PQIIN ACTION



ORAL FORMULATION OF DECITABINE AND CEDAZURIDINE (INQOVI®) FOR HEMATOLOGICAL MALIGNANCIES



NCODA'S POSITIVE QUALITY INTERVENTION IN ACTION

INTRODUCTION

In an effort to promote higher quality patient care NCODA created the NCODA Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance resource for healthcare providers. By providing Quality Standards and effective practices around a specific aspect of cancer care, PQIs equip the entire multidisciplinary care team with a sophisticated yet concise resource for managing patients receiving oral or IV oncolytics. This **PQI in Action** is a follow up to the INQOVI® (decitabine and cedazuridine) PQI and explores how the medically integrated teams at Oncology Consultants and Virginia Cancer Institute incorporate PQIs as part of their daily workflow. It will discuss how utilizing the **Oral Formulation of Decitabine and Cedazuridine (INQOVI®) for Hematological Malignancies PQI** elevates patient care.

Oncology Consultants is a physician-owned practice in the Houston, Texas area with 21 medical oncologists and two radiation oncologists. They have 12 locations, three specialty oncology pharmacies, an imaging center and a radiation center. Oncology Consultants' mission is a commitment to provide state-of-the-art cancer treatment in a caring environment.

Virginia Cancer Institute (VCI) is a private oncology practice located in the Richmond, Virginia area. VCI has six locations and a surgical institute. Progressive Pharmacy Care is their full-service pharmacy.

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MDS, MID, AND INQOVI®: AN IDEAL OPTION FOR PATIENTS

yelodysplastic Syndromes (MDS) are myeloid neoplasms that are characterized by clonal proliferation of hematopoietic stem cells, recurrent genetic abnormalities, myelodysplasia, ineffective hematopoiesis and peripheral-blood cytopenia(s).¹ They have a high risk of turning into acute myeloid leukemia (AML).¹ Chronic Myelomonocytic Leukemia (CMML), is recognized by World Health Organization (WHO) classifications as an overlap Myelodysplastic/myeloproliferative (MDS/MPN) neoplasm.²

INQOVI® is a fixed-dose combination of the hypomethylating agent decitabine and the cytidine deaminase inhibitor cedazuridine, which prevents degradation of decitabine in the gastrointestinal tract and liver and enables its absorption via oral dosing. It is indicated for the treatment of adult patients with MDS, including previously treated and untreated, de novo and secondary MDS with the following French American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and CMML and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups).³ An oral option for patients decreases clinic visits, reduces travel time associated with treatments, reduces the need for IV access and the associated infection risks, and decreases the exposure to the healthcare system.⁴

INQOVI® can be dispensed by the Medically Integrated Team, and thus offers patients more comprehensive care. NCODA defines Medically Integrated Dispensing (MID) as a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach. The MID is an outcome-based collaborative and comprehensive model that involves oncology healthcare professionals and other stakeholders who focus on the continuity of coordinated, quality care and therapies for cancer patients.⁵ The MID model can improve management of patients on therapies like INQOVI® in several ways including improved communication issues, measuring adherence, managing regimen changes, speed to therapy, increased patient satisfaction, financial assistance, cost avoidance, and producing less waste. NCODA offers multiple tools to aid the MID practice in managing oncolytics. This toolbox contains a Patient Survey that is practice-customizable, a Cost Avoidance and Waste Tracker tool, a Financial Assistance database, Treatment Support Kits, Oral Chemotherapy Education sheets, and of course the Positive Quality Intervention clinical resource doc-



A Medically Integrated Dispensing team member assists a patient at Progressive Pharmacy Care at VCI.

uments. Oncology Consultants medical oncologist Alex Nguyen, MD shares that "MID is a big part of the overall patient experience and care. Dispensing in-house benefits the patients because we can better coordinate treatment. We can also better educate and counsel the patient on the role the oral medication plays in the overall treatment."

"MID IS A BIG PART OF THE OVERALL PATIENT EXPERIENCE AND CARE. DISPENSING IN-HOUSE BENEFITS THE PATIENTS BECAUSE WE CAN BETTER COORDINATE TREATMENT. WE CAN ALSO BETTER EDUCATE AND COUNSEL THE PATIENT ON THE ROLE THE ORAL MEDICATION PLAYS IN THE OVERALL TREATMENT."

