NCODA’s POSITIVE QUALITY INTERVENTION IN ACTION

MULTIDISCIPLINARY MANAGEMENT OF ADVANCED OVARIAN CANCER PATIENTS WITHIN MEDICALLY INTEGRATED PHARMACY PRACTICES
In an effort to promote higher quality patient care, the National Community Oncology Dispensing Association, Inc. (NCODA), created the NCODA Positive Quality Intervention (PQI) as a peer-reviewed clinical guidance document 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 simple-to-use resource for managing patients receiving oral or IV oncolytics. The PQI fosters better care for patients 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.

The PQI in Action incorporates opinions and experiences from oncology experts within the medically integrated teams at six leading care organizations. These cancer treatment organizations have successfully implemented medically integrated pharmacies (MIP) as well as the use of Positive Quality Interventions throughout their care teams to improve the clinical outcomes of patients receiving niraparib and other therapies for maintenance treatment of advanced ovarian cancer.

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MEDICALLY INTEGRATED PHARMACY

Medically Integrated Pharmacies (MIP) are a type of service model in which patients receive oral therapies at the site of care with their doctor and are managed by one staff; state-of-the-art pharmacy services are built within the oncologist’s office that help to deliver timely and ongoing care as part of a single, multidisciplinary team. Complexity of cancer treatment has recently increased with a growing number of both oral and IV therapies which are delivered across an often-confusing, payer-driven healthcare system. Connectivity through the Electronic Medical Record (EMR) enables healthcare professionals to continuously interact and make decisions based upon the latest medical information available for the patient. With an ever-growing amount of information to process and disseminate to patients and colleagues alike, oncology professionals need tools like NCODA’s Positive Quality Intervention to assist them in delivering sophisticated care. In advanced ovarian cancer, disparities exist in the percentage of patients who are genetically tested and also with those patients who are offered maintenance therapy when appropriate\(^2\). The PQI offers a solution.
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A patient’s journey after diagnosis with ovarian cancer can take many paths. NCODA created this project to identify effective practices with promise for improving patient outcomes. The Positive Quality Intervention on PARP-Inhibitor (PARP-I) Eligibility enables MIP teams to better understand the ovarian cancer space. A retrospective study of 4,950 patients showed a genetic testing rate of 50%. Another retrospective data analysis showed that 49% of patients received maintenance therapy in second line or greater therapy. Current rates warrant improved methods and practices to enable professionals to offer excellence to their patients; the PQI provides consistent clinical guidance information to improve outcomes.

GENETIC TESTING: A STANDARD

A study published in the Journal of Clinical Oncology estimated that 1.2-1.3 million eligible patients are not offered BRCA testing. Because genetic testing was not previously a standard recommendation, untested patients with recurrence should be tested and evaluated appropriately. Many factors affect recurrence of disease including the primary site and method of treatment. A study done by Randall and colleagues found 50% of women with epithelial ovarian cancer underwent BRCA1/2 testing, while Buchanan and colleagues found testing rates in this patient population to be close to around 75%. Identified barriers to testing included older age and noncompliance with health screenings. Current NCCN guidelines for genetic testing recommends BRCA testing in all ovarian cancer patients. An effective practice to highlight is standard referral to a genetic counselor for specific testing recommendations for patients.

A GENETIC COUNSELOR PROVIDES SPECIFIC TESTING RECOMMENDATIONS FOR PATIENTS.

MAINTENANCE THERAPY

In ovarian cancer, maintenance therapy should be a standard of care. Resources like the PQI on PARP Inhibitor Eligibility are imperative in identifying and appropriately offering efficacious treatments to eligible patients at the right time. Data presented at a European Society for Medical Oncology (ESMO) Conference showed that the majority of eligible patients were not on maintenance therapy. A real-world data analysis by Garofalo and colleagues found that maintenance therapy was used in 49% of eligible patients, 47% of those on maintenance therapy received a PARP-I as the maintenance agent. Use of a PARP-I was higher in those with a BRCA mutation at 61%, vs 45% with wild-type or unknown status. This study looked at maintenance after second line or greater therapy; newer data shows progression free survival (PFS) benefit of maintenance following first line therapy, highlighting the need to accurately identify patients upon initial presentation. Some studies on cost-effectiveness have demonstrated an increase in the cost when therapies other than PARP-I are utilized. Further studies may provide additional insights into the role of comprehensive genomic profiling or the method of primary treatment and their impacts on treatment decisions and outcomes.

