Effective Practices in MYELOFIBROSIS Programs







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Table of Contents

- 2 Fast Facts about Myelofibrosis
- 3 Highlights of ACCC's Myelofibrosis Survey
- 4 Avera Cancer Institute
- 6 The Desert Regional Medical Center, Comprehensive Cancer Center
- 8 Norton Cancer Institute
- 12 Oral Chemotherapy Algorithm

MYELOFIBROSIS

Resources & Tools for the Multidisciplinary Team



FAST FACTS ABOUT MYELOFIBROSIS

- Classified as a myeloproliferative neoplasm, myelofibrosis can arise on its own (primary myelofibrosis), or as a progression of polycythemia vera or essential thrombocythemia.
- Myelofibrosis is thought to be caused by abnormal blood stem cells in the bone marrow. The abnormal stem cells produce more mature cells that grow quickly and take over the bone marrow, causing fibrosis (scar tissue formation) and chronic inflammation. To make up for the low number of blood cells made in the bone marrow, the liver and spleen begin to make the blood cells.
- For a small number of patients, myelofibrosis can transform to acute myeloid leukemia (AML). When AML does arise from myelofibrosis, it is often difficult to treat and can be rapidly fatal.
- In the U.S., prevalence of primary myelofibrosis ranges from 3.6 to 5.7 cases per 100,000 patients.1
- Myelofibrosis is often diagnosed relatively late in life (median age, 66 years).² At time of referral, only 13 percent of patients were younger than 50 years and 31 percent were younger than 60 years, according to one population-based study.3
- Myelofibrosis has a male preponderance.²

Symptoms of Primary Myelofibrosis



While myelofibrosis often does not cause early signs or symptoms, patients may report the following:4

- ☐ Feeling pain or fullness below the ribs on the left side
- ☐ Feeling full sooner than normal when eating
- ☐ Feeling very tired
- ☐ Shortness of breath
- Easy bruising or bleeding
- Petechiae (flat, red, pinpoint spots under the skin that are caused by bleeding)
- ☐ Fever
- Night sweats
- Weight loss.

References

- ¹ MPN Research Foundation. Primary Myelofibrosis: Prevalence. Available online at www.mpnresearchfoundation.org/ Primary-Myelofibrosis. Last accessed July 26, 2014.
- ² Tefferi A, et al. One thousand patients with primary myelofibrosis: the Mayo Clinic experience. Mayo Clinic Proceedings. 2012; 87(1):25-33.

What Programmatic Elements Contribute to a Strong **Myelofibrosis Program?***



- → The ability to control myelofibrosis symptoms in patients
- → Staff with diagnostic awareness of myelofibrosis
- → A multidisciplinary clinical management team
- → Knowledgeable providers with expertise in myelofibrosis
- → The presence of a patient advocate
- → Access to clinical trials for patients
- → Conventional and innovative treatment options
- → Close patient monitoring and follow-up
- → Patient access to and provider knowledge of targeted therapies
- → A stem cell transplant program
- → Strong supportive services, including nutrition services.
 - * Results from the 2014 ACCC Survey on Myelofibrosis (for more, see right).
 - ³ Mesa R, et al. Population-based incidence and survival figures in essential thrombocythemia and agnogenic myeloid metaplasia: an Olmsted County Study, 1976-1995. Am J Hematol. 1999; 61(1):10-15.
 - ⁴ National Cancer Institute. Primary Myelofibrosis. Available online at: www.cancer.gov. Last accessed Sept. 8, 2014.



Highlights of ACCC's Myelofibrosis Survey

In 2014 ACCC conducted a survey to identify:

- Barriers to caring for myelofibrosis patients
- Gaps in provider knowledge and resources about myelofibrosis
- Effective practices and components of a strong myelofibrosis program
- Community Resource Centers for myelofibrosis.

Survey Results

A total of 53 healthcare professionals responded to this survey questionnaire. Respondents included 30 percent hematologists and/or hematologic oncologists, followed by 25 percent oncology nurses, and 20 percent nurse practitioners. The majority (63 percent) of cancer programs treat between 1 and 20 myelofibrosis patients per year, followed by 22 percent treating between 21 and 50 myelofibrosis patients per year.

Survey findings show that a strong community-based myelofibrosis program includes the ability to control symptoms; experienced staff with diagnostic awareness of the signs and symptoms of myelofibrosis; a multidisciplinary clinical management team; access to clinical trials; and knowledgeable providers with expertise in myelofibrosis.

