, consensus-based best practices for the foundational elements that would be recommended before commencing the delivery of MID are included in the Appendix. Health information technology data elements are also included in the Appendix.

MID practices must adhere to the following standards to ensure that dispensing processes are centered on patient safety and education while maximizing treatment outcomes.

Domain 1. Patient-Centered Quality Standards

1.1 Patient relationships

1.1.1. Communications related to the dispensing process, whether directly with the patient or on the patient's behalf, should be documented in the patient record.

1.1.2 Direct access for patients to the MID team is required. Patients should have access to direct phone lines, and after-hours phone numbers should be available. All calls left on voicemail must be returned by the next business day.

1.2. Education

1.2.1 Prior to initiation of an oral anticancer drug, a formalized patient education session should occur with an experienced clinical educator such as a nurse, physician, pharmacist, nurse

practitioner, or physician's assistant. The discussion should include drug name (generic and brand), drug dose, schedule, potential adverse effects and how to properly manage them, fertility (where applicable), treatment goal, duration of therapy, and financial and affordability considerations.

1.2.2 An informed consent form (or assent if applicable) that includes the intent of patient therapy should be reviewed by the patient (and caregiver, if applicable) with a patient educator. After signing the informed consent form, the patient will receive a copy, and the original document will be included in the patient record. The patient should sign the form after all questions are answered, with the patient retaining a copy.

1.2.3 Patient education will include review of the clinical treatment–related parameters for which the patient and/or caregiver should contact the oncology team. Emergency and secondary (non-emergent) points of contact for the patient should be established and documented in the patient record.

1.2.4 At the time of any new therapy initiation, written patient education should be provided. This information should be provided in the language of preference, wherever possible, and the provider should ensure that the patient understands the information contained in the written materials.

1.2.5 Prescribing information required by law must be given to patients.

1.3 Adherence and persistence

The following tools and policies should be part of the MID services to maximize adherence:

1.3.1 Calendars or other scheduling communications are helpful. If a patient calendar is provided, the calendar should include refill dates and medication schedules, clearly outlining specific dates to take medication. Include documentation of calendar information in the patient record.

1.3.2 A systematic comprehensive follow-up process that is documented in the patient record within seven days of dispensing the oral oncolytic is required. Communication to patients is an essential element of patient education to assess adherence and toxicities. Communications should be tailored to presentation, specific medications, and patient comorbidities. Subsequent calls to the patient should be based on individual patient requirements and assessment of patient risk factors (education, comprehension, performance status, tolerance to previous therapies, and so on). The prescriber must be notified directly when issues related to compliance are identified by the MID team.

1.3.3 Pill caddies may be appropriate and helpful for patient adherence.

1.3.4 Continually evaluate electronic and manual tools that may be helpful in advancing patient adherence.

1.3.5 Establish a plan for assessment of patient adherence and toxicity at each

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Results of the Systematic Review for Primary Studies

Study characteristics. Five primary studies met the systematic review inclusion criteria including four observational studies^{8,9,37,38} and one randomized controlled trial.³⁹ Most studies were conducted in the United States,^{8,9,38,39} and one study was conducted in Spain.³⁷ Most observational studies included a preintervention/postintervention comparison, either at a single institution or delivered across multiple sites. Most studies included patients with any tumor site, and one study included patients with castrate-resistant prostate cancer.⁹ The patient

population was prescribed a wide variety of oral anticancer medications. Interventions included (1) pharmacotherapy follow-up/monitoring programs,^{9,37} (2) an automated telephone intervention,³⁹ (3) a workflow modification,⁸ (4) an integrated oral anticancer drugs program, compared with usual care, or a less intense intervention model.³⁸ Most of the interventions had multiple components that were not evaluated separately. Outcomes varied across studies and included adverse events, drug interactions, food interactions, rate of drug discontinuation without notifying a physician, rate of start date of chemotherapy within one week of prescription, adherence to prescription, mean number of interventions per patient, and relative dose intensity (ratio of dose consumed by patient to dose prescribed

clinical encounter. Variances should be documented within the patient record.

1.3.6 Adherence assessment and documentation should include (1) confirmation patient received the prescription, (2) start date for the medication, and (3) verifying that the patient understands how to take the medication, including taking with or without food, taking whole or crushing, safe handling, and so on.

1.3.7 Monitoring of drug toxicity, laboratory tests, and any prescription, over-the-counter, or herbal medication changes. Contact provider in a timely manner to address potential problems/issues.

1.3.8 Discussion of any financial issues that may be affecting adherence by the patient and assessment of the need for increased assistance.

1.4 Safety

The pharmacist or provider must check the following prior to dispensing:

1.4.1 Patient identity should be verified using two patient identifiers (eg, name, date of birth, and address) at the time of entering the prescription and at the time of dispensing the prescription.

1.4.2 The most recent provider note should be reviewed to validate treatment plan (appropriate diagnosis, allergies, correct drug, dose and directions).

1.4.3 Prescriptions for an oral oncolytic, either retained internally for processing or referred to an external pharmacy, will be reviewed by the MID personnel for potential drug interactions and/or potential toxicity risks.

1.4.4 If a patient does not pick up a prescription or accept delivery for an oncolytic, the pharmacist will notify the

prescriber and verify therapy status.

1.4.5 Patient profile is reviewed for duplicate therapies.

1.4.6 The prescription should only be filled after patient education and consent forms have been completed.

1.4.7 Drug interactions must be actively reviewed at each patient encounter. This includes a review of the patient record as well as a conversation with the

patient about recent medication changes, including over-the-counter medications, alternative medicines, and/or herbal therapies.

1.4.8 Do not refill medication unless verified with the prescriber and/or prescriber's agent and the patient/caregiver.

1.4.9 The MID team will verify that a toxicity evaluation and management—visit with a provider has been scheduled for approximately two weeks after initiation of new oncolytic therapy.

1.4.10 Labeling of prescriptions should follow legal labeling requirements.

1.5 Refilling of Prescriptions

1.5.1 Prior to refilling an oral anticancer drug, the MID team will review patient records for clinically relevant information (abnormal laboratories, prescription changes, latest progress note, and cycle of therapy, if appropriate).

1.5.2 Interventions involving a patient's refill of medication should be documented in the patient record (e.g. coordination with intravenous chemotherapy, new medications prescribed). The MID team may need to clarify this intervention with the patient and be prepared to respond to any questions the patient may ask.

1.6 Documentation

1.6.1 Every clinical encounter with a patient will be documented in the patient record. In most cases, this would be an electronic medical record, and the Expert Panel for these standards endorses the use of electronic documentation. All questions posed by the patient regarding his or her therapy will be documented in the patient's record.

1.7 Benefits investigation

1.7.1 All aspects of benefit investigation and patient assistance will be coordinated by the MID team, including prescription coverage and copay determination, copay assistance, and foundation and pharmaceutical industry patient assistance programs. All patients will receive evaluation for financial support.

1.7.2 Benefit verification information should be documented in the patient's record.

1.8 Medication disposal

1.8.1 The MID will have a standard operating procedure in place to ensure the proper disposal of patients' unused medications and expired drugs.

1.8.2 Patient education will include directions to ensure the proper disposal of unwanted or expired medications.

1.8.3 Brochures addressing proper disposal may be helpful in providing locations and addresses of local sites that accept unwanted medications.

1.9 Patient satisfaction

1.9.1 Practices are encouraged to solicit feedback from patients using surveys such as the NCODA patient satisfaction survey, to identify and address continuous improvement opportunities at MID practices.

by oncologist). Study sample sizes ranged from 319 to 272.³⁹

Study outcomes. Adherence to laboratory parameter monitoring, which is used for early identification and management of adverse effects, was significantly improved (OR, 4.95; 95% CI, 1.03 to 29.44) after intervention with a pharmacist-led oral anticancer drugs monitoring program, compared with prior to the start of the program in a study of patients with metastatic castrate-resistant prostate cancer. This study also found a significantly higher mean number of interventions per patient with the monitoring intervention ($P = .002$).⁹

In a study of reminder calls and weekly symptom management calls using an interactive voice response system, compared with weekly standard care and symptom assessment calls

only by interactive voice response, there was no difference in the ratio of dose consumed by the patient to dose prescribed by the oncologist (i.e., relative dose intensity) at any time period up to 12 weeks after treatment. There was a significant difference in the adjusted mean number of symptoms above a severity threshold at the end treatment with this intervention, but this significant difference did not persist during the follow-up time period (12 weeks after treatment).³⁹

Significant differences were found before and after a multi-component workflow modification that included “symptom assessment...adherence questionnaire, improved patient monitoring and management of symptoms.”; significant improvements