SOME DATA SUGGESTS THAT THE MAJORITY OF ELIGIBLE PATIENTS ARE NOT ON MAINTENANCE THERAPY.
The NCODA PQI on PARP Inhibitor Eligibility provides awareness of the current deficits in ovarian cancer and encourages professionals to take a more proactive approach in improving current treatment standards. By providing specific strategies to identify, offer, and manage patients who would be eligible for maintenance therapy with a PARP-Inhibitor, more patients will receive and potentially benefit from the therapy. We will now examine and report on the experience of six leading oncology organizations and, thereby, demonstrate the need to ensure patients receive efficacious therapies for ovarian cancer.

Complimentary access to all NCODA PQI’s available here: www.ncoda.org/pqi

Although the six partner organizations in this article each provide care to ovarian cancer patients in their own unique ways, commonalities exist. A consistent approach for all of them revolves around the MIP team involvement and the benefits that are inherent to the model. With multiple disciplines now playing an integral role in care, each respective member of the team should be working interdependently to achieve improved outcomes for the patients. Any team member may be handling critical aspects of ovarian cancer management including schedulers, assistants, administrators, genetic counselors, nurses, pharmacists, and the provider. Accordingly, the PQI has inherent value for all members of the team in providing awareness to standardized, effective practices.

Indeed, working together, the team becomes stronger. To deliver excellent care to their patients, these six organizations have partnered with NCODA to provide collective value by creating and using a consistent resource: NCODA’s PQI on PARP Inhibitor Eligibility.

“SELECTION OF MAINTENANCE THERAPY ULTIMATELY COMES DOWN TO TREATING THE PATIENT AND NOT JUST THE DISEASE.”
BEGINNING OF THE JOURNEY

Typical ovarian cancer patient presentation may begin with a community obstetrician or a community medical oncologist where the condition is diagnosed. Patient workup usually involves referral and meeting with a Gynecologic Oncologist to assess patient characteristics, obtain imaging (CT scans), tumor and/or blood samples, determine staging, and create a treatment plan. Genetic testing is offered to patients at all six organizations (regardless if they have a genetic counselor on site or not) as a standard practice. Genetic alterations (BRCA 1 and 2, specifically) help to identify the most efficacious treatments and appropriate steps of therapy. Real world experience from St. Luke’s Health System genetic counselor, Emily Fassi, MS, LCGC, shows that about 25% of eligible patients were not referred for genetic counseling.

Initially, patients may qualify for neoadjuvant chemotherapy plus interval debulking surgery (NACT+IDS), or, primary debulking surgery (PDS); the initial treatment decision may impact later outcomes in particular patient subsets. Based on patient response after three cycles of a platinum-based chemotherapy regimen (often Carboplatin + Paclitaxel/Docetaxel), some providers reassess with imaging while others continue treatment and assess tumor markers. For example, Chief of Gynecologic Oncology for Southern Illinois University (SIU), Laurent Brard, MD, PhD, states, “As long as tumor markers like CA-125 and HE4 are improving, there is no need for re-scanning during initial treatment.”

Following traditional initial treatment with six cycles of chemotherapy, there are ramifications around various treatment decisions. The following briefs are takeaways from each of the six organizations.

MAINTENANCE THERAPY

Once the patient has achieved an initial platinum-based regimen, the treatment path begins to split into many potential routes. Patients may be classified as non-responders, Platinum-Sensitive (recurrence was greater than six months following initial response), or Platinum-Resistant (recurrence less than six months), or may still be in response without detected recurrence.

