Baseline Evaluation of the AIM Higher Initiative: Establishing the Mark From Which to Measure

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Purpose/Objectives: To collect baseline measurements before the implementation of interventions associated with the AIM (Assessment Information Management) Higher Initiative—a quality improvement program intended to improve symptom assessment, management, and information distribution for five chemotherapy-related symptom groups: anemia, neutropenia, diarrhea and constipation, nausea and vomiting, and depression and anxiety.

Design: Subject telephone interviews and chart reviews.

Setting: 15 community oncology clinics in the United States.

Sample: 376 adult patients with cancer who visited a healthcare provider before the start of a chemotherapy cycle; patients were enrolled in the study after the initiation of chemotherapy, with at least one chemotherapy cycle remaining.

Methods: Subject interviews and chart reviews to determine the frequency, assessment, and management of and information about target symptoms.

Main Research Variables: The frequency of target chemotherapy-related symptoms and occurrence of symptom-specific assessment, information provided, and management.

Findings: The five target symptoms had occurred in a considerable proportion of patients with cancer receiving chemotherapy during their most recent chemotherapy cycles. At a substantial number of clinic visits, no documentation of cancer-related symptom assessment, information distribution, or management occurred.

Conclusions: Chemotherapy-related symptoms occur frequently but often are not assessed, managed, or handled with appropriate patient information.

Implications for Nursing: Findings in the baseline evaluation illustrate the need to improve supportive care—a key responsibility of oncology nurses.

Key Points . . .

- The inadequate assessment and management of chemotherapy-related toxicities can have substantial clinical, economic, and quality-of-life consequences.
- The AIM (Assessment Information Management) Higher Initiative is designed to optimize supportive care by improving cancer-related symptom assessment, information distribution, and management for five chemotherapy-related symptom groups: anemia, neutropenia, diarrhea and constipation, nausea and vomiting, and depression and anxiety.
- Pretreatment risk assessments often are not documented in patients; in addition, a substantial proportion of symptoms are underreported, underassessed, and therefore, undertreated.

In a National Institutes of Health ([NIH], 2002) state-of-the-science statement, Donald L. Patrick, MD, said that the undertreatment of cancer-related symptoms is unacceptable when many effective strategies to manage symptoms exist and that optimal symptom management should be received by all patients. The AIM (Assessment Information Management) Higher Initiative, a national quality improvement program, was developed to optimize supportive care for chemotherapy-related symptoms, including anemia, neutropenia, diarrhea and constipation, nausea and vomiting, and depression and anxiety. The AIM Higher Initiative is intended to provide office-based interventions to improve three key components of supportive care in cancer: symptom assessment, information distribution, and management.

Assessment

Inadequate assessment is a barrier to effective management of symptoms (NIH, 2002), and inadequate management of chemotherapy toxicities can have negative consequences. Anemia and other toxicities, for example, can have profound effects on patients' quality of life (QOL) (Cella et al., 2003). Fatigue occurs in as many as 75% of patients who are treated with chemotherapy (Gillespie, 2002), and hemoglobin levels less than 12 g/dl are associated with fatigue, a greater requirement for red blood cell transfusions, depression, sleep disorders, and reduced ability to work (Cella, 1998; Gillespie, 2002). Patients who are unable to work suffer economic burden associated with lost wages. In addition, patients who are required to travel for treatment may incur expenditures for transportation, child care, food, and hotel accommodations (Fortner, Tauer, Zhu, Ma, & Schwartzberg, 2004). Chemotherapy toxicities are of even greater concern because they contribute to morbidity and potentially life-threatening complications. An analysis of data on 55,000 hospitalizations for febrile neutropenia found in-hospital

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mortality of approximately 11% overall and 18% in patients with leukemia (Lyman & Kuderer, 2003). Similarly, uncontrolled diarrhea can necessitate hospitalization for parenteral hydration and diagnostic workup, with severe loss of fluids and electrolytes sometimes precipitating cardiovascular events (Cope, 2001).

Assessment is a crucial first step in effective management of symptoms and facilitates the initiation of patient-centered interventions by identifying any problems (Ropka & Spencer-Cisek, 2001). Risk assessment evaluates patients' risk for certain symptoms prior to treatment (Ropka, Padilla, & Gillespie, 2005). Disease state, chemotherapy regimen, and patient factors should be evaluated. Patient-specific risk factors are associated with a greater likelihood of certain problems. For example, patients who are treated with platinum-based regimens, have a history of motion sickness, and are younger than age 40 have a higher risk of experiencing chemotherapy-related nausea and vomiting (National Comprehensive Cancer Network, 2007; Tsavaris et al., 2000).