Alex Nguyen, MD

THE POSITIVE QUALITY INTERVENTION: A VALUABLE CLINICAL RESOURCE

irginia Cancer Institute pharmacist in charge Sharita Howe, PharmD shares that "the PQI is most helpful because it has such good, strong clin-

ical information." She often makes recommendations to her physicians concerning oral medications and they appreciate her backing the recommendations up with sound clinical information. She explains she can often copy and paste directly from the



PQI to send physicians clinical trial information and the exact data they want to see. She adds the information in the PQI "is concise and it is easier for our physicians, especially because they are so busy seeing patients. I do appreciate that the PQI is so clinically relevant." VCI nurse practitioner Cristina Nataniel-Jones, FNP-C echoes the sentiment. She explains, "what I like about the PQI is that one resource

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Sharita Howe, PharmD

speaks to how to monitor the patient, how to handle dose reductions, potential adverse reactions, and also the benefits in comparison to other treatments that may be given."

This article will explore the benefits of PQI utilization as a core standard of the MID and how adoption can benefit any practice. Oncology Consultants and VCI have both found successful ways to incorporate the PQI clinical resource. Each practice positions their Medically Integrated Teams in a way to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. We will take a look specifically at their MID settings, how implementing the INQOVI® PQI benefits their staff and patients, and how they advance patient care on a daily basis.

"WHAT I LIKE ABOUT THE PQI IS THAT ONE RESOURCE SPEAKS TO HOW TO MONITOR THE PATIENT, HOW TO HANDLE DOSE REDUCTIONS, POTENTIAL ADVERSE REACTIONS, AND ALSO THE BENEFITS IN COMPARISON TO OTHER TREATMENTS THAT MAY BE GIVEN."

Cristina Nataniel-Jones, MSN, APRN, FNP-C

MEDICALLY INTEGRATED DISPENSING: ELEVATING CARE

s cancer treatment continually grows in complexity containing IV, oral and combination regimens, MID continues to offer an invaluable option for patient care. The MID staff has unparalleled access to patient information and means of direct communication with other members of the multidisciplinary team. This model greatly reduces fragmentation of care. Taryn Newsome, CPhT, was a member of the VCI staff prior to the establish-

ment of MID in the practice. She notes that MID "fits really well with a full picture of the patient's treatment plan. It is very beneficial to the patient to have the well-rounded team looking at their overall treatment plans. Also, just for convenience, being able to see your doctor and then come down the hall and get all of your prescriptions."

VCI nurse Tiffeny Thomas, RN, agrees that convenience is a huge benefit of MID for patients. She also appreciates the

availability of the pharmacist to review medication profiles and side effects. She shares that pharmacist communication with the clinic staff is a benefit, because she can call them with questions on potential issues like drug interactions. She expresses that when patients are required to use outside mail order pharmacies there may be a delay in therapy, and it is not as easy for their patients to reach a pharmacist. When issues with filling the prescription arise, she says "it is easier for our staff to reach us and let us know."

"OUR PATIENTS ARE TYPICALLY VERY SICK, SO IT IS IMPORTANT THAT THINGS MOVE VERY QUICKLY. WE GO FROM THE DRUG BEING PRESCRIBED TO THEN GOING THROUGH THE CLINICAL REVIEW. THE PRIOR AUTHORIZATION IS COMPLETED AND WE HAVE ACCESS TO ALL THE INFORMATION WE NEED FOR THAT PROCESS."

Jennifer Pearson, PharmD

Oncology Consultants pharmacist Jennifer Pearson, PharmD comments, "I think the major advantage of us being integrated with the medical staff is that things can move a lot more quickly. Our patients are typically very sick, so it is important that things move very quickly. We go from the drug being prescribed to then going through the clinical review. The prior authorization is completed and we have access to all the information we need for that process. From there it comes straight to our pharmacy and we have options for the patient to come in and pick up their medication or we offer other methods of delivery to get it to the patient. Things move quicker and in the clinical part of dispensing we can be more thorough and review the medications to ensure everything is accurate."



Tiffeny Thomas, RN, BSN and Thomas Weart, MD work together to provide patient-centered care at Virginia Cancer Institute.

POSITIVE QUALITY INTERVENTIONS: QUALITY STANDARDS IN CANCER CARE

he PQI is a peer-reviewed clinical guidance document that provides Quality Standards and effective practices around a specific aspect of cancer care. The medically integrated pharmacy team is in a unique position to ensure appropriate treatment, increase compliance, and maximize clinical outcomes. Positive Quality Interventions (PQIs), an NCODA Quality Standard, are designed to operationalize and standardize those practices to achieve these positive clinical outcomes.