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were noted in patients starting drug treatment within one week after prescription (relative risk, 1.74; 95% CI, 1.11 to 2.71), and no patients discontinued drugs without notifying a physician after the workflow modifications were in place.⁸

There were also several outcomes that showed change in a positive direction but did not achieve statistical significance (e.g., a nonsignificant reduction in “interruption of chemotherapy without informing a physician” after the launch of an integrated oral chemotherapy program).³⁸

In summary, interventions that showed a statistically significant effect include:

- A pharmacist-led oral chemotherapy monitoring program improved adherence to laboratory monitoring and increased the mean number of interventions per patient in a single institution study of patients with metastatic castrate-resistant prostate cancer.⁹
- An automated telephone intervention with daily adherence reminder calls was found to improve the mean number of symptoms above a severity threshold immediately after intervention, but this effect did not persist at follow-up.³⁹
- A multicomponent workflow intervention resulted in higher rates of patients starting therapy within one week of prescription and resulted in no patients discontinuing therapy without notifying their physician.⁸

Overall, the systematic review found several studies of multifaceted interventions, many of them including an oncology pharmacist component, that were effective with respect to improving adherence and other patient outcomes. Because these interventions included multiple components that were implemented simultaneously, it is difficult to draw conclusions about which aspects of the interventions were most effective; however, it is likely that the multi-intervention strategies studied here, including patient education about drug interactions, potential toxicity, and other topics, as well as regular follow-up and monitoring, can contribute to improving the quality and safe administration of oral anticancer drugs in the outpatient setting.

In addition, tools and resources were found during systematic review and environmental scan, which may be useful for MID practices.

DISCUSSION

These ASCO/NCODA standards for MID have been developed by a multidisciplinary panel and include an evidence review of interventions to improve outcomes for patients who are being prescribed oral anticancer drugs and supportive care medications in an outpatient setting. Within the standards document, we have provided an updated systematic review of interventions, a table of suggested tools and resources, and

a list of best practice foundational elements. These standards are supportive of ASCO's Quality Oncology Practice Initiative (QOPI) and QOPI Certification Program.

While there is a significant body of literature that demonstrates the benefits of multifaceted interventions, the Expert Panel recognizes the limitations of the evidence base and calls for more prospective controlled research studies to fill gaps in knowledge, such as which specific components of interventions are most effective and which are most applicable to various target populations.

In conclusion, we hope that these standards will advance the quality of care within the emerging delivery model of MID. These standards will be reviewed for currency on an annual basis and revised as new evidence becomes available.

PATIENT AND CLINICIAN COMMUNICATION

For recommendations and strategies to optimize patient clinician communication, see Patient-Clinician Communication: American Society of Clinical Oncology Consensus Guideline.⁴⁰

ADDITIONAL RESOURCES

More information, including slide sets, and clinical tools and resources, is available at www.asco.org/mid-standards. Patient information is available at www.cancer.net and www.ncoda.org/pqi/ and www.oralchemoedsheets.com.

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FORECAST 2020:

PROMISE, WITH A CHANCE OF COUNTERPRODUCTIVITY

As healthcare policy makers grapple with complexity and campaigns, we have to ask: who wins when patients lose?

By Ben Jones

Imagine for a minute that patients were responsible for crafting healthcare policy. Setting aside different needs based on particular diagnoses, how would patients approach the delicate balance of finite resources and a desire for increased coverage?

Although interesting to consider, the question itself shines a light on an often overlooked, but largely bipartisan, consensus: healthcare policy is ultimately about advancing the health and well-being of individual patients. And, therefore, patients should be at the center of healthcare policy.



Ben Jones

This is a basic, yet powerful notion. Laws and regulations are not the end goal of policymaking. Rather, they are tools that impact how, when, and even if patients receive care for their injuries and illnesses.

Fortunately for America's cancer patients, more policymakers are recognizing this reality and working to create policies that put patient needs first.

In order to accomplish this goal, policymakers have made great strides to protect patient access to quality care,

address financial toxicity and increase transparency.

Recognizing that the United States spends more than 17 percent of its gross domestic product on healthcare, almost double the international average¹, policymakers are also exploring value-based care initiatives as one way to curb costs without sacrificing outcomes.

PRO-PATIENT POLICIES

As a result, cancer patients across the country increasingly have access to high quality care and support services at an affordable, transparent price. For example, the Oncology Care Model (OCM) provides enhanced payments to participating providers who deliver high quality care to patients undergoing chemotherapy, while simultaneously aiming to reduce Medicare spending for services below target benchmarks.

Though it's still too early to determine the full impact of the 5-year demonstration program, preliminary evidence suggests that the OCM is reducing the total cost of care for cancer patients², while incentivizing providers to offer enhanced oncology services, thereby improving the

patient experience.

Moreover, policymakers have demonstrably committed to further reducing costs and empowering patients.

An example of this commitment is the prohibition on pharmacy "gag clauses," which had historically prevented pharmacists from telling patients how they can save money on their prescriptions if the cash price of the drug was lower than the price under their insurance plan. In bipartisan fashion, a prohibition on pharmacy gag clauses was signed into law last year. In addition:

▲ The Centers for Medicare & Medicaid Services (CMS) released its Physician Compare dashboard to help Medicare beneficiaries make informed choices about their care;

▲ The Trump Administration unveiled a proposal (now tied up in the courts) to require drug companies to disclose prices in their direct to consum-

er advertising; and,

▲ Congress is debating legislation that would protect patients from surprise medical billing.

Lawmakers and regulators have made great strides to protect patient access to quality care, address financial toxicity and increase transparency.

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Congress and the Administration are even working together to expand one of the most commonsense healthcare reforms—site neutrality—which aims to limit vastly different payment rates and patient costs that are based solely on the site of service.

This unlevel playing field often allows certain facilities to take advantage of artificially higher reimbursement rates for performing the same exact services as are delivered in physician offices—thereby resulting in reduced access and increased costs.

CAUSE FOR CONCERN

We are clearly making progress toward a more patient-centered healthcare system. However, equally as important to achieving this mission, if not more so, is preventing policies that run counter to this goal. Rather than putting patients first, negative policies could quickly put patients at risk.

Some examples of these counterproductive policies include the increased use of co-pay accumulators, retroactive and unpredictable pharmacy fees and restrictive formularies.

In addition, two of the more egregious examples of this blatant disregard for patient-centered policies is the growth in step therapy and continued allowance of prior authorization—two common utilization management techniques that often delay and prevent vulnerable patients from receiving

the precise and individualized treatments prescribed by their physician.

A 2018 survey by the American Medical Association found that more than 91 percent of surveyed physicians reported care delays as a result of prior authorization, 24 percent reported prior authorizations lead to a serious adverse event and 86 percent reported that the

burden associated with prior authorizations for physicians and staff within their practice was high or extremely high.³

Meanwhile, CMS' decision to greenlight the use of step therapy in Medicare Advantage plans is likewise deeply troubling. Step therapy protocols, often called “fail first” because patients are forced to try and fail an insurer-preferred therapy before being approved to receive their doctors' prescribed treatment, make a dangerous assumption that patients have the luxury of time to test a “one size fits all” treatment plan rather than a personalized therapy prescribed by their physician.

In addition to proposals that could further restrict the use of patient assistance programs, which could cause patient out-of-pocket costs to skyrocket, the cancer care community is anxiously awaiting the fate of

another disturbing proposal that would insert a middleman between physicians and patients receiving chemotherapy treatment.

The Administration's proposed Inter-

national Pricing Index (IPI) Model would require practices to purchase Medicare Part B therapies from approved third-party vendors who in turn negotiate drug prices based on an international index. While oncologists support the goal of reducing the cost of cancer drugs, many worry that inserting a vendor in the treatment delivery process would interfere with the physician/patient relationship by allowing for the expanded use of the above utilization management tools.

PUTTING PATIENTS FIRST

If we truly want to put patients first, we must protect access to the most appropriate and convenient care by empowering patients and encouraging efficiencies. Policymakers are making great strides, but in order to be successful they need to focus on avoiding counterproductive policies that negatively impact patients in the name of purported “savings.” Americans deserve a healthcare system that is dedicated to improving outcomes, empowering patients and finding efficiencies—not simply reducing costs on the backs of patients and providers.

As the campaign season kicks into high gear with more and more healthcare policy proposals emerging, we must remember to always keep the patient at the forefront. Failure to do so risks undoing the significant progress we have made in strengthening care for all patients.

▲ Ben Jones is the Vice President of Government Relations & Public Policy for The US Oncology Network, a division of McKesson Corporation.

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Two of the more egregious examples of the blatant disregard for putting patients first are the growth in step therapy and continued allowance of prior authorization.

