Pancreatic cancer (PC) has one of the poorest five-year survival rates of all cancers: 7% and 2% for all stages and advanced stages, respectively (National Cancer Institute [NCI], 2013b). One of the major reasons that PC is so deadly is because it often is diagnosed at a late stage, with about 53% of patients having metastatic disease at the time of diagnosis (NCI, 2013b). In addition, less than 20% of patients diagnosed with PC have localized, potentially resectable tumors (Hidalgo, 2010). Few symptoms of PC may be experienced in the early stages of the disease; however, symptoms are more likely to occur with more advanced disease (American Cancer Society [ACS], 2015). Jaundice, dark urine, light-colored stools, and itchy pruritic skin are common symptoms of PC (ACS, 2015). Back or abdominal pain may occur as tumors grow larger and begin to press on nearby organs or nerves (ACS, 2015). Diabetes may develop if the cancer has destroyed insulin-producing cells in the pancreas (ACS, 2015).

**Background:** Survival for patients with advanced (locally advanced unresectable and metastatic disease) pancreatic cancer is very poor; however, several advances in treatment have been made during the past several years. Gemcitabine (Gemzar®)-based regimens, FOLFIRINOX, and nab-paclitaxel (Abraxane®)-based regimens have demonstrated efficacy in patients with advanced pancreatic cancer. Understanding the unique safety profile of each of these regimens is crucial in helping nurses identify symptoms, develop patient education strategies, and ultimately improve outcomes.

**Objectives:** This article aims to provide background information on and nursing implications of the treatment of patients with advanced pancreatic cancer by exploring the mechanism of action and efficacy and safety profiles of standard treatment regimens.

**Methods:** Key trials of standard treatment regimens used in the treatment of advanced pancreatic cancer were examined with respect to efficacy outcomes and the most commonly observed adverse events. Symptom identification and management strategies are discussed from the nursing perspective.

**Findings:** The current standard treatment options for patients with advanced pancreatic cancer have differences in efficacy and safety profiles. Nurses should educate themselves on these differences, particularly on associated adverse events and their management.
In the early 1980s, 5-fluorouracil (Adrucil®) was one of the first agents (in combination with other agents) to demonstrate a survival advantage over best supportive care in patients with PC (Mallinson et al., 1980). Gemcitabine (Gemzar®) received approval for treatment of PC in 1996 and became a standard of care for patients with advanced PC after demonstrating a significant improvement in the primary endpoint (clinical benefit response, a measurement of improvement in disease-related signs and symptoms) and significantly improved median overall survival (OS) over 5-fluorouracil (Burris et al., 1997; NCI, 2013a). However, few developments were made in the treatment of PC from 1997–2011. In 2011, the FOLFIRINOX regimen (leucovorin [Wellcovorin®], 5-fluorouracil, irinotecan [Camptosar®], and oxaliplatin [Eloxatin®]) demonstrated a greater than four-month improvement in median OS over gemcitabine in a phase III trial of patients with advanced PC (Conroy et al., 2011). In the recent phase III MPACT trial, nab-paclitaxel/gemcitabine demonstrated a significantly longer median OS versus gemcitabine in patients with metastatic PC (Von Hoff et al., 2013). In this article, the authors discuss the efficacy, mode of action, and toxicities of these regimens in patients with advanced PC. In addition, nursing management considerations with respect to the toxicity profiles of these regimens are highlighted.

Key Agents in the Treatment of Advanced Pancreatic Cancer

Gemcitabine

Gemcitabine regimens have been studied in numerous phase III trials of patients with advanced PC (see Table 1). Gemcitabine first demonstrated a significant improvement in median OS over 5-fluorouracil in patients with metastatic PC (5.7 months versus 4.4 months, p = 0.0025) (Burris et al., 1997). In that study, gemcitabine treatment was associated with significant improvement in the primary endpoint, clinical benefit response, compared with 5-fluorouracil treatment (23.8% versus 4.8%, p = 0.0022). Subsequent phase III studies of various gemcitabine combinations demonstrated median OS ranging from 6.2–9 months in the treatment of patients with advanced PC but no significant differences in OS outcomes compared with gemcitabine alone (Abou-Alfa et al., 2006; Berlin et al., 2002; Herrmann et al., 2007; Louvet et al., 2005; Rocha Lima et al., 2004). Although a phase III trial demonstrated an improved median OS with erlotinib (Tarceva®)/gemcitabine versus gemcitabine in patients with advanced PC, the difference was less than one month (6.2 months versus 5.9 months, p = 0.04) (Moore et al., 2007). Gemcitabine, an analog of cytosine arabinoside that is incorporated into DNA, inhibits DNA polymerase, prevents DNA repair, and causes cell death (Mini, Nobili, Caciglì, Landini, & Mazzei, 2006). Therefore, it affects numerous metabolic processes. In the aforementioned trials, some of the common severe (grade 3 and 4) toxicities related to gemcitabine included liver enzyme elevations, nausea, fatigue, and hematologic events (neutropenia, thrombocytopenia, and anemia); grade 3 and 4 peripheral neuropathy (PN) was rarely reported with gemcitabine use in these studies (Abou-Alfa et al., 2006; Berlin et al., 2002; Burris et al., 1997; Herrmann et al., 2007; Louvet et al., 2005; Rocha Lima et al., 2004).