Oncology Consultants Director of Drug Services, Yen Nguyen, PharmD, shares the PQI "helps the pharmacist know how to manage the patient better on these complex oral treatments. NCODA's pharmacist leaders throughout the country are participating and writing the PQIs." She says she incorporates PQIs into her practice's daily usage. Oncology Consultants oncolytic nurse navigator, Monica Martinez, LVN, adds the PQI is "a good clinical resource because I learn about the drug and how it is dosed and things to watch out for when talking with patients. I think it is something very positive to be able to reference and have on hand."

VCI medical oncologist Thomas Weart, MD appreciates his team having a clinical resource like the PQI. He comments, "As a prescriber, it is always helpful to have summarized bullet point information in relation to the criteria for prescribing this medication,

the potential adverse effects, how administration may be modified, what to monitor, and then at the end, the patient-centered activities empower patients on what they can do in the event of adverse effects and when to notify us." Dr. Weart adds that the PQI promotes consistency and standardization. Adoption of standards benefits the Medically Integrated Team by helping gain optimal adherence and persistence rates, minimizing the risk of toxicity with therapy, and positively affecting patient health outcomes.7 In the VCI MID pharmacy, Howe not only uses the PQI to present valuable clinical information to providers, but she also builds aspects of the PQI into her pharmacy software. Following the publication of a PQI that involves dosing changes or adding a supportive medication, Howe builds an alert into her pharmacy software that pops up for the team when they dispense the prescription. She also brings the PQIs for newer medications to VCI's pathways committee, to help serve as a clinical resource and guide.

"AS A PRESCRIBER, IT IS ALWAYS HELPFUL TO HAVE SUMMARIZED BULLET POINT INFORMATION IN RELATION TO THE CRITERIA FOR PRESCRIBING THIS MEDICATION, THE POTENTIAL ADVERSE EFFECTS, HOW MAY ADMINISTRATION BE MODIFIED, WHAT TO MON-ITOR, AND THEN AT THE END, THE PATIENT-CENTERED ACTIVITIES TO EMPOWER PATIENTS ON WHAT THEY CAN DO IN THE EVENT OF ADVERSE EFFECTS AND WHEN TO NOTIFY US."

Thomas Weart, MD

PUTTING THE INQOVI® PQI INTO ACTION

The **Oral formulation of Decitabine and Cedazuridine (IN-QOVI®) for Hematological Malignancies PQI** is written in sections beginning with a Description and ending with Patient-Centered Activities and References. Following the Description, the Background section gives pertinent historical data and information, clinical trial experience and the main focus of the intervention. Regarding INQOVI®, the Background discusses the approval, indication and published data leading to approval. Again, it notes that development of an oral DNA methytransferase (DNMT) inhibitor alleviates much of the burden associated with the treatment of MDS/CMML for patients currently on IV DNMT inhibitors.⁴

A recent study also showed that a significant proportion of patients with higher risk MDS who receive treatment with hypomethylating (HMA) agents discontinue treatment prematurely. ⁸This premature discontinuation results in substantial economic impact when compared to the HMA persistent group.⁸ According to study authors, "there was a significantly higher proportion of older patients and those who were without a partner (unmarried or unknown marital status) in the HMA-nonpersistent group compared to the HMA-persistent group, suggesting that these patient sub- groups may need more support getting to the treatment center to receive consecutive treatment cycles."⁸ This study suggests an additional possible benefit of an oral formulation in this population. The oral bioavailability of decitabine is typically limited because of rapid inactivation by cytidine deaminase (CDA) in the gastrointestinal (GI) tract and liver.⁹ The Background section explains that cedazuridine is a CDA inhibitor which prevents degradation of decitabine in the GI tract and liver and enables absorption via the oral route.⁴ According to Category 2A evidence in the NCCN guidelines for Myelodysplatic Syndromes, oral decitabine and cedazuridine can be considered as a substitution for intravenous decitabine for treatment of intermediate- or high-risk MDS.¹⁰ Dr. Alex Nguyen comments "for the patient, the benefit is obvious. There is a treatment, and they take it at home for five days versus coming in for an infusion for five days."