ONCOLYTIC TREATMENT UPDATES FOR FOLLICULAR LYMPHOMA

By Ciera Patzke, PharmD, BCOP
and Alison Duffy, PharmD, BCOP

Accounting for approximately 20% of all non-Hodgkin's lymphoma (NHL), follicular lymphoma remains the most common subtype of indolent NHL. Although typically indolent in nature, follicular lymphoma remains an ongoing challenge.

While response rates >90% can be achieved with rituximab-based chemo-immunotherapy in patients with advanced stage disease, complete remission rates are significantly lower and patients will undoubtedly relapse.

The inability to achieve a complete remission and an early progression of disease have recently been determined to be indicators of poorer long-term outcomes.¹ A greater understanding of follicular lymphoma pathogenesis has facilitated the development of targeted therapies, which may improve standard treatment approaches.

Newer antibody-based therapies, immune-directed agents and small-molecule inhibitors are becoming incorporated into the treatment algorithms for patients with follicular lymphoma in an effort to both improve long-term efficacy outcomes and tolerability for patients.²

This article will focus specifically on National Comprehensive Cancer Network (NCCN) guideline recommendations and recent primary literature treatment updates.

FIRST-LINE THERAPIES

For early-stage follicular lymphoma, NCCN guideline recommendations remain unchanged.¹ For non-bulky disease, radiation therapy continues to serve as the mainstay of treatment. For bulky stage disease, anti-CD20 monoclonal antibodies serve as the backbone to treatment, with consideration for the addition of chemotherapy with or without radiation therapy.

For stage III or IV follicular lymphoma, NCCN still equally recommends bendamustine, CHOP, and CVP, with the addition of either rituximab or obinutuzumab as the preferred first-line regimens.¹ Based on the BRIGHT study, increasing support exists for the preferential use of bendamustine rituximab (BR) over the RCHOP or RCVP regimens based on improved five-year progression free survival rates (66% vs 56%); this has not yet changed NCCN's preference of first-line regimens.³

Ciera Patzke, MD

Alison Duffy, MD

A new addition to NCCN's list of preferred regimens for stage III or IV follicular lymphoma is rituximab plus lenalidomide ("R2" regimen), based on the RELEVANCE trial.^{1,4} Patients received rituximab 375mg/m² IV on days 1, 8, 15, and 22 of cycle 1, and days 1 of cycles 2 through 6, and then every eight weeks thereafter for 12 cycles. Lenalidomide was dosed as 20mg PO daily on days 2 through 22 of each 28-day cycle for six cycles, and then 10mg daily for 12 cycles.

This trial established this regimen as an equally effective option for patients with previously untreated follicular

lymphoma, based on similar overall response rates and progression free survival when compared to rituximab plus chemotherapy (investigator's choice of bendamustine, CHOP, or CVP).

Patients treated with R2 experienced different toxicities, with lower rates of most high-grade toxicities such as neutropenia and febrile neutropenia but significantly higher cutaneous reactions.

Notably, this trial was originally designed as a superiority trial, which it did fail to meet as an endpoint. Other considerations that may limit R2's use as a first-line regimen include financial toxicity (with its duration being much longer compared to a standard six cycles of chemo-immunotherapy – CD20-directed maintenance discussions aside), as well as any concerns for medication nonadherence.

At the American Society of Hematology (ASH) Annual Meeting 2019, a phase 2 trial was presented that evaluated a similar regimen of obinutuzumab plus lenalidomide ("O-len" regimen) in previously untreated follicular lymphoma.⁵ This regimen has previously shown promise in the relapsed/refractory setting, demonstrating a two year PFS of 65% and OS of 87%.⁶

Though the present study lacks a comparator arm, authors report an astounding 94% CR rate and 96% estimated two-year PFS, with only two of 90 patients experiencing a progression after a median follow-up of 22 months.

Still, NCCN has yet to incorporate O-len into its recommendations for either first or later lines of therapy.

SUBSEQUENT LINES OF THERAPIES

At least 20% of patients with follicular lymphoma experience early relapse,

CONTINUED ON NEXT PAGE

FOLLICULAR LYMPHOMA

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within two years of initiating frontline treatment, particularly based on high-risk FLIPI scores.

These patients have markedly lower five-year overall survival (50-90%). Drug resistance and cumulative toxicities are concerns. “Double-refractory” follicular lymphoma may be refractory to chemotherapy and antibody therapy. Multiple therapies lead to additive toxicities and potentially long-term complications.

Anti-CD20 therapies \pm chemotherapy are preferred treatment options as second-line options but many patients develop resistance.¹ Phosphoinositide 3-kinase (PI3K) inhibitors have demonstrated efficacy following two prior lines of treatment.⁷⁻⁸

Rituximab plus lenalidomide (“R2” regimen) as a second-line regimen may be more promising, as compared to its use in the front-line setting, based on the AUGMENT study.⁹

This trial was largely comprised of follicular lymphoma patients (82%) and reported an impressive median progression free survival of 39.4 months with R2 compared to rituximab monotherapy (14.1 months).

This regimen may be particularly useful in patients with early first relapse (less than two years) where re-challenging with the same first-line regimen is not preferable and as therapies such as phosphoinositide 3-kinase (PI3K) inhibitors are not yet available for use as these agents should be reserved for after failing two prior therapies.

Ultimately, the decision to use R2 versus other regimens should remain an individualized decision based on the patient. For patients with relapsed/refractory follicular lymphoma, a novel triplet regimen of polatuzumab vedotin, obinutuzumab, and lenalidomide was also presented at the ASH Annual Meeting 2019.¹⁰ This phase Ib/II trial included a heavily pre-treated population, yet still demonstrated an objective response

While anti-CD20 therapies with or without chemotherapy and radiation remain as mainstays of therapy in the front-line setting of follicular lymphoma treatment, the treatment landscape continues to evolve both in the front-line and relapsed/refractory setting.

rate of 76%. Fifteen of the 21 patients that were refractory to their most recent treatment achieved complete remission.

The safety profile of this regimen was as expected, with neutropenia, thrombocytopenia, infection, and anemia being the most common grade 3 or 4 adverse events. All patients experienced at least one adverse event.

SUMMARY

Treatment selection and initiation is often dictated by age, comorbidities, and disease-specific risk factors. While anti-CD20 therapies with or without chemotherapy and radiation remain as mainstays of therapy in the front-line setting of follicular lymphoma treatment, the treatment landscape continues to evolve both in the front-line and relapsed/refractory setting.

Pharmacists play an integral role in disease state management including symptom management, adherence, education and monitoring, optimizing risk

evaluation mitigation strategy (REMS) programs, and recommending cost-savings initiative when possible.

▲ Ciera Patzke, MD, and Alison Duffy, MD, are Clinical Pharmacy Specialists in Hematology/Oncology at University of Maryland Greenebaum Comprehensive Cancer Center. Duffy is also an Associate Professor at University of Maryland School of Pharmacy.

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PHARMACEUTICAL PARTNERS **VALUE** **FEEDBACK** FROM PRACTICE LEADERS

NCODA's first Oncology Institute provided more than 180 pharmaceutical industry and GPO representatives a unique opportunity to meet with oncology practice leaders from across the country. Many participants said the event gave them a chance to learn first-hand about the challenges that oncology practices and patients face today:

▲ "It's really good to come here and get an education and updates on what the hot topics are and, probably more important, where the market is heading," said **Jean-Luc Frande**, Director of Oncology Corporate Accounts and Health Systems for Astellas Pharma US.



Jean-Luc Frande

▲ "I'd like to gain an understanding of what more we can do as a company to partner with NCODA to the benefit of the practices and the patients," said **Tim Holmes**, National Sales Director-Oncotherapy for Bayer Pharmaceuticals.



Tim Holmes

▲ "I'm thrilled to have manufacturers in the audience today," said **Valerie Russo**, Director of In-Office Dispensing Operations for U.S. Oncology/McKesson Specialty Health. "That is a platform I have not been a part of previously."



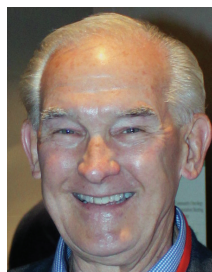
Valerie Russo

The first-of-

its-kind institute, hosted by 20 practice leaders and NCODA Executive Council members, was held Aug. 21, 2019, in Chicago.

"We constantly work to create collaborations with all of the stakeholders and, of course, one of the most important is our pharmaceutical partners," said

Bob Orzechowski, NCODA Executive Council member and Chief Operating Officer at Lancaster Cancer Center in Lancaster, Pennsylvania.