FOLFIRINOX

FOLFIRINOX (or variations of the regimen) is also commonly used to treat advanced PC. A phase II/III trial enrolled 342 chemotherapy-naive patients with metastatic pancreatic adenocarcinoma with an Eastern Cooperative Oncology Group performance status of 0–1 to assess the efficacy and safety of FOLFIRINOX compared with gemcitabine (Conroy et al., 2011). FOLFIRINOX demonstrated a superior survival to gemcitabine (11.1 months versus 6.8 months; p < 0.001). The individual components of FOLFIRINOX (leucovorin, 5-fluorouracil, irinotecan, and oxaliplatin) have various mechanisms of action, but many act on DNA processes to inhibit cell growth, affect metabolic pathways, and cause apoptosis (Alcindor & Beauger, 2011; Pinedo & Peters, 1988; Xu & Villalona-Calero, 2002). Some of these agents also have demonstrated synergistic antitumor activity with one or more of the other agents in the FOLFIRINOX regimen (Conroy et al., 2005). As a consequence of its mechanism of action, oxaliplatin may affect voltage-gated channels on sensory neurons, leading to PN (Adelsberger et al., 2000). Each individual agent in the FOLFIRINOX regimen has its own common toxicities that contribute to the overall side effect profile of the regimen. In the phase III trial of patients with advanced PC, the most common grade 3 and 4 toxicities related to FOLFIRINOX were neutropenia, fatigue, vomiting, diarrhea, thrombocytopenia, sensory PN, anemia, thromboembolism, and elevated liver enzymes (Conroy et al., 2011).

nab-Paclitaxel

In the phase III MPACT trial, nab-paclitaxel/gemcitabine was compared with single-agent gemcitabine in 861 patients with metastatic pancreatic adenocarcinoma with a Karnofsky performance status of 70 or greater who had not previously received chemotherapy for metastatic disease (Von Hoff et al., 2013). nab-Paclitaxel/gemcitabine demonstrated a significant improvement in median OS versus gemcitabine (11.1 months versus 6.8 months; p < 0.001). nab-Paclitaxel is a solvent-free albumin-bound formulation of paclitaxel (Celgene Corporation, 2013). Similar to other taxanes, nab-paclitaxel stabilizes microtubules, which leads to apoptosis (Jordan & Wilson, 2004). By affecting microtubules, taxanes often can damage the peripheral nerves (Argyriou, Koltzenburg, Polychronopoulos, Papapetropoulos, & Kalofonos, 2008). In the MPACT trial, the most common severe toxicities related to nab-paclitaxel/gemcitabine included PN, neutropenia, leukopenia, fatigue, thrombocytopenia, and anemia (Von Hoff et al., 2013).

Adverse Events Associated With the Treatment of Advanced Pancreatic Cancer

The physician or advanced practice nurse may not see the patient at every office visit. In addition, nurses are often the first line of communication with patients during telephone
TABLE 1. Select Grade 3 and 4 Adverse Events From Key Phase III Trials of Agents in Advanced Pancreatic Cancer