Challenges & Barriers

Less than half (43 percent) of respondents' cancer programs are involved in myelofibrosis clinical trials. Most of these trials (78 percent) are sponsored by pharmaceutical companies. Barriers to clinical trial involvement (as reported by 38 percent) are the lack of appropriate trials at their cancer centers, while 29 percent reported financial considerations and a lack of a clinical research infrastructure for clinical trials as barriers.

Additional Education Needed

Many community cancer programs diagnose only 20 or fewer patients with myelofibrosis each year, which may explain why practice patterns and resources are not well established for patients with this less common hematologic condition. In addition, community cancer programs may find it challenging to keep up with evolving treatments, new anti-cancer medications, and the availability of clinical trials for these patients.

Respondents reported that they would benefit from additional education in these areas:

Clinical

- 1. Diagnosis and classification
- 2. Therapeutic treatment options
- 3. Prognostic scoring systems
- 4. Symptom management
- 5. Clinical trial options

Supportive care

- 1. Financial assistance
- 2. Home community support
- 3. Palliative care
- 4. Nutrition
- 5. Transition between care settings

When asked what elements of their myelofibrosis programs needed strengthening, respondents identified needing help:

- Implementing new molecular markers for treating myelofibrosis patients
- Identifying financial assistance for co-pays for oral medications
- Accessing appropriate clinical trials
- Improving psychosocial services and patient support groups
- Educating providers about early diagnosis of myelofibrosis
- Conducting more effective outreach to family physicians.

Community Resource Centers

Through survey responses, ACCC identified three member programs with experience and expertise in treating myelofibrosis patients. In this publication these programs share practical strategies and insight into improving the delivery of quality care to myelofibrosis patients and their families. These programs will serve as Community Resource Centers for ACCC's Improving Quality Care in Myelofibrosis education project, answering questions and providing guidance to cancer programs with less experience in treating myelofibrosis patients. Go to www.accc-cancer.org/CRC to contact any of these programs:

- Norton Cancer Institute, Louisville, Ky.
- Desert Regional Medical Center, Comprehensive Cancer Center, Palm Springs, Calif.
- Avera Cancer Institute, Sioux Falls, S.D.

Each of these programs offers an array of services as well as an expert multidisciplinary team with diagnostic awareness of signs and symptoms of myelofibrosis and an engaged support staff.

FRONTIER SERVICE WITH TELEMEDICINE

Avera Cancer Institute Sioux Falls, S.D.

Avera Cancer Institute serves a mostly rural population at six regional centers in South Dakota and Minnesota. The lead program, based in Sioux Falls, serves 25 unique outreach sites through an on-site presence or telemedicine services. Its service area encompasses a 250-mile radius, including parts of Iowa, Minnesota, Nebraska, and North Dakota. The cancer program sees close to 2,000 new analytic cases a year. Of this number, just one to three are myelofibrosis patients.

With such small numbers Avera Cancer Institute does not have a dedicated multidisciplinary team for these patients or a dedicated nurse navigator. However, patients have access to a comprehensive hematology program (Avera Medical Group Hematology) and, if appropriate, the region's only bone marrow transplantation program (Avera Bone Marrow Transplant) in Sioux Falls.

Patient Monitoring & Support

Typically, Avera Medical Group Hematology makes the initial diagnosis in these patients, who often are referred by their primary care or internal medicine physicians because of fatigue and spleen-related symptoms such as abdominal pain. After further work-up, a bone marrow biopsy, and radiology scans of the spleen, a management plan is developed, coordinated by a nurse practitioner.

"When these patients are diagnosed, they are followed closely. Some patients require very frequent follow-up appointments. Most are seen monthly to manage side effects from medication, take blood work, and track their symptoms. Monitoring helps to guide the ongoing care," said Kristen D. Hurley, MSN, CNP, who has trained Avera nurses in management of myelofibrosis and myelodysplastic syndromes.

Avera Cancer Institute offers a dedicated supportive care clinic to help myelofibrosis patients control pain and manage weight loss. A full complement of services includes physical therapy, occupational therapy, exercise classes, yoga, and low impact activities to ease bone and muscle pain, for example.