Bob Orzechowski

"They are the source of the products that we use to treat our patients, so it's extremely important to get face time with them and give them the opportunity to pose issues and questions of concerns that they have."

Sessions focused on establishment of meaningful relationships with practices, the effect of PBMs and their impact on oncology, an overview of vertical integration, updates on USP 797 and 800, implementation of biosimilars and a discussion of upcoming legislation.

The event generated a slew of questions from pharmaceutical representatives, especially concerning the effectiveness and appropriateness of marketing methods and material, and ways to improve their relationships with oncology practices.

"I think one of the points that resonated today was how to realign some of the funding channels that pharmaceutical companies have," Orzechowski said.

Another was the effectiveness of utilizing NCODA initiatives, such as

Treatment Support Kits and Positive Quality Interventions.

Robert Doig, Senior Director of Market Access for Puma Biotechnology, Inc., noted the value of NCODA's ability to provide unbranded patient education.



Robert Doig

"All pharma usually develops support kits to help patients," Doig said. They're fair and balanced in terms of safety with warnings for the patient. But the challenge that most companies have is that there are certain institutions that don't allow the distribution of branded materials."

Since NCODA's Treatment Support Kits are unbranded, they help fill this critical void, Doig said. "They reinforce the importance of side-effect management and provide the tools to help the patients do so. They provide tremendous value."

Frande of Astellas emphasized the value of NCODA's Positive Quality Intervention (PQI) initiatives.

"We currently have a PQI and a PQI In Action for Xospata," Frande said. Xospata, or gilteritinib, is the first new treatment for relapsed or refractory FLT3 mutation-positive acute myeloid leukemia in about 40 years. Proper patient education is critical for this breakthrough oral oncolytic, he said.

"We work with NCODA to make sure the education that needs to be done is done because it's such a paradigm change," Frande said. "It's been a great work in progress."

Another key takeaway was NCODA's

unique ability to help connect all aspects of the oncology continuum – from manufacturers and distributors all the way through to practices and patients.



Deepak Singh

Deepak Singh,
Director of Clinical
Value and Out-
comes at Seattle

Genetics, said partnering with NCODA gave his company a chance to collaborate with community oncology.

“Instead of working with payers’ health plans, this gives us an opportunity to connect with community oncology all across the country to really understand how we empower those providing care at the point of service,” Singh said.

Michael Reff, Executive Director and

Founder of NCODA, said the Institute provided yet another platform for NCODA members to share insights with industry partners.

“Promoting better understanding and establishing closer relationships benefits all aspects of oncology,” Reff said.

“NCODA’s goal is to continue offering the Oncology Institute each year for our pharmaceutical and GPO partners.”

WE ARE NCODA

AN ORAL CHEMOTHERAPY NURSE NAVIGATOR AND A PATIENT CARE COORDINATOR TELL THEIR STORIES

ELIZABETH BETTENCOURT, MSN, RN, OCN

TITLE: Oral Chemotherapy Nurse Navigator at Palo Alto Medical Foundation/Sutter Health in Sunnyvale, California.

TELL US ABOUT YOUR

BACKGROUND: I have been working in the oncology department in varying roles for 27 years. I have been the only oral chemotherapy nurse navigator for more than 10 years. We recently added three more nurses to our program. Sutter Health does not have medically integrated dispensing services. Pharmaceutical dispensing is mandated by specialty pharmacy contracts with individual patient insurances.

RESPONSIBILITIES: My role as an oral chemotherapy nurse navigator involves all aspects of care of patients receiving oral chemotherapy, including patient access to medication, education, toxicity and adherence assessments. I work with patients, pharmacies, drug companies, insurance companies and charitable organizations.

This role provides me with an opportunity to support, encourage and educate patients throughout the course of treatment.

There are many challenges with supporting patients on oral oncolytics and I have found it invaluable to connect with the oncology community nationally and internationally to keep abreast of all things related to oral oncolytics.

WHEN DID YOU JOIN NCODA? In 2018.

WHY? Being an active member of NCODA has allowed me to connect with other nurses involved in the care of patients on oral oncolytics. Through participation in the NCODA Nursing Committee I have been able to share



what I have learned during my many years working with oral oncolytics, assist with the development of resources for other nurses, and provide education to and support nurses with the development of their own oral oncolytic programs. These connections also have provided me with opportunities to further expand my exposure to more nurses within the oncology community.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? NCODA provides many resources

that I have been able to adapt and utilize in my oral oncolytic program.

The Oral Chemotherapy Education (OCE)

sheets are excellent comprehensive patient education medication sheets that I have adapted for use in my program.

I utilize the Positive Quality Interventions (PQIs) for drugs and side effects along with the Oncology Nursing Society's Putting Evidence into Practice (PEP) guidelines to assist with management of patients, as well as educating nursing staff.

The NCODA Nursing Committee recently completed work on a Welcome Letter which I will be adapting for use within my program. This has been a long-overdue document that I have wanted to develop for my program. I anticipate the use of this letter to reduce patient anxiety by providing important information about the prescription process and

the oral oncolytic team during the first conversation with the oncologist about treatment.

Finally, I use the Financial Assistance Tool frequently to assist patients who need help with paying for medication. This reference allows me to quickly access the correct resource for a specific drug.

KARI BUCK, LPN, GC

TITLE: Patient Care Coordinator at Bassett Cancer Center in Cooperstown, New York.

TELL US ABOUT YOUR BACKGROUND:

I have worked at Bassett Medical Center for the past 24 years. My last 12 years have been in the Oncology Department as an Advanced LPN with a certification in gerontology.

Bassett Medical Center's main campus is in Cooperstown, with additional oncology clinics in Herkimer, Oneonta and Cobleskill. In my current role, I focus on organizing pharmacies, insurance companies and charitable organizations to obtain oral oncolytic in a timely manner at minimal cost to our patients.

Additionally, I serve patients through follow-up phone calls to assess adherence and toxicity and help guide patients through needed lab and clinic visits.

WHEN DID YOU JOIN NCODA? In 2018, I was encouraged to join NCODA by Ricki Foreman, RPh, Region 8 Regional Leader. I attended my first NCODA event at the Fall Summit that year. I met many wonderful people there with exceptional ideas, insight and tools. I returned from the conference with vigor and a mission to have my colleagues join NCODA. So far I have successfully recruited 10 members!

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE?

In 2018, Bassett Medical Center was involved in the beta test for NCODA capecitabine Treatment Support Kit (TSK). The TSK was well-received by patients and provided insight into patient's needs regarding side effect management.

In 2019, I officially joined the NCODA Nursing Committee and initiated use of the NCODA Cost and Waste Avoidance Tracker.

Since joining NCODA's Nursing Committee, my patient-tracking process has included use of the *First Fill* form, *After the First Fill* form, and Oral Chemotherapy Education (OCE) sheets.

Having uniform communication tools has facilitated clearer interactions with my colleagues regarding the status of our oral oncology patients.

At our facility we do not have an oral nurse navigator; the work regularly performed



The NCODA conferences serve as excellent opportunities to network with fellow professionals. I especially enjoy meeting members of the Nursing Committee in person.

by a nurse navigator is shared amongst many staff and these tools have proved invaluable. Our patients especially utilize the clear, concise information offered by OCE sheets.

Additionally, OCE sheets provide consistency in patient education amongst staff. Also, I am always interested to learn and hear about the practices and challenges of other oncology facilities during the NCODA Monthly Webinars.

In October 2019, I attended my NCODA second Fall Summit in Orlando. I am looking forward to seeing everyone again this spring in Dallas at the 2020 Spring Summit.

The NCODA conferences serve as excellent opportunities to network with fellow professionals. I especially enjoy meeting members of the Nursing Committee in person and reading the poster presentations highlighting NCODA members' great work.

LISA HARRISON: AMERISOURCEBERGEN

AmerisourceBergen, through ION Solutions and Oncology Supply, has been a strong supporter of NCODA. Share with us areas where AmerisourceBergen and NCODA have collaborated in the past, as well as any initiatives that we may be working on in the future.

AmerisourceBergen and NCODA have been collaborative partners for five years. In fact, NCODA's founder, Michael Reff, was formerly a member of ION Solutions, AmerisourceBergen's physician service organization and GPO. We have been a collaborator since the very early stages of NCODA's development to discuss how to differentiate the organization from others in the industry and provide the added value that practices and patients are looking for.

Since then, we have continuously advocated for NCODA as a valuable resource for our member practices. We also encourage the manufacturers we work with to partner with NCODA to better understand the needs of community oncologists. At AmerisourceBergen, we truly believe collaboration across the industry is the key to innovative solutions.