Documenting risk factors in patients will increase the oncology team's awareness and provide a rationale for interventions. Documentation also can help prevent problems and determine what ongoing symptom screening is required and whether proactive measures should be taken (Donohue & Carbo, 2004). For instance, several risk models have been developed to determine which patients are most likely to develop febrile neutropenia and, consequently, are most likely to benefit from proactive granulocyte–colony-stimulating factor (G-CSF). Models that rely entirely on pretreatment assessments can be used to determine which patients are at high risk before the first cycle of chemotherapy, when the risk of febrile neutropenia is greatest (Cappozzo, 2004; Crawford, Dale, & Lyman, 2004; Lyman et al., 2005; Lyman & Kuderer, 2003). Nurses easily can perform risk assessments by incorporating them into the existing standard evaluations for patients who are to be treated with new therapies. Integrating risk assessments can facilitate targeting symptom-specific screening or prophylactic measures to patients who are most likely to benefit from them.

Patients with cancer tend to underreport or neglect to report their symptoms if they are not prompted to do so (Fortner, Okon, Ashley, et al., 2003; Rutledge & McGuire, 2004; Ward et al., 1993). When patients begin to receive chemotherapy, ongoing assessment for symptoms should be routine. Structured, systematic assessment has been implicated in improving symptom distress in patients with advanced lung cancer (Sarna, 1998). Routine, systematic assessment can give patients the opportunity to report symptoms at every visit, which enables the oncology staff to identify and manage problems appropriately during therapy. Consistent and routine symptom assessment is important because not all symptoms occur when they are expected. Serial screening with a standardized QOL assessment tool may detect changes in functioning that signal the onset of patient symptoms.

Once a symptom has been identified, further assessment to determine its cause may help guide management and prevent greater complications. In addition, ongoing assessment allows the oncology team to communicate to patients the value of reporting symptoms and patient collaboration. Ongoing assessment may include monitoring laboratory measures, patient-reported symptoms and severity, functional status, and psychosocial status (Cella et al., 1993; Cope, 2001; Gillespie, 2003). The Patient Care Monitor™ (Supportive Oncology Services, Inc.) is an example of a comprehensive, psychometrically validated cancer symptom screening tool. The Patient Care Monitor prompts patients to rate physical symptoms, indicators of mental health, and measures of physical functioning on a scale of 0–10 and provides assessment documentation (Fortner, Okon, Schwartzberg, Tauer, & Houts, 2003). Documentation of ongoing assessments is valuable because it provides a reference of patient status over time, rationale for treatment plans, and communication for the oncology team. Documentation of patient-reported severity also is important because the significance patients give to a symptom may change over time, which alters the perception of symptom burden and thus influences clinical decision making (Rutledge & McGuire, 2004).

Information Distribution

Patient education is a crucial component of supportive care, not only for detecting symptoms and toxicities but also for preventing and managing them (Chelf et al., 2001; Fernsler & Cannon, 1991). Many patients with cancer have considerable anxiety about the disease and treatment because of uncertainty and fear of the unknown. Anticipatory guidance provided through information to patients can help alleviate anxiety, facilitate communication, and empower patients to partner in their care. Providing patients with information on likely symptoms and toxicities, as well as strategies for minimizing them, has been shown to reduce anxiety and depression

Table 1. Target Symptoms Assessed in Subject Interviews and Chart Reviews

	Measures	
Target Symptom	**Interview**	**Chart Review**
Diarrhea	X	X
Constipation	X	X
Nausea	X	X
Vomiting	X	X
Depression		X
Feeling sad or blue	X	X
Loss of interest or pleasure	X	X
Feeling bad even when something good happens	X	X
Feeling worthless	X	X
Feeling hopeless	X	X
Anxiety		X
Feeling nervous, anxious, or tense	X	X
Worrying	X	X
Difficulty sleeping	X	X
Anemia	X	X
Low red blood cell count	X	X
Fatigue, tiredness, no energy[a]	X	X
Trouble breathing, chest pain	X	X
Neutropenia	X	X
Low white blood cell count	X	X
Fever[a]	X	X
Sore throat	X	X
Shortness of breath	X	X

[a] Additional measures were collected, but the analysis focused on patient-reported fatigue and fever as symptoms of anemia and neutropenia, respectively.