"Myelofibrosis is a noncurable disease, most often seen in older patients. We would like to see our patients' quality of life improved for whatever time they have left," said Hurley.



With a population spread over an expansive, "frontier" area in the Northern Plains, treating patients in their home community becomes particularly important. All new patients, including those with myelofibrosis, receive financial counseling. "They see a patient advocate to talk about insurance coverage, outof-pocket expenses, opportunities for access to compassionate use medications, and co-pay assistance," said Kelly Carlson, RN, MS, director of Outpatient Cancer Services.

Telemedicine Program

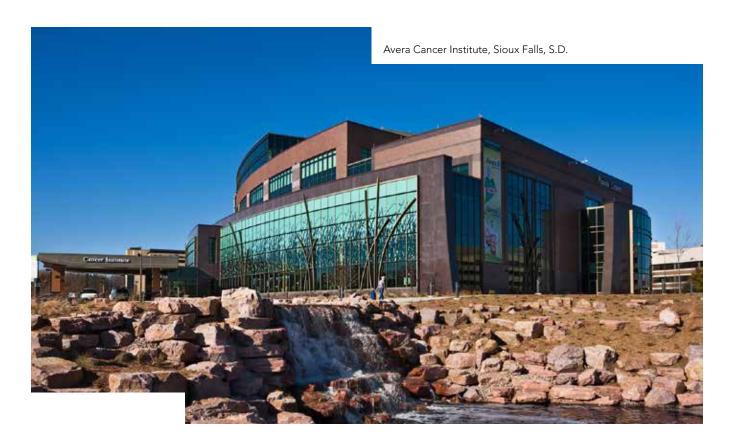
With a population spread over an expansive, "frontier" area in the Northern Plains, treating patients in their home community becomes particularly important. To ease the burden of travel across large distances and difficult weather, patients in rural areas or in surrounding states can access Avera Cancer Institute's long-established telemedicine practice. When patients return home, if they are stable and in relatively good health, they have the choice to be seen face to face or by webcam inside an exam room at their primary care physician's office.

"If we can safely do the visit through telemedicine, we do," said Carlson. "The telemedicine program ensures that the physician on one side of the camera is available through a regularly scheduled appointment slot. At the patient location, the site provides a certified nurse practitioner who can perform a clinical work-up, physical assessment, and vitals." The CNP serves as the liaison between the patient and the physician.

Oral Adherence Program

In addition to its telemedicine program, Avera has developed an oral chemotherapy adherence program that applies to all cancer patients. Prescriptions are entered into the EMR, then electronically routed to Avera's own specialty pharmacy and infusion center pharmacy. The specialty pharmacy obtains the drug and provides oversight for refills. The infusion center pharmacy verifies dose and safety as well as drug-todrug or drug-to-food interactions. Patient education is provided by infusion pharmacists and documented in the EMR. (Turn to page 12 for a sample oral chemotherapy algorithm.)

Avera Cancer Institute takes a holistic, team approach to care for its myelofibrosis patients. "For smaller cancer programs that don't have all these resources and expertise," advised Hurley, "remember that there's always someone at the other end of the phone who can help you. If you don't have experience with these patients, ask others for guidance."



AN EMPHASIS ON SUPPORTIVE CARE

The Desert Regional Medical Center, Comprehensive Cancer Center

Palm Springs, Calif.

The Desert Regional Medical Center, Comprehensive Cancer Center is a 60,000-square-foot outpatient facility, designed specifically to provide coordinated cancer screening and treatment for residents and visitors in the greater Palm Springs area. Its population tends to be elderly. Many patients reside only temporarily from October to June, when they return to their primary residence and their primary care physician (PCP).





Partnering with PCPs

"Thirty to forty myelofibrosis patients are monitored or in active treatment here, many moving between Palm Springs and the East Coast," said Timothy Tyler, PharmD, FCSHP, director of Pharmacy Services. "Patients with myelofibrosis have a unique, special situation. We provide them with a personalized approach to care, helping them make very well-informed decisions regardless of the therapy. At the end of the day, there's no substitute for conversation between the practitioner and the patient."

The goal is to transition patients back to their home community. "Once these patients are on a maintenance plan, we try to help their primary care doctor identify what we've done and the kinds of follow-up we suggest. Particularly for this chronic hematologic condition, these patients can be followed every three or six months, and for those difficult cases, every month," said Tyler. "We share progress notes with the primary care physician; they copy us on their progress notes."