We are currently supporting NCODA's efforts to develop an accreditation standard alongside the American Society of Clinical Oncology (ASCO). Once that effort comes to fruition and is available to the market, AmerisourceBergen and ION Solutions will advocate to get it recognized by payers and assist our member practices in meeting those standards.

As we expect challenges in the payer landscape, we are focused on advocating for the value of Medically-Integrated Dispensing (MID) to payers/PBMs. To that end, we would like to continue this dialogue and coordinate efforts to promote the value of MID.

In what ways has NCODA brought value to your organization? Are any of the NCODA initiatives particularly useful from your perspective?

Overall, NCODA has been very effective at driving the industry standard for MID. An established standard of care sets expectations for practices of all sizes and gives AmerisourceBergen a framework to reference in the consulting services we provide for practices.

NCODA also works to establish Positive



Lisa Harrison, RPh, is President of Oncology Supply, a leading provider of oncology products and supportive services to community practices and a part of AmerisourceBergen, a global healthcare solutions company headquartered in Valley Forge, Pennsylvania.

Formerly, Ms. Harrison served as a Senior Vice President in AmerisourceBergen's Specialty Physician Services. In that role, she oversaw a suite of solutions that enhanced business performance for community practices and empowered patient care.

Quality Interventions (PQIs) for existing and emerging therapies, which outline product-specific clinical management guidelines that should be adhered to when working with patients. We think PQIs help lead to better patient outcomes, which is why we not only promote the use of them within our member practices but also encourage manufacturers to collaborate with NCODA to develop PQIs for their products.

Can you share with us any examples of how NCODA resources / initiatives have brought value to dispensing practices?

Community oncology practices are often small and strapped for time and resources, so the fact that they can leverage NCODA's tools and initiatives without having to do the heavy lifting is extremely beneficial. On the patient education front, for example, NCODA's Oral Chemotherapy Education (OCE) sheets are great resources for patients and their caregivers. Member prac-

tices can pass them on to their patients to help answer drug-related questions and empower them to become more active participants in their treatment journey.

Additionally, there is value in tracking lost dollars with the current specialty environment. As such, the Cost Avoidance & Waste Tracker (CAWT) tool has been important in educating payers on how dollars can be saved through MID.

Is there anything specifically that NCODA can do in the future to continue to support AmerisourceBergen and its respective member practices?

As we look to the future, we believe that maintaining community oncology practices' ability to fill prescriptions within their practice will be one of our biggest challenges. AmerisourceBergen is committed to working alongside industry groups like NCODA to advocate for MID.

We believe in the value of MID because it enables a level of care coordination that is central to a patient's success on therapy. When practices fill prescriptions in-house, they have the ability to work through insurance challenges with the patient on-site and increase speed to therapy. When prescriptions are filled outside of the practice, it separates the patient from the point of care, causes strains in communication and can result in treatment delays. To that end, AmerisourceBergen will welcome any efforts, such as additional accreditations and certifications, that will add credibility and further validate MID in the eyes of payers.

Oral oncology is growing dramatically, with up to a half dozen new oncolytics receiving FDA approval every six months. Many of these drugs are very specialized and expensive. How do GPOs and distributors deal with these challenges, while still delivering added-value to their members?

We have devoted a number of resources to supporting medically-integrated dispensaries. Within ION Solutions and Oncology Supply, we currently have six clinical practice consultants, five licensed pharmacists, four certified pharmacy technicians and two certified oncology pharmacists out in the field, who are dedicated to helping our practices improve operational flow, cap-

CONTINUED ON NEXT PAGE

We truly believe that MID models in oncology drive the highest quality of care for patients and we will always be supportive of NCODA's efforts to tell that story.

Lisa Harrison
AmerisourceBergen

LISA HARRISON

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ture prescriptions and stay abreast of new and emerging therapies coming to market. The full team is accredited by the Accreditation Commission for Health Care (ACHC), and they assist our practices in achieving the accreditation, as well. On the GPO side, ION Solutions works with manufacturers as early as 18 months prior to a new drug launch to ensure our practices will have access to the product and negotiate contracts that deliver the most value.

From your perspective, what are the greatest challenges you see in the short- and long-term future?

Across the industry, we should look for every opportunity to have proactive and collaborative conversations on the issues that matter to us and our patients. As I mentioned, I think one of our biggest challenges will be protecting

MID, so it will be important for organizations like AmerisourceBergen and NCODA to align on and advocate for the value that physician and retail pharmacy dispensing models provide. The more stakeholders we have driving the same message, the better chance we have of achieving a solution that works for everyone.

As you know, NCODA is GPO/Distributor-agnostic. In your opinion, what are the benefits of this as it relates to NCODA being able to provide collaborative/unique resources to cancer centers across the country?

We truly believe that MID models in oncology drive the highest quality of care for patients and we will always be supportive of NCODA's efforts to tell that story. We want to see the industry investing in the model, regardless of distributor or GPO. The more stakeholders to whom we can communicate the value of MID, the better.

Start Utilizing the Patient Satisfaction Survey Today!

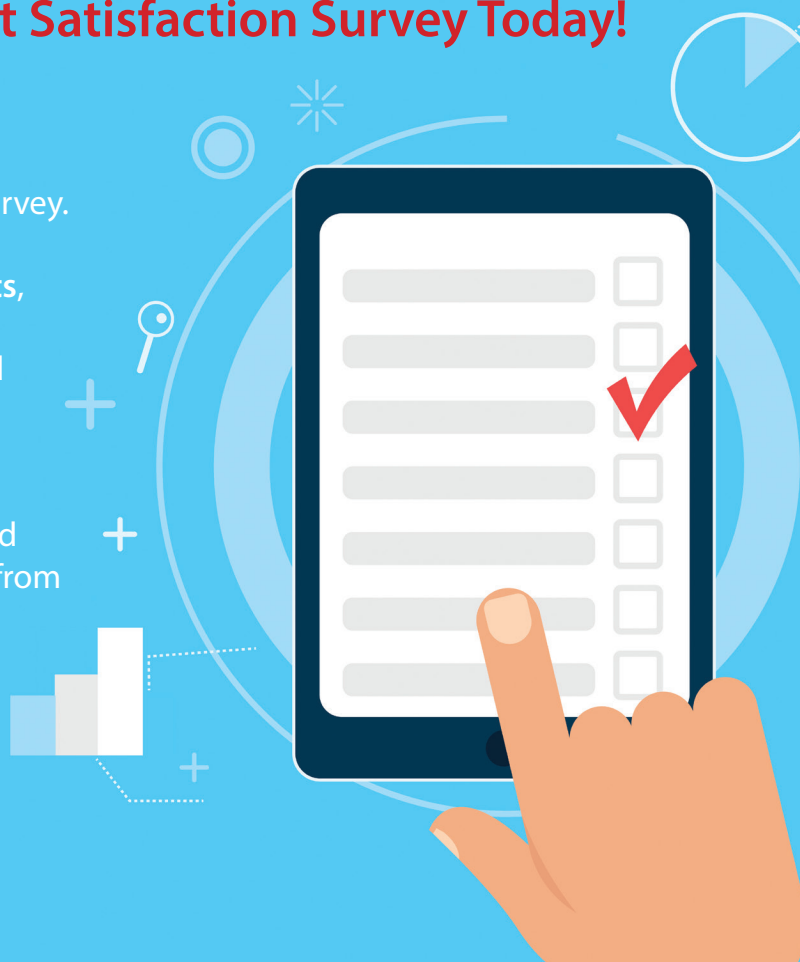
NCODA, in collaboration with Syracuse University's Maxwell School, has developed a Patient Satisfaction Survey.

This survey quantifies data that **patients, providers and payers** are interested in. Responses from this survey help us and our member organizations identify opportunities for improvement.

Over **1,200** surveys have been collected with a **95% overall satisfaction rate** from NCODA practices.



Learn more at
www.ncoda.org/other



NCODA PSO CHAPTER TAKES ROOT AT ALBANY COLLEGE OF PHARMACY

By Shayna DeMari

Albany College of Pharmacy and Health Sciences (ACPHS) students were introduced to NCODA during the 2019 Fall Involvement Fair.

Since many of us are seeking opportunities in oncology pharmacy, we were very interested in starting an NCODA Professional Student Organization chapter on campus. That interest led to a general information meeting.

Dr. Matthew Yacobucci, PharmD, who later became NCODA's PSO chapter faculty advisor at ACPHS, and Stephen Ziter, NCODA Senior Manager of Stakeholder Engagement, discussed the organization's commitment to patient care.

They also reviewed collaborations our PSO chapter members could take part in. Following the meeting, it was evident that an NCODA PSO chapter would thrive at ACPHS.