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Regimen</th>
<th>Neutropenia</th>
<th>Thrombocytopenia</th>
<th>Anemia</th>
<th>Fatigue</th>
<th>NV</th>
<th>PN</th>
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</thead>
<tbody>
<tr>
<td><strong>Gemcitabine (Gemzar®)</strong></td>
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<td>Abou-Alfa et al., 2006</td>
<td>349 patients with LAPC or MPC</td>
<td>1,000 mg/m² qw</td>
<td>23</td>
<td>15</td>
<td>7</td>
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<td></td>
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<td>1,000 mg/m² plus oxaliplatin 2 mg/m² qw 2/3</td>
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<td>1,000 mg/m² qw 3/4</td>
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<td>NR</td>
<td>11</td>
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<td>NR</td>
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<td></td>
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<td>1,000 mg/m² plus 5-fluorouracil (Adrucil®)</td>
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<td>NR</td>
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<td>1,000 mg/m² qw 3/4</td>
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<td>Berlin et al., 2002</td>
<td>327 patients with LAPC or MPC</td>
<td>1,000 mg/m² qw 3/4</td>
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<td>NR</td>
<td>11</td>
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<td>1,000 mg/m² plus 5-fluorouracil (Adrucil®)</td>
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<td>NR</td>
<td>19</td>
<td>10</td>
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<td>Burris et al., 1997©</td>
<td>126 patients with LAPC or MPC</td>
<td>1,000 mg/m² qw</td>
<td></td>
<td>26</td>
<td>10</td>
<td>10</td>
<td>NR</td>
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<td>Herrmann et al., 2007</td>
<td>319 patients with LAPC or MPC</td>
<td>1,000 mg/m² qw</td>
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<td>12</td>
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<td>6</td>
<td>NR</td>
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<td>1,000 mg/m² qw 2/3</td>
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<td>Louvet et al., 2005</td>
<td>326 patients with LAPC or MPC</td>
<td>1,000 mg/m² qw</td>
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<td>28</td>
<td>3</td>
<td>10</td>
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<td>1,000 mg/m² plus oxaliplatin (Eloxatin®)</td>
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<td>1,000 mg/m² qw</td>
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<td>Moore et al., 2007</td>
<td>569 patients with LAPC or MPC</td>
<td>1,000 mg/m² qw</td>
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<td>24</td>
<td>10</td>
<td>NR</td>
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<td>1,000 mg/m² qw</td>
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<td>Rocha Lima et al., 2004</td>
<td>360 patients with LAPC or MPC</td>
<td>1,000 mg/m² qw</td>
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<td>24</td>
<td>14</td>
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<td>1,000 mg/m² plus irinotecan (Camptosar®)</td>
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<td>FOLFIRINOX</td>
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<td>Conroy et al., 2011</td>
<td>342 patients with MPC</td>
<td>FOLFIRINOX®</td>
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<td>1,000 mg/m² plus oxaliplatin (Eloxatin®)</td>
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<td>1,000 mg/m² gemcitabine qw</td>
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<tr>
<td>nab-Paclitaxel (Abraxane®)</td>
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<td>Von Hoff et al., 2013</td>
<td>861 patients with MPC</td>
<td>nab-Paclitaxel 125 mg/m² plus gemcitabine</td>
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<td>1,000 mg/m² plus gemcitabine 1,000 mg/m² qw 3/4</td>
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<td>1,000 mg/m² plus gemcitabine 1,000 mg/m² qw 3/4</td>
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</table>

* Gemcitabine was administered weekly for seven of eight weeks, then weekly for three of four weeks.
* Reported as neurotoxicity.
* World Health Organization grades reported.
* Oxaliplatin, 85 mg/m²; irinotecan, 180 mg/m²; leucovorin (Wellcofam®, 400 mg/m²; and 5-fluorouracil, 400 mg/m² given as a bolus followed by 2,400 mg/m² given as a 46-hour continuous infusion every two weeks.
* Reported as vomiting only.

LAPC—locally advanced pancreatic cancer; MPC—metastatic pancreatic cancer; NR—not reported; NV—nausea and vomiting; PN—peripheral neuropathy; qw—every three weeks; qw 2/3—first two of three weeks; qw 3/4—first three of four weeks.
tria. Therefore, nurses should be able to identify, assess, and understand adverse events related to treatment. Nurses also play a role in the management of these toxicities and in patient education, both of which are key factors in ensuring that patients receive safe, appropriate treatment. In this section, the authors discuss three of the most common toxicity-related issues associated with the treatment of patients with advanced PC: hematologic toxicities and fatigue, generally associated with gemcitabine, FOLFIRINOX, and nab-paclitaxel treatment, and PN, which is associated with FOLFIRINOX and nab-paclitaxel.