Patients can participate in a robust clinical trials program, although studies targeted specifically to myelofibrosis patients are generally uncommon. Today, however, a registry trial is in process for patients with myelofibrosis and polycythemia vera. The trial looks at quality of life progression every three months.

Supportive Care is Key

According to Tyler, offering supportive care services is key to patient well-being. For example, the cancer center offers exercise and mobility classes, Tai Chi, and yoga, all geared to a more elderly, sedentary population. Another innovative program, the Lenscape Program, provides cameras to patients in treatment to create their own memory book. They are encouraged to chronicle their progress and express the emotional aspects of their journey with myelofibrosis.

Woo, PharmD.

"We have found that patients with myelofibrosis, who don't do anything, continue to feel bad. That's why we aggressively promote through fliers and posters our many activities, which are aimed specifically for older adults," said Tyler.

Desert Regional Medical Center, Comprehensive Cancer Center, opened in 1989 to offer the Palm Springs area's first multidisciplinary outpatient cancer care program, and in 2011 expanded with the opening of a 4,000-square-foot satellite in nearby La Quinta. The patient population at both facilities mirrors that of the greater Palm Springs area—people from many different regions, walks of life, and income levels. A boon to the cancer program is its social workers and financial counselors, who help ensure that patients have what they need to be safe and secure during treatment. They also free up physicians to care for patients, instead of dealing with insurance coverage issues.

Aggressive Management of Side Effects

Since its inception, the cancer program has recognized the importance of establishing a relationship with each patient that addresses his or her overall well-being. Key is the concept of patient-focused care—a wagon wheel with the patient in the center and disciplines as the spokes. These spokes include psychology, pharmacy, nurse educators, dietitians, and social workers as well as medical oncology, hematology, infectious disease, radiation oncology, and surgical oncology. This multidisciplinary team shares a common electronic health record (EHR) system and meets regularly. Physicians refer for dietary screening by protocol and routinely have patients screened for psychosocial distress.

"The general complaint from these patients is: 'I just don't feel like I used to,'" said Tyler. "When we drill down, fatigue is a core issue. The anemia that these patients experience changes their lifestyle."

In addition to conventional agents used to treat myelofibrosis-associated anemia, an important component of care for myelofibrosis patients is counseling, especially practical advice about dealing with fatigue and learning how to prioritize and downsize daily activities.

"The secret to the success of our program is that we ask the patient: What activities can you get rid of? Too often, no one has ever asked these elderly patients what exactly they do all day. No one has ever listened or helped them conserve energy," said Tyler. "Our psychologist helps them come to terms with doing less."

Psychologist Anita Chatigny, PhD, counsels myelofibrosis patients on how to cope with their diagnosis and shows them how to plan for the "new normal" that reduced energy levels can bring. Fatigue in the myelofibrosis patient can emanate from many different sources—lower blood cell count, fever, or sleeplessness from night sweats, for example. Through counseling, Chatigny assesses a patient's fatigue, noting when he or she feels more or less energetic throughout the day.

"Complete depletion of energy, that zero balance, can come in the morning or afternoon," said Chatigny. "We give myelofibrosis patients a better understanding of where that zero balance point is and what they can do to restore their energy, whether it's taking a 15 to 20 minute rest or improving nutrition. The message we tell these patients is to create a collaborative relationship with their body and be proactive with their medical care."

One 45-year-old myelofibrosis patient with young children had difficulty dealing with the fears around death and dying, as well as managing the high costs of his medical treatment and extreme fatigue. "Distress pulled him to work harder than he should have. He became so exhausted that he could not lift his head from the pillow," said Chatigny, who helped the patient move away from an overwhelming feeling of defeat to a more even psychological perspective. Over a series of eight counseling sessions, the patient learned fatigue and stress management skills.

"The patient developed an ability to mediate his own fatigue. Now he manages very well on his own. We also addressed his fears around death and dying. And in active collaboration with the oncology social worker, we mediated his insurance issues," said Chatigny.

Although psychosocial services are not revenueproducing, they are necessary to fully take care of patients with myelofibrosis, according to Chatigny. "There is tremendous benefit from oncology supportive care as an integrated part of oncology care."