In the maintenance setting for BRCA-mutated patients, all six organizations would consider use of a PARP-I. For example, medical oncologist at Swedish American Health, William Schulz, MD, said “I tend to use olaparib (Lynparza).” While niraparib (Zejula) and rucaparib (Rubraca) are both part of ongoing clinical studies in the first-line maintenance treatment setting before recurrence, an FDA-approved indication currently exists for olaparib.
At Joliet Oncology & Hematology Associates, responsive patients will generally receive additional chemotherapy or IV treatments until recurrence, at which time they would be offered a PARP-I like niraparib. Upon recurrence, all organizations would similarly consider offering any of the PARP-I options, regardless of BRCA status. Additional PARP-I options that are FDA-indicated after recurrence include niraparib and rucaparib. Upon recurrence, all six organizations would consider genetic testing again, particularly if not done initially. Medical oncologist at Northwest Oncology & Hematology, Steven Kanter, MD, shared, “Previously we would test at recurrence but now all patients receive initial genetic testing.” Dr. Laurent Brard also seeks additional patient-specific characteristics through genetic testing beyond BRCA. He stated, “I will look into BRCA, TP53, CHEK2, RAD51, BRIP1, and PALB2 mutations; if any patients test positive for any of those mutations, they will likely receive a PARP-I.” Future treatments will likely be developed around these mutations and offer further options for patients. To ensure patients are not overlooked for a maintenance therapy, organizations should adopt the standardized practices as described in NCODA’s PQI on PARP Inhibitor Eligibility.

SELECTING A PARP-I

In the setting that PARP-I’s are indicated, selection is largely based upon individual patient characteristics. Pharmacy Manager at Texas Oncology, Leslie Giang, PharmD, stated, “We primarily look at the side effect profile, potential patient tolerance, drug interactions, dosing schedules, degree of adherence, as well as insurance coverage for the PARP-I”. Some agents may cause elevated creatinine, transaminases, or myelosuppression and would be inappropriate for certain patients. Dr. Brard of SIU mentioned, “A patient with hypertension, for example, would not be an ideal candidate for Avastin (bevacizumab) and may benefit from a PARP-I instead.”

Similarly, medical oncologist of Texas Oncology, Sudha Teerdhala, MD, shared, “PARP-I treatment depends on if anemia is significant; if the patient’s counts haven’t recovered or cytopenic, it’s hard to put them on full dose inhibitors if their numbers and labs don’t look good.” Use of NCODA resources, such as the PQI on Niraparib: Dose Modification, can assist all members of the MIP team to make sophisticated recommendations for optimal dosing.

I WILL LOOK INTO TP53, CHEK2, RAD51, BRIP1, AND PALB2 MUTATIONS; IF ANY PATIENTS TEST POSITIVE FOR ANY OF THOSE MUTATIONS, THEY WILL LIKELY RECEIVE A PARP-I.

Texas Oncology utilizes a unique EMR system that includes a decision-making and treatment-ordering tool. Dr. Sudha Teerdhala said, “Pathway options within this tool are aligned with NCCN guidelines and are clinically supported by evidence. All patient care is done through this one system with all levels and disciplines of care sharing the same interface, including diagnosis, staging, treatment decisions, supportive tests, imaging, and all related documentation. Additionally, as an active participator in the Oncology Care Model, Texas Oncology providers ensure eligible patients are presented with the choice to continue their care with the available options.” With a medically integrated and multidisciplinary approach, the entire team is well-positioned to deliver optimal, collaborative care. Maintenance options, including PARP-I, are prebuilt within the EMR. The pharmacist here serves as a source of drug information and education and is able to share the PQI principles with the entire multidisciplinary team.

Simmons Cancer Institute at Southern Illinois University (SIU) utilizes another EMR to manage unique patient experiences. Here, collaborative care occurs with rural community oncologists outside of SIU’s main location in Springfield, IL. Referrals from community providers reach Gynecologic Oncologist Laurent Brard, MD, PhD, who assists in determining the patient’s potential for surgery and treatment options. The nursing and scheduling teams track patients and deliver excellent care together. Without oncology-specific focus, there are no set flags, tracking mechanisms, or prebuilt treatment regimens within this EMR system. Oftentimes, patients use their local treatment center for neoadjuvant or adjuvant chemotherapy regimens which are administered by a community oncologist. With varying EMR systems from each community partner, Dr. Brard offers a solution by following every patient via thorough treatment plans he creates and shares with his team. Additionally, SIU standard processes...
ensure at least a triple-check verification of orders between the prescriber, nursing, and pharmacy teams. SIU will be increasing multidisciplinary engagement by opening up their own internal pharmacy by the end of this year. Members of the team, like certified nurse practitioner Lorie Sporrer, FNP-BC, look forward to having dispensing capability on site. She said, “Having our own pharmacy in operation with clinical pharmacists playing an increasing role will help us all to improve patient care.” During his extensive experience, Dr. Brard said, “Options are always available for patients.” He continued, “Surveillance is a critical time for ovarian cancer patients.” NCODA recognizes and values the intimate relationships that exist between providers, patients, and the full team; SIU demonstrates a coordinated care effort over great distances in a rural community setting. The PQI on PARP Inhibitor Eligibility connects the various treatment settings and cancer care providers through one standardized, effective practice. The nurses here help disseminate the principles of the PQI with the rest of the team to ensure appropriate appointments and follow-ups are conducted.