Peripheral Neuropathy

PN is a common side effect of certain chemotherapy agents, including oxaliplatin, one of the agents in the FOLFIRINOX regimen, and nab-paclitaxel. PN, which is attributable to the mechanism of chemotherapy agents, differs by agent with respect to onset, duration, and intensity. For example, PN caused by nab-paclitaxel may appear later during treatment and may improve or resolve following dose interruptions or modifications (Goldstein et al., 2013; Gradishar et al., 2012; Socinski et al., 2012). PN related to oxaliplatin also may occur later in treatment and be of longer duration (Alejandro, Behrendt, Chen, Openshaw, & Shibata, 2013). Multiple types of chemotherapy-induced neuropathies exist (e.g., sensory, autonomic, motor). However, many clinical trials do not differentiate between the types when reporting adverse events (Lavoie Smith, 2013). Symptoms of sensory PN include numbness, tingling, burning/stabbing pain, cold sensations, throbbing, “pins and needles,” and other sensations in the upper or lower extremities or digits (Swain & Arezzo, 2008; Toftshagen, 2010). Symptoms of motor PN can include muscle weakness or difficulty controlling muscles (Swain & Arezzo, 2008; Toftshagen, 2010). Autonomic motor adverse events of these drugs may include abdominal cramps, constipation, and urinary retention (Swain & Arezzo, 2008).

Patients may be reluctant to directly report neuropathic symptoms, worrying that treatment may be discontinued or that additional medication may have to be added to their regimen. However, patients may provide clues to help identify PN, including mentioning that they have trouble using their hands or fingers or that they have experienced falls. Nurses may perform neurologic assessments. Unfortunately, many oncology nurses are limited in training, proficiency, and confidence concerning neurologic assessment techniques, as evidenced by a cross-sectional exploratory study of 39 nurses from two hospital-based outpatient chemotherapy clinics (Binner, Ross, & Browner, 2011). In that study, although 82% of nurses believed that PN was a significant problem, 75% rated their chemotherapy-induced PN assessment skills as fair or poor. Nurses must be self-aware of and take responsibility for educating themselves on neuropathic assessment techniques to provide the best care possible. Several PN assessment tools exist, and their advantages and limitations from a nursing perspective have undergone extensive review (Lavoie Smith, 2013). Implementation and use of one standard PN assessment tool among oncology centers would provide consistency and improve assessment, reporting, and intervention.

Numerous medications for managing PN have been studied, including gabapentin (Neurontin®) and pregabalin (Lyrica®); however, few effective treatment options exist (Kautio et al., 2009; Rao et al., 2007, 2008). In a phase III study, duloxetine (Cymbalta®) demonstrated efficacy compared with placebo in patients with chemotherapy-induced PN (Lavoie Smith et al., 2012). In this study, duloxetine demonstrated a significantly larger average decrease in pain score compared with placebo (p = 0.004). In addition, duloxetine showed minimal toxicity.

Some patients also try to manage PN with alternative therapies, including high-dose vitamin B, calcium/magnesium supplements, acupuncture, massage, physical therapy, cutaneous electrical nerve stimulation, and topical ointments (Ang et al., 2008; Chen, Yang, Liu, Manheimer, & Liu, 2013; Kim et al., 2013; Loprinzi et al., 2013; Smith, Coyne, Parker, Dodson, & Ramakrishnan, 2010). Trials of some of these therapies are ongoing, and, although some completed studies were moderately successful, others were not. Because of the limited number of effective treatments for PN, dose modifications of the chemotherapeutic regimen remain common. In summary, still no standard treatment for PN exists, and treatments vary widely.

Nurses play a pivotal role in educating patients about the potential for PN and the safety implications. Patients with PN should be advised to take precautions when cooking and wear gloves when washing dishes because patients affected by PN may not feel burns or cuts. Similarly, patients should be informed that they may be at increased risk of falls. Removing rugs from floors, moving furniture out of pathways, and ensuring adequate lighting in dim areas may help prevent falls. If necessary, patients can be educated on assistive ambulatory devices (e.g., canes, walkers), but they may be resistant to using them. Other suggested patient education strategies are outlined in Figure 1.

Hematologic Toxicities

Because chemotherapy agents affect rapidly dividing cells, including those in the bone marrow, pancytopenias are common (Mouser, Antoniou, Tadros, & Vassiliou, 2014). Although the incidence of certain hematologic events varies, these are commonly observed with gemcitabine, FOLFIRINOX, and nab-paclitaxel (Celgene Corporation, 2013; Conroy et al., 2011; Eli Lilly and Company, 2014). Neutropenia itself may not display symptoms; however, it can increase susceptibility to infection. Therefore, nurses should monitor patients for signs of infection, including fever, cough, and even mouth sores or dysuria, because infections are not always limited to the respiratory tract (Boxer, 2014). Symptoms of low hemoglobin (anemia) can include pallor, tachycardia, dyspnea, chest pain, dizziness, cognitive problems, headaches, cold intolerance, and fatigue (Cavendish, 2007; U.S. Department of Health and Human Services, 2011). Symptoms of thrombocytopenia may include easy or excessive bruising, petechiae, or issues related to clotting, such as epistaxis, bleeding gums, hematuria, or persistent bleeding from cuts (Crawford & Blackwell, 2008; National Heart, Lung, and Blood Institute, 2012). Nurses should be knowledgeable about the often subtle symptoms of hematologic adverse events. In addition, nurses should educate patients about the signs and symptoms of hematologic adverse events because with prompt...
reporting, early identification, and early intervention, patients often can continue to receive therapy with little to no interruption in treatment or dose adjustment.