In November 2019, our PSO chapter organized a trip to volunteer at the Ronald McDonald House in Albany, New York. Ronald McDonald House is a non-profit organization that provides a home environment for families while their children battle cancer and other serious conditions at Albany Medical Center Hospital.

This incredible orga-



Above: Members of the NCODA Professional Student chapter of Albany College of Pharmacy and Health Sciences visit New York Oncology Hematology.



Left: Chapter members volunteer at Ronald McDonald House in Albany.

nization needs constant volunteer help to operate, and the ACPHS PSO chapter members were eager to sign up. The students cooked and served a big breakfast for the families staying at the house.

Also during the visit, the students were given a tour of the facility and learned about the history of the organization. This event introduced students to the widespread effects of cancer on families, and

showed students what they can do to get involved and give back to the community.

Later that month, NCODA assisted us with organizing two events for our PSO members. The first event was a webinar presentation given by a previous graduate of ACPHS who is currently working for a pharmaceutical company that develops anti-cancer medications. The presenter spoke for more than an hour about her experience after graduating from ACPHS, and provided students with tips when applying for fellowship programs during their final

academic year.

The second event was an opportunity to visit New York Oncology Hematology to see first hand how a Medically Integrated Pharmacy operates.

Members of our chapter really got a sense for how NCODA tools and resources – such as Oral Chemotherapy Education sheets and Positive Quality Intervention documents – help members of a specific medically integrated team.

Although students receive didactic exposure to oncology in the fifth year of the Doctor of Pharmacy program, there is still so much more that students can learn by being involved in NCODA's Professional Student Organization. Our chapter already has motivated students to learn more about oncology.

NCODA has been an amazing asset to our campus by encouraging student involvement in the community, inciting a larger interest in pursuing oncology pharmacy as a career, exposing students to the newest oncology drugs and innovations and much more. We are thankful to NCODA for establishing a PSO chapter at ACPHS, and we hope it continues to grow and attract more students.

▲ **Shayna DeMari** is a P3 student at Albany College of Pharmacy and Health Sciences in Albany, New York. She is also an active member of the college's NCODA's Professional Student Organization chapter.

THE IMPORTANCE OF REPORTING ADVERSE DRUG REACTIONS

By Eric P. Borrelli PharmD, MBA,
& Conor G. McGladrigan, PharmD

Randomized controlled trials (RCT) are considered one of the highest quality study designs and their results play an important role in evidence-based medicine.¹

Although RCTs have distinct advantages and are required to receive market approval from the Food and Drug Administration (FDA), they also have important limitations that must be understood when interpreting their results:

- RCTs for new medications include only a small number of patients, typically between 100 and 4,000 patients.²
- In order to reduce the risk of potential confounders, RCTs have strict inclusion and exclusion criteria. This leads to excluding potentially important patient populations such as pediatrics, geriatrics and pregnant women, as well as patients with significant comorbidities or concurrent medications.³
- Potential biases in study design and data analysis can be problematic, and under-recruitment of minority and low-socioeconomic populations is concerning, as well.

These factors mean that data from RCTs may not always be generalizable to the population of real-world patients who will ultimately receive these medications.

In oncology, this inability to extrapolate is intensified. The FDA allows for certain new medications to be approved through breakthrough or accelerated approval designations.

These pathways allow the primary outcome for the RCT to be a surrogate

outcome if the surrogate has been validated. A surrogate outcome is a marker that is not a direct measure of clinical benefit, but is known or reasonably likely to predict clinical benefit.⁴

Accelerated approval may be granted for a serious condition if the medication fulfills an unmet medical need.^{5,6}

Using surrogates as primary outcomes reduces the follow-up time needed for clinical trials to assess safety and efficacy. In addition, it allows for reduced sample sizes when the condition of interest is rare or uncommon.^{7,8} From 2009 to 2014, 66 percent (55 of 83) of oncology drug approvals were based on surrogate endpoints.⁹

The World Health Organization defines an adverse drug reaction (ADR) as rare if it occurs between one in 1,000 and

one in 10,000 patients, and as very rare if it occurs in fewer than one in 1,000 patients.

The median targeted sample size for oncology RCTs is estimated to be less than 600 patients.¹⁰ Due to small RCT sample sizes, it is likely these trials do not generate enough data to observe rare or very rare ADRs.

With most agents in oncology approved under accelerated pathways, the established safety of these agents is even less certain. This highlights the growing need of pharmaco-vigilance and adverse event reporting.

One way that patients, clinicians and caregivers can improve safety data is by reporting suspected ADRs to the FDA's Adverse Event Reporting System

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ADVERSE DRUG REACTIONS

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(FAERS). ADR reporting is voluntary for patients and physicians, however pharmaceutical manufacturers are required to submit ADR reports to the FAERS database anytime they become aware that a reaction has occurred.

Data from the FAERS database is publicly available as raw data files, allowing researchers, as well as the public, to assess potential risks associated with certain medications. While there is a lot of information that can be gathered by assessing these FAERS data files, there are important limitations that must be understood.

First and foremost, determining the incidence or prevalence of ADRs is not possible because reporting is not mandatory, and therefore there is no denominator in terms of total patient population exposed to a medication.

Also, causality does not need to be confirmed before a drug specific ADR is submitted. There are some statistical methods available that allow researchers to detect significant safety signals such as calculating the reporting odds ratio (ROR) and proportional reporting ratio (PRR) – a more in-depth discussion of these methods available in other literature.^{11,12}

Studies utilizing FAERS data are meant to be hypothesis generating, requiring future studies to confirm the potential association and causality of medication related adverse events.¹³

Over the years, numerous medications have been removed from the market and new warning labels added to package inserts due to safety risks identified post marketing studies, including FAERS analyses.¹⁴ Approximately 10% of medications that were approved by the FDA between 1975 and 1999 had a new black box warning added to their label post-approval.¹⁵

This highlights the fact that not only at product launch, but even after years on the market, the full safety profile and

risks associated with medications may not be fully known.

It is important that members of the healthcare team should report adverse events, especially for newly approved agents. Even so, safety reporting from clinicians has been less frequent than expected.¹⁶

If more clinicians and patients report suspected ADRs, potential risks of medications may be found sooner, especially in oncology. More frequent reporting may mean identifying treatment emergent adverse reactions earlier, which can improve patient outcomes.

Adverse events can be reported to the pharmaceutical company of said medication or directly to the FDA through their MedWatch website at: www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

▲ **Eric Borrelli** is a PhD student in health outcomes research and graduate research assistant at the University of Rhode Island College of Pharmacy. **Conor McGladrigan** is an Outpatient Hematology/Oncology Pharmacist at the Mass General North Shore Cancer Center and is earning his JD in the evening program at New England Law | Boston.

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SUPPORTIVE CARE TEAMS MAKE EXCELLENT CANCER CARE POSSIBLE

*To cure sometimes
to relieve often
to comfort always*

Anonymous, 15th Century AD

By Andrew N. Davies, MD, FRCP

Supportive care is an increasingly important aspect of modern oncology, but the term remains misunderstood by many healthcare professionals.

A number of definitions have been suggested,¹ and these definitions are often quite variable in phrasing.

The Multinational Association of Supportive Care in Cancer (MASCC) definition of supportive care,² which summarises the essential aspects of “true” modern supportive care, i.e. the management of the complications of the cancer and/or the cancer treatment throughout the entire cancer journey and irrespective of the actual outcome (see Box 1).



Andrew Davies

MASCC is the international, multi-professional organization

that promotes the development of evidence-based supportive care within oncology².

Recently, MASCC has initiated an accreditation scheme for “MASCC-Designated Centers of Excellence in Supportive Care in Cancer,” which recognizes oncology centers that provide completely integrated, best-practice (evidence-based) supportive care².

MASCC states that “supportive care makes excellent cancer care possible”².

BOX 1: MASCC DEFINITION OF SUPPORTIVE CARE

Supportive care is “the prevention and management of the adverse effects of cancer and its treatment. This includes management of physical and psychological symptoms and side effects across the continuum of the cancer experience from diagnosis through treatment to post-treatment care. Enhancing rehabilitation, secondary cancer prevention, survivorship, and end-of-life care are integral to supportive care.”

– MASCC, 2020

Thus, the potential benefits of supportive care for patients include decreased morbidity, improved quality of life, and potentially decreased mortality (i.e. secondary to optimal cancer treatment). The potential benefits of supportive care for healthcare services include decreased utilization of healthcare resources (and improved treatment outcomes).³

Indeed, supportive care offers patients more than many so-called “palliative” oncological treatments, and it should be considered an essential component of modern oncology (and not just an optional extra).