INQOVE (decitabine and cedazuridine) 35mg / 100mg tablets

THE PQI PROCESS: A TEAM EFFORT

he next section of the INQOVI® PQI is the PQI Process. This section lays out the intervention in step by step points, contains clinician directed guidance and critical clinical criteria that can benefit the entire team. The first section of the INQOVI® PQI Process discusses identification via EMR of eligible patients for INQOVI®, educating providers that the new formulation is available, and lays out the data that supports the approval of INQOVI®.

The first step of the INQOVI® PQI process states, "utilize the reporting tools available in your EMR to identify patients who are receiving IV decitabine for MDS or CMML and discuss the option of converting them to oral decitabine/cedazuridine with their physician."4 Howe shares that when this PQI was published, "I read through it and was able to take information that was in the PQI and actually then run a report for all of our patients who are on IV decitabine and send each prescribing physician an email. The email shared that INQOVI® is approved, provided the study, provided the specific points from the study, and let the physician know that if they have patients that may benefit from being switched to the oral send us a prescription." The first step also includes an alert for the team that INQOVI® should NOT be substituted for an IV decitabine product WITHIN a cycle. Howe elaborates, "so I was able to use the PQI to highlight exactly what we wanted to do and then to give the providers the information, like to not start the INQOVI® in the middle of the cycle."

Dr. Weart has been on board with patient conversion to IN-QOVI® when appropriate from the beginning. He shares, "it's very clear and the data from the clinical trials suggests there doesn't appear to be any difference in efficacy for these indications in CMML and MDS, and in the context of COVID-19, I'm a firm believer that if we can keep people out of the office as much as possible, we can safeguard them, and in line with the drug's FDA approval. For me, trying to put myself ever so slightly in the patient's shoes, and think of the benefit of taking something at home rather than coming in for an infusion. In this case decitabine is being given for five consecutive days and every one of those times coming in is another possible chance for exposure to COVID-19. I think the biggest benefits are patient convenience, similar efficacy, and also risk reduction in terms of COVID-19 and other infection risks as well."

Both practice physicians agree that INQOVI® does require careful patient selection. Dr. Alex Nguyen comments, "I think you have to select the patients carefully. There are some folks where mentally in terms of early Alzheimer's and things like that, you have to think about whether or not they are reliable in terms of starting on a date that you have designated and make sure that they do not miss a dose and continue for the five days you have designated." He does point out that "the majority of patients will benefit." Dr. Weart adds, "It definitely requires careful patient selection and appropriate use but frankly I would argue for most patients with these disorders, particularly the frail elderly population, this agent is a good choice for the reasons that I mentioned previously."

Newsome agrees with the benefits of the oral option, "especially because of the time we are in right now. A patient will have to come into the office for five consecutive days with the IV decitabine and with INQOVI® they can just take the medication at home. Some patients are elderly, and they have trouble getting here. They don't have rides. So just being able to take it at home and if they do have side effects, manage their side effects at home instead of coming into the office every single day, is a huge benefit." Thomas elaborates and shares, "transportation into the office five days in a row can be a burden to families and patients." She gives the biggest benefits being convenience and decrease of exposure in general of patients not having to come into the clinic.



Jennifer Pearson, PharmD and Alex Nguyen, MD discuss a patient prescription.

PQI PROCESS: DOSING AND LABS

he next steps in the INQOVI® PQI Process describe the dosing and lab monitoring parameters. The recommended dosage of INQOVI® is one tablet (containing 35 mg decitabine and 100 mg cedazuridine) orally once daily on days one through five of each 28-day cycle for a minimum of four cycles until disease progression or unacceptable toxicity.3 When Oncology Consultants physicians want to start a patient on INQOVI®, they pass the treatment request on to the clinical pharmacist. The clinical pharmacist then doses the medication and sends the order to the pharmacy. As an example, after Yen Nguyen, PharmD doses the medication, Jigna Patel, PharmD performs initial clinical evaluations. She completes initial assessments, making sure the dose is appropriate and there are no drug interactions. She completes a form called "initial assessments." Following the initial assessments, Lincy George, PharmD, Thu Tran, PharmD, and Jennifer Pearson, PharmD work on actually filling the medication. They work with Isabel Barraza, CPhT to get the prior authorization and financial assistance approved and counsel the patient. According to Tran, the filling pharmacist is also completing a dosage check. "As the filling pharmacist, I am also completing the dosage check and looking at all of the important information such as renal and hepatic dosing, and double checking the patient's complete medication list."