Management of hematologic toxicities ranges from a “watch and wait” approach to growth factor support and transfusions. Patients with neutropenia should be instructed on ways to avoid infections, including using good handwashing techniques, avoiding those with illnesses, and making diet modifications when necessary. Commonly, white blood cell growth factors are used for patients who develop neutropenia and are at increased risk of sepsis (Boxer, 2014). Treatment with erythropoiesis-stimulating agents may be required for patients who develop anemia, but severe, symptomatic anemia may warrant a blood transfusion. Other causes of anemia during chemotherapy treatment should be ruled out. For example, iron deficiency, folate deficiency, and vitamin B₁₂ deficiency also can cause anemia, and each of these can be corrected with appropriate supplementation. For thrombocytopenia, interventions are limited. Corticosteroids and IV immunoglobulin may be used in special circumstances (Liel, Recht, & Calverley, 2014). If severe, potentially life-threatening thrombocytopenia occurs, platelet transfusions are warranted (Crawford & Blackwell, 2008; Liel et al., 2014). For thrombocytopenia, treatment delays and dose modifications are among the more common interventions, particularly for gemcitabine-induced thrombocytopenia.

Patients must understand that hematologic abnormalities can occur with chemotherapy treatment. Patients should be educated about the expected onset and duration, potential types of symptoms, precautions, and available treatment options. Informing patients that interventions and treatments are available is particularly important because it may increase the likelihood that patients will report symptoms. Encouraging patients to adhere to laboratory monitoring schedules is equally important so that abnormalities can be identified and treated early, potentially before symptoms develop.

Fatigue

Fatigue is one of the most common side effects of treatment with gemcitabine, FOLFIRINOX, and nab-paclitaxel. Because healthy cells are destroyed by chemotherapy, fatigue can occur. However, fatigue also can be related to other issues, including anemia, depression, poor nutrition, and lack of sleep (Berger, 2003). Fatigue can also be a side effect of concomitant medications, such as narcotics (Berger, 2003).

Identifying the underlying cause of fatigue in patients receiving chemotherapy is challenging, but ensuring optimal treatment and implementation of appropriate supportive care is essential. Fatigue can be dangerous if it occurs during everyday activities, such as driving a car or caring for a child. It can also be particularly dangerous if it occurs at night because patients are already more vulnerable to falls in darkness.

Communicating with patients about their fatigue is important at all stages of treatment. Asking patients more specific questions about their fatigue may be helpful. For example, gather information about when fatigue is occurring (morning or evening). Ask patients complaining of fatigue if they are getting enough sleep or if they are up several times a night because of other symptoms, such as nocturia, nausea, or pain. Inquire about nutritional and fluid intake. Ascertain whether
Because nurses are at the forefront of initial identification of the common side effects, providers rely on their knowledge and skills not only to educate their patients, but also to assess early signs of toxicity. Nurses play a crucial role in patient care from the beginning of treatment. Continued education on new therapies, potential side effects, and interventions are of the utmost importance to keep patient care at the highest levels.

References

Discussion and Conclusion
Treatment outcomes in advanced PC have improved in recent years; however, nurses must be aware of the potential side effects of newer agents. Although two of the newest chemotherapy regimens used for the treatment of advanced PC, FOLFIRINOX and nab-paclitaxel/gemcitabine, were associated with a significantly improved OS compared with single-agent gemcitabine, they also had higher rates of adverse events (Conroy et al., 2011; Von Hoff et al., 2013). Proper management of toxicities may result in improved outcomes with FOLFIRINOX or nab-paclitaxel/gemcitabine. In addition, awareness of common side effects of these regimens is critical to identification, assessment, management, and patient education. Early identification and intervention are key to improving patient tolerance and, ultimately, outcomes.

Implications for Practice
- Provide appropriate patient care by understanding the differences in efficacy and safety among the most commonly used regimens in advanced pancreatic cancer.
- Improve quality of care by being able to identify early signs of some of the most common adverse events, including peripheral neuropathy, hematologic toxicities, and fatigue.
- Develop and implement patient education strategies, and encourage patients to report and seek early intervention for adverse events.