As discussed, supportive care encompasses the entire cancer journey, and so necessitates the involvement of most clinical specialties, and many non-clinical services (see Figure 1). Indeed, modern supportive care cannot be provided by a single clinical specialty (or a single professional group).

However, as with other cancer multidisciplinary teams, a dedicated “core team” is needed to manage everyday problems, with timely input from the “extended team” as and when the need arises. Importantly, the core team needs specific education and training in the principles of supportive care.

Supportive care has been used as a

euphemism for palliative care (or “early” palliative care)⁴, and research suggests that a change in name (from palliative care to supportive care) results in more referrals, and also earlier referrals, to hospital-based services.⁵

Palliative care is an integral component of supportive care, but supportive care is much more than palliative care. Moreover, although palliative care professionals are often “core” members of many supportive care services, other healthcare professionals (with alternative competencies) are equally important members of these supportive care services (see Figure 1).

As discussed, symptom control is one of the major aspects of supportive care. Palliative care professionals are generally proficient in managing symptoms in patients with advanced cancer, but the management of patients at other stages may need to be different, and the management of symptoms secondary to cancer treatment is often very different.

For example, opioid analgesics may be an appropriate intervention for pain in patients with advanced cancer, but may be a less-appropriate intervention for pain in cancer survivors. Similarly, the antiemetics used to treat nausea and vomiting in patients with advanced cancer,⁶ are seldom the antiemetics used to treat nausea and vomiting due to anti-cancer treatment (and vice versa).⁷

Thus, palliative care professionals also need specific education and training in aspects of supportive care.

Finally, the development of specialist supportive care services must be supported by the education/training of the wider oncology workforce in the principles of supportive care (and the management of common problems).

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SUPPORTIVE CARE

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Indeed, specialist supportive care services will only ever be able to see the “tip of the iceberg,” and so we’ll need to focus on more complex problems (and ones requiring specialist interventions).

Moreover, for example, it is much more appropriate for the team that gives the oncological intervention to manage the adverse effects of that oncological intervention.

*To cure sometimes
to control often
to ‘support’ always*

Palliative Medicine physician, 21st Century AD

▲ **Andrew N. Davies**, MD, FRCP, is a consultant in Palliative Medicine at St. Luke’s Cancer Centre, Guildford, United Kingdom, and president-elect of the Multinational Association of Supportive Care in Cancer (MASCC).

FIGURE 1: EXTENDED SUPPORTIVE CARE TEAM



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NCODA HONORS BRITNY ROGALA, NORA HANSEN FOR THEIR WORK

The recipients of NCODA's 2019 Living the Mission Award were Britny Rogala, PharmD, BCOP, and Nora Hansen, CPhT.

The two healthcare professionals, selected from a group of 12 nominees, received their awards Oct. 25 during NCODA's 2019 Fall Summit at the Gaylord Palms Resort & Convention Center in Orlando, Florida.

BRITNY ROGALA

Rogala was nominated for her work on NCODA's Oral Chemotherapy Education committee.

"I joined NCODA in the fall of 2017, after Mike Reff and Josh Nubla came to visit campus," Rogala said. "It was at that time I learned about the Oral Chemotherapy Education sheets and felt impassioned to help with the project."

"I had previously helped to implement pharmacist-led oral chemotherapy education and monitoring programs and wanted to share my experiences with the group," she explained. "Shortly after I was asked to help lead the committee."

Rogala is a Clinical Assistant Professor at the University of Rhode Island (URI). Her clinical practice site is Women & Infants Hospital. She also coordinates the university's oncology curriculum and serves as a preceptor in oncology for pharmacy students.

A faculty co-advisor for the university's chapter of the Student National Pharmaceutical Association, Rogala also helped establish the NCODA Professional Student Organization chapter at URI.

"As an assistant professor, students are always one of my priorities," Rogala said. "So, when I heard that NCODA



ABOVE: Nora Hansen (left) and Britny Rogala were honored at the 2019 Fall Summit.

LEFT: Rogala, (left) a Clinical Assistant Professor at the University of Rhode Island, also serves as faculty co-advisor for URI's Student National Pharmaceutical Association and helped establish the school's NCODA Professional Student Organization chapter.

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ACHIEVEMENTS

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wanted to establish student organizations, it was a no-brainer that URI would create a chapter. It's an amazing opportunity for students, because they typically don't get exposure to oncology until their last didactic semester. Now they are learning bits and pieces as soon as freshman year."

Rogala said receiving the award was extremely humbling.

"For me, NCODA has been a refreshing organizational experience, where the patient is at the center of everything we do," she said.

NORA HANSEN

Hansen was nominated for her role as co-chair of the 2019 Fall Summit and the 2019 and 2020 Spring Forums, as well as her role of Midwest Regional Leader and other leadership initiatives.

"I'm thankful for all that NCODA has done for me," Hansen, a pharmacy technician with Illinois Cancer Specialists, said after receiving the award. "It's given me an incredible sense of accomplishment and confidence in the work I'm doing."

Hansen has worked in the industry for more than 30 years, starting out at a "neighborhood mom and pop pharmacy" before moving to a local community hospital, where she performed every task possible for a technician, along with working as a pharmacy buyer.

Hansen made the switch to oncology pharmacy about five years ago as a "temporary assignment." Within a week, she was asked to help open a Medically Integrated Pharmacy. It was a daunting task.

"Then one day my wholesale rep came in and told me about NCODA," Hansen said. "I immediately emailed Mike Reff and asked to join. I was thrilled there was a whole network of people who had already accomplished what I was pursuing. They helped me immensely!"

Hansen has been an active NCODA



Nora Hansen is a pharmacy technician with Illinois Cancer Specialists.

ABOUT THE LIVING THE MISSION AWARD

NCODA's Living the Mission Award recognizes members who exemplify the mission and values of NCODA in its quest to advance the value of dispensing practices for oncology physicians and deliver positive outcomes through collaboration in the care of oncology patients.

NCODA members wishing to highlight the accomplishments of their colleagues submit nominations for the award.

Twelve NCODA members were nominated in 2019, including Britny Rogala and Nora Hansen.

• **Rogala's nomination paper stated:** "Britny has lead the way for NCODA's OCE Committee, helping to create a complete team for updating and maintaining the Oral Chemotherapy

Education sheets. She has advocated for NCODA greatly in her area as a strong NCODA ambassador as well as help support NCODA's student engagement initiative through supervising pharmacy students interested in oncology with NCODA."

• **Hansen's nomination paper stated:** "Nora has been instrumental in the growth of NCODA as a speaker at NCODA national meetings and serving as a Fall Summit Chair and as a Regional Leader for Illinois, Missouri and Arkansas, which has grown to be one of the largest NCODA regions in the country. Nora has always been willing to help however she can with NCODA working around her busy schedule."

Nominations for the 2020 Living the Mission Award will begin in April. For more information or to download a nomination form, go to ncoda.org/awards.

member since joining the organization in 2015.

"At the first meeting in New Orleans, there were only a few dozen of us,"

Hansen recalled.

"I met people that I now consider to be friends. And I am in awe of how NCODA has grown."

SPRING 2020

ONCOLOGY CARE MODEL

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The pharmacist should involve a process that utilizes insurance approval and prior authorizations. The pharmacist should assist in completing all necessary paperwork. This will inform the pharmacist of whether or not the prescription can be filled within the medically integrated pharmacy.

Filling the prescription within the medically integrated pharmacy will improve the utilization of co-pay assistance programs and enrollment into local and national foundations. This will ultimately help reduce the financial burden to the patient.

Free drug programs should be considered when all else fails in an effort to get the medication to the patient.

The ability to fill a second prescription rests with the patient to successfully complete the first prescription. Irrespective of any practice differences, this goal should be the same.

ADHERENCE AND SATISFACTION

Adherence is important for improved outcomes. Communication improves adherence. It requires that the pharmacy ensure the patient understands the medication and any potential side effects, the patient notifies the practice once toxicity begins, and follows up with proper documentation if the medication is not creating any toxicity.

INTEGRATION CONSIDERATIONS

The goal of any private practice with pharmacy integration should include the following:

Access: Increased and improved access for patients to receive oral oncolytics;

Adherence: Increased or improved adherence of patients to their oral oncolytics to maximize efficacy/response to therapy;

Cost/Risk: Mechanisms in place to minimize cost/risk to the patients and practice to reduce the likelihood of financial toxicity:

Logistics: Processes and pathways in place to quickly identify, intervene and prevent toxicity associated with oral oncolytics; and

Satisfaction: The ability to capture, measure and maximize patient satisfaction for those receiving oral oncolytics.