VCI completes clinical checks and drug utilization review when filling a prescription for INQOVI®. Howe evaluates

the patient chart to ensure the prescription is correct. She shares one of the first things her team does is "verify that the prescription is correct and entered for days one through five every 28 days. We also look at patient lab values and demographics." The VCI pharmacists also read the physician's note to make sure they are filling exactly what the prescriber intends, and check that the treatment summary in the EMR is correct, especially for the patients moving from IV decitabine to oral INQOVI®. On these patients Howe also checks to make sure the patient is not starting in the middle of a cycle. "I am making sure the patient finishes their cycle of IV decitabine and has that period in between."

The INQOVI® PQI also discusses CBC and CMP results and potential dose reductions for hematologic toxicity. Yen Nguyen shares one important item on the top of her list when managing patients on INQOVI®. "Make sure the patient returns to the office on day six to receive the G-CSF injection if needed." Dr. Alex Nguyen remarks, "the CBC is going to be the key. You need to monitor CMP as well because beyond the blood count you want to make sure the renal function and electrolytes are acceptable." He does comment that one must remember these patients are not starting out with normal blood counts to begin with and the physician monitoring is very nuanced depending on the patient.

PHASE 3 STUDY (ASCERTAIN STUDY): PRESENTED AT ASH 2019 - COMPARED ORAL DECITABINE/CEDAZURIDINE (DEC-C) TO IV DECITABINE

138 MDS intermediate or MDS high risk or CMML patients randomized to receive sequence A (DEC-C35/100mg daily x 5 days or IV decitabine 20mg/m2 daily x 5 days) or sequence B (IV decitabine 20mg/m2 daily x 5 days or DEC-C- (35/100mg) daily x 5 days). All patients then received DEC-C on cycles 3 and onward.

5 day oral: IV AUC ratio wasLINE 1 demethylation is a PD marker and the difference between IV and PO was < 1%, confirming the PK findings.Overall response rate of 65% (com- plete response + partial response + marrow CR + hematologic improvement) is in line with what is seen with conven- tionally dosed IV	Transfusion independence noted in 50% of patients in phase 2 trial and 32.7% of patients in phase 3 trial.	No differences were noted in any common side ef- fects between the IV and PO formulations.
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PATIENT-CENTERED ACTIVITIES: KEEPING THE FOCUS ON PATIENTS

The Patient-Centered Activities section follows the PQI Process and gives patient-centered guidance for the team. The INQOVI® Patient-Centered Activities section starts with various educational points to review with patients including educating patients on the schedule of the medication, food consumption, when to contact the care team, and to avoid taking over the counter medications that can thin the blood. Both Oncology Consultants and VCI prioritize patient education.

In 2019 the Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards were published to provide standards for Medically Integrated Dispensing of oral anticancer drugs and supportive care medications.⁷ Standard 1.2 of the ASCO/NCODA Standards reads:

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 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.⁷

"THE MAIN THING I TALK TO PATIENTS ABOUT IS INCREASED RISK OF INFECTIONS. THAT IS HUGE. WE TALK TO THEM ABOUT WHEN TO CALL US."

According to Howe, VCI patients receive two forms of education. They receive education first from the clinic nurse practitioner and then from the pharmacy team. Nataniel-Jones is one of VCI's nurse practitioners who provides this education. She shares that, "when you have a regimen such as this where the dosing is day one through five every 28 days, I really educate patients on how to take the medication. It can be very confusing if a patient receives a bottle of several pills and they are liable to keep taking it past that time period." She adds that at VCI patients are typically given one cycle at a time to cut down on this confusion. She continues, "it is just so important to make sure I let patients know how to

RECOMMENDED DOSE REDUCTIONS FOR MYELOSUPPRESSION



take their medications. I usually write out a schedule on a month calendar marking the days where they are to take the medication."