Oncology Supportive Care Services team: (L to R) Anita Chatigny, PhD, director of Oncology Supportive Care Services; Nicole Verner, RD, registered dietitian; and social workers, Vicky Pulido, LCSW, and Mercy Perez, MSW.

NAVIGATION, CONSISTENT MONITORING

Norton Cancer Institute

Louisville, Ky.

Norton Cancer Institute is a leading provider of comprehensive cancer care in Kentucky and Southern Indiana. The first floor of its new facility in Louisville houses a radiation center, while the entire second floor is dedicated to a growing number of multidisciplinary clinics with expert teams specially trained in diagnosing and treating advanced and less-common cancers.

In 2013 Norton Cancer Institute diagnosed 13 patients with myelofibrosis.



Mary K. Anderson, RN, BSN, OCN, oral chemotherapy nurse clinician



David Kwasny, PharmD, BCOP, oncology pharmacist

Making the Diagnosis

Norton Cancer Institute's hematologists and pathologists make the initial diagnosis, distinguishing myelofibrosis from polycythemia vera or essential thrombocythemia, the other myeloid neoplasms, or from myelodysplastic syndromes.

After diagnosis, clinicians use the Dynamic International Prognostic Plus Scoring System (DIPSS-plus), which helps determine appropriate intervention and allows recognition of categories of patients with survival times ranging from decades to less than two years.1 According to Tefferi and colleagues in their study at the Mayo Clinic, "At initial diagnosis, approximately 24 percent of patients display transfusionrequiring anemia; 29 percent, severe constitutional symptoms; and 21 percent, marked splenomegaly. However, within one year of diagnosis, the corresponding incidences were increased to 46 percent, 38 percent, and 22 percent, respectively, which indicates the need to wait for a few months after diagnosis before establishing a prognostic score for the individual patient."1

The DIPSS-plus includes eight risk factors:

- 1. Age greater than 65 years
- 2. RBC transfusion needed
- 3. Hemoglobin level less than 10 g/L
- 4. Leukocyte count greater than $25 \times 10^9/L$
- 5. More than or equal to 1 percent blasts in the peripheral blood
- 6. Platelet count less than 100 x 109/L
- 7. The presence of constitutional symptoms, such as night sweats and loss of more than 10 percent body weight in the last six months
- 8. Unfavorable karyotype.

According to the American Society of Hematology (ASH), the scoring system is especially important for therapeutic decisions that include allogeneic stem cell transplantation. If physicians believe a patient would benefit from transplantation, Norton Cancer Institute coordinates the treatment with transplant specialists at the University of Kentucky Markey Cancer Center and provides follow-up care.

Norton Cancer Institute follows ASH (American Society for Hematology) guidelines for its myelofibrosis patients. Before embarking upon a treatment decision, a team of clinicians accurately determines the patient's immediate needs, overall performance status, potential benefits and risks of conventional treatment, availability of novel therapies, and—perhaps most importantly—the patient's wishes.

Symptom Management

Since myelofibrosis is slow-progressing, patients are often symptomatic without necessarily knowing they have the disease. These symptoms can include fatique and pain or fullness below the ribs as a result of an enlarged spleen. Patients may bruise easily due to thrombocytopenia. For many patients, the most important symptoms to be managed are:

- Anemia
- Splenomegaly (enlarged spleen)
- Extramedullary hematopoiesis (the formation of blood or blood cells outside of the medulla of the bone)
- Thrombosis (the formation of a blood clot inside a blood vessel) and thrombohemorrhagic complications
- Leukocytosis (white blood cell count above the normal range)
- Thrombocytosis (the presence of high platelet counts in the blood)
- Bone and joint pain
- Gout.

"Patients with myelofibrosis have access to expert multidisciplinary teams at seven medical oncology practices and four hospitals throughout the Norton Healthcare System," said Judy Fisher, RN, BSN, OCN, who is director, Community Resource & Support Services.

"Although we do not have a multidisciplinary clinic specific to myelofibrosis or a hematologic-specific navigator, our nurse navigators are aware of best clinical practices for the patient with myelofibrosis," said Fisher. "The main purpose of our nurse navigator program is to be the central contact point for support services and education, as well as to facilitate appointments and coordinate care."

Supportive care services include complementary therapies (Reiki massage and art therapy, for example) at no cost, as well as nutritional and psychological counseling. Educational resources for patients include a cancer resource center and myelofibrosis-specific materials. To complement its educational and support services, the cancer program works with a variety of community agencies, including The Leukemia & Lymphoma Society, the American Cancer Society, and Gilda's Club.