Table 2. Patient Characteristics

Characteristic	n	%
Female	269	72
White	327	87
Married	268	71
High school education or greater	344	91
Cancer Diagnosis	**n**	**%**
Multiple myeloma	8	2
Breast	115	31
Gastrointestinal	71	19
Genitourinary or gynecologic	84	22
Leukemia	10	3
Lung	40	11
Non-Hodgkin lymphoma	25	7
Other	23	6

N = 376

Note. The mean age of subjects was 59 years, with a standard deviation of 13.

Note. Because of rounding, not all percentages total 100.

in later treatments (Thomas, Daly, Perryman, & Stockton, 2000). Oncology nurses often are responsible for patient education, but teaching tools and methods vary considerably. Standardized educational tools in a variety of formats that address patients' learning needs can help ensure that patients are given consistent, current, and clinically relevant information. Materials should be understood easily and made accessible to patients. They can be used by novice and experienced nurses at the time of diagnosis, before therapy is initiated, during therapy to reinforce concepts as symptoms arise, and as needed to meet the needs and interests of patients.

Management

Suboptimal management of cancer symptoms and chemotherapy toxicities may lead to compromised treatment. Severe anemia, for example, can delay surgical interventions. Several studies have found that anemia may lessen the efficacy of radiotherapy—a possible consequence of low tumor oxygenation that limits the cytotoxicity of radiation (Gillespie, 2003). Many reports have noted lower overall and disease-free survival in patients with anemia who are treated with radiotherapy (Gillespie, 2003). For instance, neutropenia frequently necessitates chemotherapy dose reductions or delays, which have been associated with lower disease-free and overall survival, especially in patients with curable tumors (Bonadonna et al., 2005; Kwak, Halpern, Olshen, & Horning, 1990). Lyman, Dale, and Crawford (2003) found dose reductions in 37% and dose delays of seven days or more in 25% of patients with breast carcinoma, resulting in 56% of patients being treated with less than 85% of the relative dose intensity.

Because of the substantial human and clinical toll exacted by cancer symptoms and treatment, detecting and ameliorating symptoms are expected to help minimize declines in QOL, maintain the optimal delivery of cancer treatment, and reduce complication-related morbidity and mortality. A meta-analysis of 14 randomized trials found that the proactive management of chemotherapy-induced neutropenia with G-CSF reduced rates of febrile neutropenia and helped make giving chemotherapy at full dose and on schedule possible. Infection-related mortality was 48% lower in patients treated with G-CSF than in the control group (Kuderer, Crawford, Dale, & Lyman, 2005). Furthermore, increases of 2 g/dl or greater in hemoglobin levels of patients treated with epoetin alfa for anemia correlated with significant improvements in QOL (Crawford et al., 2002), which has been shown to be an independent predictor of survival. Psychosocial interventions to reduce depression and anxiety and improve QOL have been found to increase disease-free and overall survival (Chang et al., 1998; Kash, Mago, & Kunkel, 2005).

Depending on symptoms that occur and are identified in assessment, management strategies for reducing severity and duration may include therapeutic as well as supportive interventions, such as dietary recommendations and counseling. The optimal management of any symptom depends on its cause and can be achieved by using evidence-based practices, which incorporate current scientific findings with relevant clinical knowledge. Evidence-based practice in supportive care facilitates developing management plans that are known to be effective, using appropriate therapies, dosing, and timing; minimizing the negative effect on QOL; preventing the interruption of the cancer treatment; and lowering the risk of significant morbidity or mortality. Evidence-based practice may include integrating clinical guidelines and standard orders into everyday care, which sets a standard for obtaining favorable clinical outcomes and makes providing high-quality, efficient care possible for clinicians.

AIM Higher Initiative

Although practice-based algorithms or standing orders (e.g., for managing anemia or neutropenia) are in place at many institutions and have been shown to improve quality indicators, such as chemotherapy delays (White, Maxwell,

Table 3. Chemotherapy Regimens

Regimen	n	%
Carboplatin or gemcitabine, with or without bevacizumab	9	2
Cisplatin or carboplatin and docetaxel or paclitaxel with or without trastuzumab	59	16
Cisplatin or carboplatin, etoposide	16	4
Cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab	14	4
Doxorubicin, cyclophosphamide, paclitaxel or docetaxel, with or without trastuzumab	19	5
Doxorubicin or epirubicin, cyclophosphamide	29	8
Fluorouracil and leucovorin or fluorouracil, leucovorin, oxaliplatin, with or without bevacizumab	29	8
Fluorouracil, leucovorin, irinotecan, with or without cetuximab or bevacizumab	14	4
Fluorouracil, cyclophosphamide, methotrexate	8	2
Gemcitabine with or without bevacizumab	11	3
Liposomal doxorubicin	7	2
Other[a]	124	33
Paclitaxel or protein-bound paclitaxel or docetaxel, with or without bevacizumab or trastuzumab	37	10

N = 376

[a] Single- or multiple-agent chemotherapies with an overall incidence less than 2%

Michelson, & Bedell, 2005), the efforts typically have focused on a single symptom. The AIM Higher Initiative intends to develop practical, multidisciplinary, nurse-driven interventions to improve clinical processes in supportive care for five chemotherapy-related symptoms groups: anemia, neutropenia, diarrhea and constipation, nausea and vomiting, and depression and anxiety.