Oncology Consultants also provides education as a team effort. George shares one important counseling point for her is that "INQOVI® should be taken on an empty stomach. We remind the patient not to have a meal two hours before or two hours after the dose." Other important counseling points she discusses are to "swallow the tablets whole and not to crush, what to do in the event of a missed dose and potential adverse reactions." Dr. Alex Nguyen is sure to stress upon patients that even though the medication is oral, it has potential for myelosuppression like the IV. He comments that sometimes patients may be "nonchalant about the oral formulation" so the most important point is to make sure they are returning for proper lab monitoring. Howe and Nataniel-Jones also stress the infection risk and when to contact the care team to VCI patients. Nataniel-Jones notes, "the main thing I talk to patients about is increased risk of infections. That is huge. We talk to them about when to call us." Howe educates patients on letting the team know if they have a fever and on other adverse events including nausea, constipation and diarrhea. Both teams share that many patients already have anti-emetics on board from IV treatment and are able to continue with those if necessary.

The PQI lists additional events that require a patient to contact the care team including unusual bleeding, black/tarry stools, bloody urine, and painful mouth sores.⁴ The PQI includes examples of ways patients can mitigate infectious risks associated with bone marrow suppression including avoiding sick contacts, prompt recognition and reporting signs of fever, recognition of signs and symptoms of bruising/bleeding, and feelings of excessive fatigue.⁴ It again reminds the team to educate patients, just as our clinics prioritize, on the importance of lab monitoring before each cycle, focusing on neutropenia.⁴ Martinez adds that follow up calls are an important piece of patient education and monitoring. "Follow up calls are important because if there are any issues, you can then report back to the physician." These calls and touch points with the patient are another way the MID closes any gaps in care.

"INQOVI® SHOULD BE TAKEN ON AN EMPTY STOMACH. WE REMIND THE PATIENT NOT TO HAVE A MEAL TWO HOURS BEFORE OR TWO HOURS AFTER THE DOSE." Lincy George. PharmD

MID: PROVIDING UNMATCHED SERVICE AND FINANCIAL ASSISTANCE FOR PATIENTS

n addition to close follow up and detailed education, MID renders the practice able to provide excellent customer service, unmatched patient care, and help with finding funding so the patient can actually afford to take the medication. Many times, insurance mandates require that prescriptions must be filled outside of the practice in a PBM owned mail-order pharmacy instead of by the MID pharmacy inside the clinic. This can cause delays in therapy and more anxiety for the patient. VCI and Dr. Weart are no strangers to these issues with outside mail-order pharmacies. He shares, "I would argue that the biggest criticism of mail-order is delays. Now to the mail-order pharmacy credit I know they have tried to deliver these medications overnight and on time, but I have many, many patients as the time goes on, who are delayed a week or more for reasons that are unknown. The mail-order pharmacy will come back to us and say they are waiting for the practice to approve another fill and we haven't heard anything. We will check our database and we haven't been contacted by the pharmacy and everything is current, so it lends itself to larger administrative burdens that limit patients from getting these medications on time."

MID allows for optimization of all aspects of cancer drug therapy management and significantly decreases time to therapy.¹¹ Yen Nguyen, PharmD points out that time to dispense is a benefit of using her MID over outside mail-order, "our time to dispense is on average around 3.5 days and that includes finding financial assistance and so forth. So, that tells you the efficiency of my staff." Dr. Alex Nguyen shares a "huge benefit of MID is finding a funding source for the patient, because there is foundation assistance and support that they may not get from a mail-order pharmacy." He adds that in the outside mail-order scenario, "when you have to do a prior authorization, that is another hassle. Getting clinical information back and forth through the mail-order is a huge challenge, whereas our pharmacy is right here. They have access to the patient record. They have direct access to the physician, and then as I said funding wise, there are a number of support programs available for the patient." He comments his MID pharmacy does a "tremendous" job in helping the patients find copay cards and alleviating that burden from the practice physicians.

Barraza sums up the Oncology Consultants' process, "one of the benefits of patients using the OC Pharmacy is the prescriber is notified of exactly when the patient receives the medication. Notification of when the patient receives the medication prompts our nurse navigator to reach out the patient. At this time, she will ensure that the patient has started the medication and will monitor for any side effects and compliance. Our in-house prior authorization technician makes sure that medications are approved through the insurance and maintains those prior authorizations so that patients do not experience any lapse in therapy."

VCI also assists patients with funding and has two designated patient financial coordinators designated to their MID pharmacy. Newsome explains "they are helping us get copay cards, virtual credit cards, grants, and are extremely helpful." She continues, "when we do give patients their copay information, a lot of them are obviously in shock. When we are able to help them get this medication, help obtain their treatments at no cost, they are very grateful, and I am happy we can do that for them." Newsome adds that when they are required to send prescriptions to the outside mail-order pharmacy "sometimes they can get lost in the system. We have had patients get three months of refills at one time. That is just too much. It is hard when we have to send the



Taryn Newsome, CPhT prepares a prescription at Progressive Pharmacy Care at VCI.

prescription away, especially when patients do not understand what a cycle is, and we have to explain. Patients can get confused."