Patient Education & Compliance

The hospital and all Norton Cancer Institute oncology practices use the same electronic health record (EHR). Accurate and consistent monitoring of patients throughout the Norton Healthcare System is key to good care, particularly for those myelofibrosis patients on an oral agent.

If the decision is made to treat the myelofibrosis patient with oral medication, the oral chemotherapy nurse navigator and the oncology pharmacist help ensure that the patient is getting the maximum benefit. The oncology pharmacy provides written protocols specific to each oral chemotherapy drug. In addition, patients are monitored through an oral medication adherence program.

"The pharmacist watches the doses. The physicians watch the patient's health. And the nurse navigators make sure the patient is well educated about the possible side effects of the medication and is able to take the oral agent at home," said oncology pharmacist David Kwasny, PharmD, BCOP.

In August 2013 Kwasny and Mary K. Anderson, RN, BSN, OCN, oral chemotherapy nurse clinician, helped develop the role of the oral chemotherapy nurse navigator. Today, Anderson has primary responsibility for tracking adherence. "I identify patients starting oral chemotherapy and make sure every patient receives education, including information about adherence and monitoring. There was a time when patients were handed a prescription and sent out the door. Today, we have measures in place so this no longer happens."

In addition, Anderson narrated a series of YouTube videos for patients about chemotherapy. Safety Tips and Directions for Oral Medicine (www.youtube.com/ watch?v=SfYitH_K6dY), for example, provides patients with practical strategies to safely store, track selfadherence, and dispose of oral anti-cancer agents.

(continued next page)

Norton Cancer Institute (continued)

The Norton Cancer Institute has its own specialty pharmacy, which dispenses oral anti-cancer agents. "That way we can not only check on the acquisition of the drug, but also make sure refills are done on time," Kwasny noted. "In addition, the pharmacist makes sure our physicians are up to speed on the newest medications."

Patients beginning oral and cancer medication receive a safety education sheet that specifies the drug name, dose, schedule, and frequency. Safety measures such as proper storage, handling, disposal, and what to do if a dose is missed are also addressed. The patient is instructed when to call the office and when to report to the Emergency Department. We want every patient and family member to leave the clinic feeling confident about taking their oral cancer therapy in the home setting," said Anderson.

Anderson makes sure each patient receives a start date and monitoring is appropriately scheduled. Based on lab values, starting doses may vary from those recommended by the pharmaceutical company. Doses are adjusted based on recommended monitoring points, lab values and liver function, and if the patient experiences side effects.

"One week after the patient starts the medication, the nurse places a call to check on side effects and discuss adherence. If adherence concerns are noted, for example, if a patient is elderly, has cognitive difficulty, or emotional concerns, such as anxiety or depression, the nurse will contact me so I can continue to follow and support the patient," said Anderson.



Before embarking upon a treatment decision, a team of clinicians accurately determines the patient's immediate needs, overall performance status, potential benefits and risks of conventional treatment, availability of novel therapies, and, perhaps most importantly, the patient's wishes.

As the oral chemotherapy nurse navigator, she documents dose and frequency in the patient's EHR. The EPIC EHR features a new tracking system for patients receiving oral chemotherapy. At all locations throughout the Norton Healthcare System, chemotherapy nurses are aware of the safety precautions, storage, handling, and disposal of oral anticancer medications. Anderson provides education to other navigators throughout the healthcare system.

"We are proactive in following patients. We do not wait for them to call us about problems. We identify issues before they become a problem," said Anderson.