Similarly, the delivery of care within a third EMR system ultimately relies on the individual staff members working together as demonstrated with Joliet Oncology & Hematology Associates in Illinois. Oncology Clinical Pharmacist Florence Osisanya, PharmD, said, “Full patient workup is shared in real time amongst all professional disciplines, including past histories of treatments and genetic testing results. Treatment regimens are built for ovarian cancer that reflect NCCN Guidelines.” Upon progression, these patients are strictly monitored not only by providers but also by nurses, pharmacists, and schedulers within that connected EMR. Nurses initiate adherence and check-in calls and the PQI informs them of appropriate tracking and timing around maintenance therapy. Again, utilizing the PQI on PARP Inhibitor Eligibility, the MIP team adopts standard principles within their organization. Here, the pharmacist and nurse disseminate the PQI principles to the rest of the team to track the timing of treatment milestones and ensure appropriate maintenance therapy.

**OPTIONS ARE ALWAYS AVAILABLE FOR PATIENTS… SURVEILLANCE IS A CRITICAL TIME.**

The medically integrated pharmacy team at Swedish American Hospital in Illinois is currently bringing value to patients by building and implementing oral treatment plans within a fourth EMR system that is commonly used in hospital systems. Treatment regimens and plans are not standardized in the maintenance setting and they vary considerably among oncologists. Once in place, these treatment plans will allow prebuilt scheduling and tracking of treatment milestones including labs and follow-up appointments. During this transition, the clinical information contained within the NCODA Positive Quality Intervention documents enables the entire care team to deliver consistent practices. Oncology Pharmacist Ralitza Anguelova, PharmD, said, “Although we are not using clinical pathways at this time, we keep track of the patient’s progress in the EMR, which contains detailed treatment plan information.” Patient management software is also utilized to assist after an oral therapy is dispensed. Medical oncologist William Schulz, MD, explained that he works closely with other providers and the multidisciplinary team to deliver quality care. He added, “With no set flags within the EMR to prompt maintenance therapy in ovarian cancer patients, our teamwork and ability to exchange knowledge is imperative.” By sharing knowledge via the PQI and leaving detailed notes within the
EMR increases the likelihood that an ovarian cancer patient receives an appropriate maintenance therapy.

Northwest Oncology & Hematology in Illinois also delivers coordinated care to their patients through the connectivity of the entire MIP team. Medical oncologist Steven Kanter, MD, stated, “Having a pharmacist in the practice is extremely beneficial.” An integral member of Dr. Kanter’s team is Clinical Pharmacy Manager Lisa Raff, PharmD, BCPS, BCOP. As an active and engaged NCODA member, Lisa brings valuable peer-reviewed clinical information via the PQI to her colleagues.

“HAVING A PHARMACIST IN THE PRACTICE IS EXTREMELY BENEFICIAL.”

Without any prebuilt regimens within this fifth unique EMR system, the pharmacist has built all flow sheets and regimens for the organization. Both Lisa and Dr. Kanter advocate for referral to genetic counselors as a standard process. Further tracking is done via the EMR with all staff including scheduling. Having been an author for a PQI and also by serving on the PQI Review Committee, Lisa stays well-informed of the latest topics in oncology care. There is recognizable trust demonstrated by this intimate team. Undoubtedly, this integrated model and adoption of PQI principles has resulted in improved care for patients at Northwest Oncology & Hematology.

**PATIENT TRACKING VIA SCHEDULING AND FOLLOW-UP**

This research at six leading oncology organizations with five different EMR systems has revealed that the mechanics of the individual EMR are not critical. Instead, patients benefit from improving the standard processes for personnel. By providing recommendations for effective processes, the PQI on PARP Inhibitor Eligibility ensures that a coordinated effort by the entire MIP team is the reliable standard. Although software systems differ from one organization to the next, a consistent effective practice among them is to ensure proper scheduling of patient follow-up through the shared EMR.

“This multidisciplinary approach to scheduling and follow-up works well for us. We create reminders in the EMR that are effective and have improved safety.”