Nataniel-Jones agrees and shares, "I think it works out really well for patients to receive their medication here in the same place where they have their follow-up visits. They do not have to wait until a home delivery service happens to deliver it, and we are able to see and make sure they have actually picked up their medications, rather than the responsibility lying with the patient to contact an outside pharmacy for home delivery. You know, that is hard, patients are responsible at that point. When they are here in our office, we are able to make sure they are adhering to their medications and assist with complex regiments of not taking something every single day." She adds, "I have seen the delays, where something happens, but the patients do not know they should contact us, whereas you know the staff is following up with the patients in our pharmacy and can alert us to an issue. I feel like it is a barrier. We always appreciate when a patient's insurance allows them to pick up their medications here, it is eyes on the prescription versus a package left on a doorstep."

MID AND PQI: REDUCING FRAGMENTATION OF CARE AND IMPROVING ADHERENCE

ne of the biggest benefits of MID and the PQI is less fragmentation of care, due in part to ease of communication between the healthcare team. The US has a problem with fragmentation of care, which is noted as a key factor in high cost and less-than-optimal-quality.¹² MID is one step the practice can take towards reducing this fragmentation. When coupled with utilizing the PQI, better communication amongst the healthcare team can take place. Thomas believes in the benefit of the team to patients. She says the team approach provides increased continuity of care and better communication. She adds that the entire team has access to the medical record as a base. There are also many diverse members of the VCI team working towards the same goal of excellent care for the patient, from the medical team and pharmacy to social workers and dieticians, and all have direct access to each other.

"I WOULD CONTEND THE SAFETY PROFILE, FOR THESE AGENTS, FOR OUR PATIENTS IS IMPROVED BECAUSE OF THE DIRECT RELATIONSHIP AND COLLEGIALITY WITH OUR PHARMACY COLLEAGUES IN-HOUSE, UNDER ONE UMBRELLA." Thomas Weart, MD

Patel comments that this continuity of care improves adherence. "During each cycle, I evaluate each patient and if there are any adherence issues, we will address them. The patient using us in-house increases adherence because we have someone overlooking the medication profile on a monthly or cycle basis." Martinez often has patients comment on this follow-up. When she reaches out to patients for her checkin, "they definitely are very appreciative because they feel not only supported by the clinic staff and the pharmacy, but they also have someone who reaches out to them. If something does come up during the interval when I am not scheduled to call, they can call me directly, let me know what is going on, and know that there is someone there they can reach out to that can help them with whatever their needs may be at that moment." Patel also shares "with oncolytics there are often dosage changes, and a lot of times when those changes happen the patient may forget. The system that we have ensures the patient knows or is informed if the dosage has been changed and that the patient is taking the medication correctly."

According to Newsome, the communication with the patient is not only about adherence. It is also "just that personal touch, being able to call and speak to the technician or pharmacist by name." Howe adds that before the MID pharmacy, the providers were relying on faxing and e-prescribing to outside pharmacies and would need to wait on the pharmacy to alert them of any issues. "So, what ends up happening is the patient is impacted because there is a communication breakdown. By having the MID pharmacy, we are able in real-time to provide updates if there is any new information. The communication is enhanced. If we do have a patient who has side effects, we are automatically putting notes into the nurse or the physician. In our office here we can actually just walk down to the prescriber and let them know what is going on. We are able to provide enhanced services in an enhanced time frame."

Dr. Weart is also a proponent of this improved communication. "In my experience, I think MID is exponentially more beneficial to patients, and the reasons being knowing our pharmacy staff is interacting with them regularly and then being able to contact us rapidly to address potential contraindications, to address potential side effect profiles, and having to adjust in relation to those and trying to acquire medications at the lowest possible price for our patients." He goes on, "I would contend the safety profile, for these agents, for our patients is improved because of the direct relationship and collegiality with our pharmacy colleagues in-house, under one umbrella." Howe agrees that "nothing is going to compare" to actually having access to the pharmacist as part of the clinic. In her experience when patients are forced to go outside of the practice to receive their prescription, "it adds a lot of different layers of frustration to our patients and their care."