References

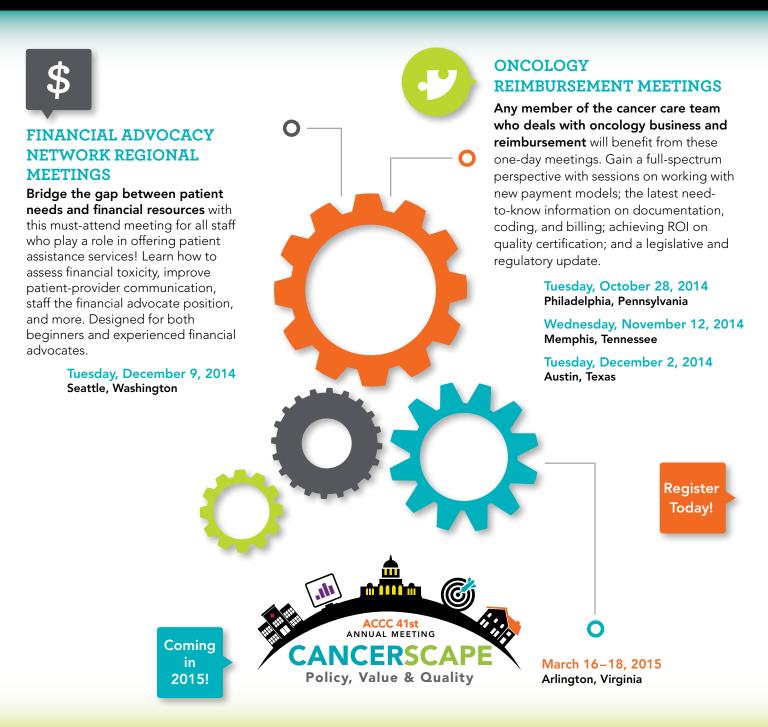
¹ Tefferi A, et al. One thousand patients with primary myelofibrosis: the Mayo Clinic experience. *Mayo Clinic Proceedings*. 2012; 87(1):25-33.



ACCC: MEETING YOUR NEEDS

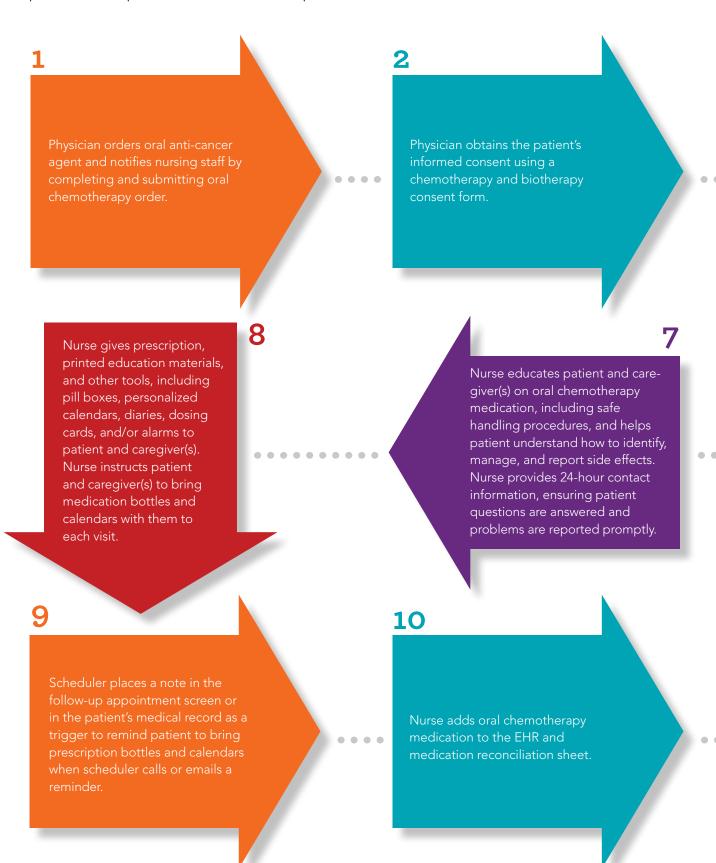


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ORAL CHEMOTHERAPY PROGRAM ALGORITHM

The most successful oral chemotherapy programs have developed a formal process that outlines the steps and staff responsible. Below is an example of one such flowchart.



3 Financial specialist conducts benefits investigation and obtains pre-authorization, if needed. Meets with patient and caregiver(s) to go over treatment costs, including the Physician or nurse sends patient's responsibility. oral chemotherapy order to If necessary, financial specialist pharmacy. helps patient and caregiver(s) identify an assistance program or refers patient and caregiver(s) to a social worker. 6 Pharmacist screens for drug/drug Nurse makes an education interactions by comparing the appointment for patient and his or her caregiver(s). 11 12 Nurse sends prescription bottles to Nurse conducts weekly follow-up pharmacy for pill counts at each visit phone calls to patient during the first to ensure patient adherence and as month of treatment, and every other week during the second and third a trigger for patient and caregiver months of treatment. re-education if necessary.

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