The AIM Higher Initiative is based on principles from a previously developed model, the Symptom Management Model, which identified three interrelated realms that must be addressed for effective management of treatment-related symptoms: experience, management, and outcomes. The AIM Higher Initiative used the Symptom Management Model to guide interventions and research (Dodd et al., 2001; Larson et al., 1999) but extended its goals to include improving cancer-related symptom assessment, information distribution, and management. Because nurses play vital roles in providing supportive care to patients, the AIM Higher Initiative was designed to improve patient outcomes and encourage nurses to provide care that is more efficient and evidence-based, increase awareness of the importance of managing symptoms, and provide other nurses with ideas for improving supportive care in collaboration with oncology teams. The goal of the current study was to perform a baseline evaluation to gather information on symptom management for the AIM Higher Initiative before interventions were implemented.

Methods

An institutional review board–approved research protocol was used to collect baseline data at 15 outpatient community oncology practices in the continental United States, using a convenience sample of approximately 25 subjects from each practice. The sites were selected based on willingness to participate in the AIM Higher Initiative and desire to improve process outcomes. Subject inclusion criteria included having one cycle of IV chemotherapy for cancer treatment, with at least one more cycle planned; a recent (i.e., within seven days before the start of a cycle of chemotherapy) provider visit; Eastern Cooperative Oncology Group performance status of 0–3; and written informed consent, as well as being at least 18 years old. Exclusion criteria included weekly chemotherapy regimens or participation in a research protocol using investigational agents. Patients treated with weekly chemotherapy regimens were excluded so the study could reach patients in a familiar home environment, prevent interview responses from being skewed by potentially stressful clinic schedules, ensure that responses reflected experiences at the clinic and home, and avoid patient confusion about when one cycle ended and the next began.

Site staff obtained informed consent and verified subject eligibility. Subjects were interviewed via telephone by a contract research organization to maintain objectivity and avoid bias while providing subjects with full confidentiality, thereby encouraging honest responses about experiences at the clinic. Target symptom groups were evaluated during the interviews (see Table 1). Responses provided to the sites were kept anonymous. Subjects were asked how frequently symptom groups occurred in the previous cycle of chemotherapy, if any symptoms were problematic during the cycle, and if any symptoms were discussed during the most recent provider visit.

Charts on all subjects were retrospectively reviewed by trained site staff. The complete medical record, including orders, laboratory work, physician and nurse interviews, completed forms, consultations, and referrals, was reviewed for evidence of documentation of the symptoms. The chart review targeted symptom occurrence, assessment, information provided to patients, and symptom management. The chart review investigated whether risks for each symptom group had been assessed before the start of the chemotherapy regimen.

Table 4. Documented Evidence of Pretreatment Risk Assessments

Symptom	n	%
Diarrhea	64	17
Constipation	56	15
Nausea	83	22
Vomiting	64	17
Depression	22	6
Anxiety	26	7
Anemia	92	24
Neutropenia	96	26

N = 376

Table 5. Symptoms Reported During Telephone Interviews

Symptom	n	%
Diarrhea	120	32
Constipation	151	40
Nausea	172	46
Vomiting	55	15
Depression	162	43
Anxiety	273	73
Fatigue, tiredness, no energy[a]	297	79
Fever[a]	52	14

N = 376

[a] Additional measures were collected, but the analysis focused on patient-reported fatigue and fever as symptoms of anemia and neutropenia, respectively.

Results

Data on 376 subjects were available for analysis. Subjects predominantly were married (71%), white (87%), and female (72%), and had a high school education or greater (91%) (see Table 2). The mean age was 59. See Table 3 for participants' chemotherapy regimens.

Chart review showed that symptoms were not documented or most patients had not been assessed for the risk of the target symptoms before chemotherapy was initiated. The most common risk assessments were for neutropenia (26%) and anemia (24%), and the least common were for depression (6%) and anxiety (7%) (see Table 4).