With the help of the pharmacy, a practice can establish supportive processes to minimize, improve and reverse any toxic event.

Patient satisfaction is self-explanatory. If there is good communication, immediate intervention, minimization of financial toxicity and medication is delivered in an efficient manner, then the patient will be pleased with the service given and the quality improves.

TIME TO CHANGE IS NOW

If you do not have a medically integrated pharmacy within your prac-

tice, now is the time. Changes within healthcare and payment alternatives from conventional volume-based fee for service are becoming obsolete and unsustainable. For practices to remain solvent and survive, they must evolve to a value-based model.

NCODA can provide essential resources to assist in this process, including Positive Quality Intervention documents, Oral Chemotherapy Education sheets, Treatment Support Kits, financial assistance and patient monitoring/tracking tools.

Together we can improve the delivery of healthcare, reduce costs, improve outcomes and, most importantly, be there in direct care of our patients for their success.

▲ **William R. Mitchell, MD**, is founder of Southern Oncology Specialists in Charlotte, North Carolina.

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OPTAMIZING PATIENT OUTCOMES

The Oncology Pharmacy Technician Association (OPTA) is proud to be an association for technicians, by technicians.

OPTA is the first and only association for this integral member of the Medically Integrated Pharmacy (MIP) team.

The year 2020 will be a hallmark year, with membership doubling over the past 12 months and many innovative offerings in the pipeline.

The quality and value of content being offered through OPTA can readily be seen by everyone attending the group's monthly teleconferences, which are held at 3 p.m. the first Wednesday of each month.



Here, members exchange knowledge and adopt best practices in a friendly and productive environment. Any relevant topics are worthy of inclusion and no problem is too small to discuss with colleagues within this interactive platform.

Looking ahead, OPTA is establishing quality standards and identifying all competencies that oncology pharmacy technicians are meeting today – a list that continues to grow and astound those who still view technicians in a traditional role.

Indeed, the future is bright for the evolving role of the oncology pharmacy technician and OPTA is here to pave the path for professional development while

improving patient outcomes and increasing organizational efficiency.

If you're a pharmacy technician in oncology, you don't want to miss out on this opportunity to define the future of your profession.

By developing Continuing Education (CE) and a certification program that is meaningful and relevant to your daily practice, OPTA's grassroots approach ensures that your voice is heard. By working together, we become stronger. Come join us today!

▲ The OPTA webpage and link to sign-up can be found at: www.ncoda.org/oncology-pharmacy-technician-association-opta.

▲ For more information, contact: Matthew.Schulz@ncoda.org.

YEN NGUYEN: ONCOLOGY CONSULTANTS



Yen Nguyen, PharmD, is Director of Pharmacy at Oncology Consultants, PA, in Houston, Texas. Previously she served as a pharmacist at St. Luke Hospital in Houston and CVS Pharmacy, and as a pharmacy manager for Kroger. She received her doctorate in pharmacy from the University of Texas at Austin in 2001. She has served as a member of the NCODA Executive Council since 2017.

How did you become involved with NCODA and what prompted you to join its Executive Council?

I met Mike Reff about four years ago. At that time, I was looking for an organization whose primary focus was patient care and helping pharmacies within oncology practices manage oral oncolytics. After talking to Mike, I spearheaded the NCODA Financial Assistance Resource and Cost Avoidance and Waste Tracker tool, and redesigned the NCODA website. Mike then invited me to join NCODA's Executive Council.

Tell us a little about your expertise and what you bring to the table in helping shape NCODA's strategies:

I have been in the medically integrated pharmacy (MIP) business for more than 13 years. I served on the original SONS ION Committee, have GPO experience with ION and Onmark and managed my own PBM contracts. I also opened and managed three pharmacies. I actively network with the pharmaceutical industry contacts and colleagues that have shared my professional journey over the last 13 years and my background in retail, mail-order, hospital and PBM.

The current payer environment presents challenges both from the perspective of patient care and the business health of the dispensing practice. What changes would you like to see to help improve the quality of patient care?

Oncology care needs to be focused on the patient, not on the PBM bottom line. With oncology regimens now combining intravenous and oral therapies, the complexities, setbacks and copay costs are delaying cutting-edge treatments to oncology patients.

This is unfair. The "Any Willing Provider" law should be required not only for Medicare contracts, but commercial contracts as well. It would force PBM-owned pharmacies to improve their quality of care to the level of MIPs.

How can NCODA members who share your expertise best focus their efforts on improving delivery of oral oncolytics and ultimately improve the level of patient care?

I truly believe NCODA members are currently providing excellent quality of care, but they only have so much time in a day. Too much of their time is spent on secretarial work, coordinating prescriptions for PBM-owned pharmacies rather than directing patient care aimed at improving patient-focused outcomes. Ultimately, this results in health-care provider burn-out.

NCODA faces many daunting challenges in trying to bring forth its message of the efficacy of Medically Integrated Pharmacy to a diverse audience that includes providers, payers, legislators and manufacturers. How do we keep that message on target, and how do we measure success?

NCODA needs to continue to educate and advocate for MIPs. It needs to keep developing qualitative and quantitative tools to build relationships with payers, legislators and manufacturers, and to show these entities the value of MIPs through published data. Finally, we need to show a unified front to ensure that the "Any Willing Provider" Law is enacted for all PBM contracts – both Medicare and commercial.



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A NEW ERA: ASCO/NCODA STANDARDS RAISE THE BAR FOR PATIENT CARE



Michael Reff

NCODA has been a passionate advocate for medically integrated pharmacy since 2014. Our partnership with ASCO and publication of these jointly-produced standards brings our efforts to a whole new level.

NCODA has entered a new year, a new decade and a new era – our partnership with the American Society of Clinical Oncology (ASCO) brings to scale the standards for medically integrated dispensing of oral oncolytics.

Our recently published paper, “Patient-Centered Standards for Medically Integrated Dispensing: ASCO-NCODA Standards,” (see Page xx) is the culmination of more than a year of collaboration between our two organizations, as well as more than six years of development by NCODA to create a path to provide better patient care for patients receiving oral therapies.

These evidence-based standards were based on a systematic review of six publications that assessed quality and safety improvement interventions for ambulatory patients receiving oral anti-cancer drugs.

During the process, ASCO and NCODA were careful to consider all aspects of oncology health-care. A multidisciplinary expert panel consisting of individuals with expertise in medical oncology, pharmacy, nursing, and health care administration, as well as a patient representative, all took part in the review and creation of the standards.

The result was a cohesive and comprehensive paper that specifically detailed all aspects of patient-centered quality standards for patients on oral oncolytics, specifically:

- ▲ **Patient relationships:** Patients should have direct access to the MID team, particularly by phone.
- ▲ **Documentation:** All clinical encounters should be documented in the patient record.
- ▲ **Benefits investigation:** An investigation of prescription coverage and co-pay determination and assistance programs should be conducted by the MID team.
- ▲ **Medication disposal:** Education on proper unused/expired prescription disposals is highly recommended.
- ▲ **Patient satisfaction:** Use of the NCODA patient satisfaction survey may be helpful for soliciting patient feedback and identifying continuous improvement opportunities.

NCODA has been a passionate advocate for medically integrated pharmacy since 2014. Our partnership with ASCO and publication of these jointly-produced standards advances our mission to a whole new level.

With a membership of nearly 45,000 world-wide, ASCO represents physicians of all oncology sub-specialties.

ASCO published the new standards in December 2019 in its peer-reviewed publication *Journal of Clinical Oncology* (JCO).

Read in print and online by thousands of healthcare professionals each month, JCO is considered to be the single most credible, authoritative resource for disseminating significant clinical oncology research.

I'd like to thank everyone involved in the publication of the ASCO-NCODA standards. The team, which worked for several months on the project, included Melissa S. Dillmon, MD; Erin B. Kennedy, MHSc; Mary K. Anderson, BSN, RN, OCN; Michael Brodersen, PharmD; Howard Cohen, RPh, MS; Steven L. D'Amato, BScPharm; Patty Davis, BSN, RN, OCN; Gury Doshi, MD; Stuart Genschaw, MHA, MBA; Issam Makhoul; Wayne Ormsby, MD; Rajiv Panikkar, MD; Eileen Peng, PharmD; Luis E. Raez, MD; Ellen A. Ronnen, MD; and Bill Wimbiscus.

Our message proclaiming the value of medically integrated pharmacy is quickly spreading across the country and around the world.

Coupled with the transition from volume-based to value-based oncology care actively being advocated by the Center for Medicare & Medicaid Services (CMS), the future of our new patient-based standards is very bright, indeed.

Michael J. Reff, RPh, MBA
Executive Director and Founder of NCODA