CONCLUSION: NCODA, THE MID AND INQOVI® PQI: OPTIMIZING PATIENT OUTCOMES

ll team members agree that the MID model and the PQI Clinical Resource are valuable to the team and to patients. Every day the MID team can make a difference in the life of patients. Every day the team can learn something new or can begin a process that optimizes care. The PQI fosters this through appropriate patient identification, selection, increased speed to therapy, reduced cost, and hospitalization and by improving adherence techniques for the patient and their Medically Integrated Teams. INQOVI® gives patients with MDS/CMML that would normally require an IV DNMT inhibitor another treatment option that allows more time spent in the comfort and safety of their home. The PQI gives the MID program an easy to use, compact clinical resource guide when discovering the right patient and dispensing INQOVI®. It helps the team ensure they are providing patients with the tools and education to improve clinical outcomes. Pairing Medically Inte-

grated Dispensing with the **Oral formulation of Decitabine** and Cedazuridine (INQOVI®) for Hematological Malignancies PQI meets NCODA's Guiding Values of being Patient-Centered and Always Collaborative.



REFERENCES

- 1. Cazzola, M. "Myelodysplastic Syndromes." N Engl J Med. 2020;383:1358-1374.
- 2. Itzykson, R., Duchmann, M., Lucas, N. et al. "CMML: Clinical and molecular aspects." Int J Hematol. 2017;105:711–719.
- 3. INQOVI® (decitabine and cedazuridine) [prescribing information]. Princeton, NJ: Taiho Oncology; July 2020.
- Resnick, Y. Positive Quality Intervention: Oral formulation of Decitabine and Cedazuridine (INQOVI®) for Hematological Malignancies. NCODA. https://www.ncoda.org/oral-formulation-of-decitabine-and-cedazuridine-inqovi-for-hematological-malignancies/. Accessed January 2021.
- NCODA. NCODA Announces the defining of the Medically Integrated Dispensing Pharmacy. https://www.ncoda.org/ medically-integrated-dispensing-pharmacy/. Accessed January 2021.
- Wimbiscus, B. "Medically Integrated Dispensing: An Alternative to How Oral Drugs Get Dispensed." Am J Manag Care. March 14, 2019. https://www.ajmc.com/view/medically-integrateddispensing-an-alternative-to-how-oral-drugs-get-dispensed. Accessed January 2021.
- Dillmon MS, Kennedy EB, Anderson MK, et al. "Patient-Centered Standards for Medically Integrated Dispensing: ASCO/NCODA Standards." J Clin Onco. 2019;38(6):633-644.

- Joshi, N, Kale H, Corman S, Wert T, Hill H, Zeidan AM. "Direct Medical Costs Associated with Treatment Nonpersistence in Patients with Higher Risk Myelodysplastic Syndromes Receiving Hypomethylating Agents: A Large Retrospective Cohort Analysis." Clin Lymphoma Myeloma Leuk. 2021;21(3):e248-e254. DOI 10.1016/j.clml.2020.12.002.
- Garcia-Manera G, Griffiths EA, Steensma DP, et al. "Oral cedazuridine/decitabine for MDS and CMML: a phase 2 pharmacokinetic/pharmacodynamic randomized crossover study." Blood. 2020;136(6):674-683.
- NCCN. NCCN Clinical Practice Guidelines in Oncology, Myelodysplastic Syndromes Version 3.2021. https://www.nccn.org/ professionals/physician_gls/pdf/mds.pdf. Accessed March, 2021.
- Egerton NJ. "In-office dispensing of oral oncolytics: A continuity of care and cost mitigation model for cancer patients." Am J Manag Care.2016;22(4, Suppl):s99-s103.
- 12. Castro, C. "Medically Integrated Pharmacies: Rising to the Challenge." Oncolytics Today. 2019;1(2):7-9.

PQI PRINCIPLES:



Helpful Online Resources



NCODA Website



Positive Quality Interventions



Oral Chemotherapy Education Sheets



Oral Formulation of Decitabine and Cedazuridine (INQOVI®) PQI

ON THE COVER:

• Lincy George, PharmD, counsels a patient on INQOVI®.

Practice panelist's comments reflect their experiences and opinions and should not be used as a substitute for medical judgement.

Important notice: NCODA has developed this Positive Quality Intervention in Action platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.