In the telephone interview, many subjects reported that target symptoms had occurred during their most recent cycle of chemotherapy (see Table 5), despite the lack of chart documentation (see Table 6). The most frequently reported symptoms were fatigue (79%) and anxiety (73%), and the

least frequently reported were fever of any cause (14%) and vomiting (15%). The incidence of assessment ranged from 16% (for anxiety) to 67% (for fever).

Subjects who reported one or more symptoms during the most recent chemotherapy cycle often lacked symptom assessment, patient education, and management of symptoms and toxicities (see Table 7). A chart-documented assessment of symptoms was reported in telephone interviews in as many as 71% of subjects (for fever) and in as few as 18% (for anxiety). Symptom-specific information was provided for as many as 19% of subjects (for nausea) and as few as 3% (for depression). Evidence of management was apparent in as many as 44% of subjects (for nausea) and as few as 9% (for depression).

Discussion

Baseline evaluation confirms that target symptoms frequently occur in patients with cancer. Furthermore, the findings show a substantial need to document and improve supportive care for the symptoms in patients with cancer. Pretreatment risk assessment was not performed for target symptoms in most patients. In addition, a substantial proportion of reported symptoms lacked documented evidence of having been addressed, suggesting underassessment and undertreatment. Symptoms related to depression, for example, were reported by 43% of patients in phone interviews, but assessment documentation and management of depression were found in only 21% and 9% of patient charts, respectively. Similarly, documentation stating that fatigue was assessed and addressed in patients reporting it occurred in 49% and 12% of patient charts, respectively. Symptom-specific patient information generally was lacking, being provided for symptoms less than 20% of the time.

Limitations

The findings are limited because the methods provide results documented over a limited time with consecutive patients. Some assessment, information, and management may have occurred that was not documented. This methodologic limitation suggests that, with the exception of the provision of information, the weaknesses in routine care at baseline may have been overestimated. For example, assessments and management steps could have taken place but were not documented. Lack of assessment and management documentation likely reflects real weaknesses because documentation is routine for medical and legal reasons as well as for auditing by third-party payers. Conversely, incentives to document the provision of information do not exist. Patient education may occur without being documented.

Table 6. Documented Evidence for the Assessment of Symptoms During Provider Visits

Symptom	n	%
Diarrhea	185	49
Constipation	175	47
Nausea	226	60
Vomiting	189	50
Depression	80	21
Anxiety	62	16
Fatigue, tiredness, no energy[a]	184	49
Fever[a]	253	67

N = 376

[a] Additional measures were collected, but the analysis focused on patient-reported fatigue and fever as symptoms of anemia and neutropenia, respectively.

Table 7. Documented Evidence of the Assessment and Management of and Information Provided About Symptoms in Subjects Who Reported Symptoms During Telephone Interviews

	Assessment		Information		Management	
Symptom (N)	n	%	n	%	n	%
Diarrhea (120)	65	54	13	11	28	23
Constipation (151)	74	49	14	9	21	14
Nausea (172)	115	67	33	19	76	44
Vomiting (55)	31	56	8	15	19	35
Depression (162)	34	21	5	3	15	9
Anxiety (273)	50	18	15	5	36	13
Fatigue, tiredness, no energy[a] (297)	146	49	28	9	37	12
Fever[a] (52)	37	71	3	6	7	13

[a] Additional measures were collected, but the analysis focused on patient-reported fatigue and fever as symptoms of anemia and neutropenia, respectively.

Conclusion

Baseline evaluation provides insight into problems of inadequate assessment, information, and management and can be used to make changes in practice patterns. In addition, baseline evaluation establishes a starting point for comparison with measurements after intervention. Four intervention strategies have been identified to optimize symptom assessment, information given to patients, and management of symptoms, which are (a) pretreatment assessment symptom risk; (b) routine, standardized, ongoing assessment throughout treatment for the presence and severity of symptoms; (c) patient education about actual and potential symptoms, using standardized materials and delivery mechanisms; and (d) evidence-based symptom management strategies to reduce the severity and duration of symptoms.

Now that the present baseline evaluation is completed, participating community oncology practices are implementing practice-specific interventions in assessment, information, and management for each target symptom group. Trained nurse champions at each practice are leading the efforts by using the three-step AIM Higher Initiative process of completing a practice analysis, developing a quality improvement plan, and implementing the plan. The ongoing program evaluation will capture additional data after the assessment, information, and management phases of the initiative have been implemented. The final program evaluation will determine whether the AIM Higher Initiative has produced improvements in baseline measurements.

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