The MIP team carefully marks the dates for treatment milestones including scans after initial chemotherapy, anticipated surgery, adjuvant chemotherapy, regular follow-up around three months or when the physician dictates. In keeping all details electronic within one system, scheduled appointments, scans, etc. can be viewed and tracked by all staff. Dr. Steven Kanter stated, “This multidisciplinary approach to scheduling and follow-up works well for us. We create reminders in the EMR that are effective and have improved safety.” Within a different setting, Clinical pharmacist Stephanie Matta, PharmD, stated, “When it comes to patients who are receiving PARP inhibitors, medical oncologists send the initial treatment plan and pharmacists create a list of personal reminders which are sent to the oral chemotherapy pharmacy team to track those patients.” For teams that provide care in concert with community oncologists in rural settings, manual tracking of patients, including those in surveillance, assures appropriate therapy is offered. Effective triple-checking practices ensure all patients are seen one month following their last cycle. Again, these teams deliver consistent care to their patients by working together and utilizing the consistent processes described in the PQI.
CONCLUSIONS

The PQI on PARP Inhibitor Eligibility enables MIP teams to employ key principles to deliver quality care to ovarian cancer patients. By utilizing these effective practices, organizations can track and treat patients with an appropriate therapy at the appropriate time. One such PQI principle is to ensure all patients are referred to a genetic counselor for evaluation. Clinical, evidence-based EMR Pathways, Regimens, Treatment Plans, or Patient Management Software should be utilized when available. If PARP inhibitors are not currently built within the regimens or potential treatment options listed in the EMR, teams need to work with the vendor to ensure these options are included and not overlooked. Another effective process is scheduling appropriate timing of follow-up visits, imaging scans, and next lines of therapy following initial diagnosis and subsequent treatment (surgery/chemotherapy) within the EMR. Although systems differ from one organization to the next, a consistent effective practice among them is to ensure proper scheduling of patient follow-up through manual data entry within the medical record. Typical anticipated treatment milestones (such as final cycle of chemotherapy, surgery, and appropriate time to maintenance therapy) are manually tracked at all six organizations and serve as a critical patient safeguard. By building treatment plans with bundled order sets of labs and appointments, team efficiency is improved. Utilizing the PQI on PARP Inhibitor Eligibility, the entire MIP team consistently checks the EMR to ensure these appointments and calls are made accordingly.

While following up with patients during treatment, professionals have shared that patient education is another key factor. Effective practices include constant evaluation and reassessment of emesis, depression, and quality of life. Dr. Sudha Teerdhala stated, “Patient perception as to what is the standard of care (IV vs PO) or the ‘best’ way to be treated (IV > PO) can be a critical area for education and clarification. We also consider the emotional response to the perceived cost of therapy by the patient.” Another key aspect is ensuring that the patient has confidence in the treatment and ability to improve quality of life.

Lastly, ovarian cancer care is best delivered by a multidisciplinary, medically integrated team; this is the model that enables professionals to achieve positive outcomes for patients. Utilization of consistent clinical information like that contained within NCODA’s PQI standardizes knowledge exchange within an organization. Clinical pharmacists should play a proactive role in treatment decisions with the prescriber whenever possible. Nurse navigators are recommended not only for the more common cancers like breast but also ovarian and all other oncology patients. Genetic counselors, schedulers, pharmacists, providers, technicians, financial counselors, assistants, administrators, and more all play an integral role in the delivery of care. All members of the MIP team should be NCODA members to stay informed of the current NCODA PQIs and to disseminate the clinical PQI principles to their colleagues.

In closing, the Positive Quality Intervention tool has brought value to the medically integrated care teams at these six leading oncology organizations. The NCODA PQI in Action has collaborated with experts to create the PQI on PARP Inhibitor Eligibility and has assisted healthcare professionals to deliver higher quality care to their ovarian cancer patients. Through this medium, NCODA brings awareness to the fact that PQIs are publicly available on the website. Furthermore, NCODA recommends a wider adoption of new procedures to utilize clinical guidance information and employ the consistent principles contained within all PQI documents to help professionals to deliver improved outcomes for oncology patients.

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Key PQI Principles

- Genetic Counseling
- EMR Utilization (regimens, plans, scheduling)
- MIP Team (awareness, coordination)
REFERENCES


