Published in final edited form as:

Clin J Oncol Nurs. 2017 August 01; 21(4): 473–479. doi:10.1188/17.CJON.473-479.

Palliative Care and Phase 1 Trials: Intervention to improve quality of life and provide education

Betty R. Ferrell, RN, PhD, MA, FAAN, FPCN, CHPN®, Vincent Chung, MD, Marianna Koczywas, MD, Anna Cathy Williams, RN, MSN Ed., PHN, Denise Gallagher, RN, BSN, Patricia Fischer, BSN, MBA, and Thomas J. Smith, MD

Betty R. Ferrell, RN, PhD, MA, FAAN, FPCN, CHPN®, is a professor and director of the Division of Nursing Research and Education, Vincent Chung, MD, is a physician, Marianna Koczywas, MD, is a professor and thoracic medical oncologist, and Anna Cathy Williams, RN, MSN Ed., PHN, is a senior research specialist in the Division of Nursing Research and Education, all at the City of Hope Comprehensive Cancer Center in Duarte, CA; and Denise Gallagher, RN, BSN, and Patricia Fischer, BSN, MBA, are senior research nurses, and Thomas J. Smith, MD, is a professor, all in the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University in Baltimore, MD

Abstract

Background—Phase 1 clinical trial patients often have a significant symptom burden and QOL concerns which increase as a result of the progression along the cancer trajectory and clinical trial drug toxicities. This paper describes an intervention in progress to support patients on clinical trials.

Objectives—This randomized clinical trial tests a Palliative Care Intervention that is administered concurrently to cancer patients with solid tumors who are participating in a Phase 1 clinical trial. The interdisciplinary intervention is aimed at providing optimum palliative care to support patients through clinical trials.

Methods—The intervention includes a baseline evaluation using quantitative surveys, a comprehensive palliative care assessment by a Research Nurse based on patient baseline evaluation, and goals of care discussion by the treating oncologist. The second component includes an interdisciplinary meeting where palliative care recommendations are made, followed by two patient educational sessions.

Findings—Initial experience with this palliative care intervention suggests the need for support for this population and the potential benefits of integrating palliative care for patients on Phase 1 Clinical Trials.

Keywords

palliative care; Phase 1 clinical trials; quality of life; symptom burden

Background

Phase 1 clinical trials offer the opportunity to advance science in oncology and improve survival. This paper presents development of an intervention and a study in progress supporting the need for integration of palliative care for patients on clinical trials.

Phase 1 clinical trial patients are generally less symptomatic with higher function than most advanced disease cancer patients in order to qualify for participation. Often, however, they have a significant symptom burden. An M. D. Anderson Cancer Center study reported that Phase 1 patients had better performance scores (ECOG 0–4), but a symptom burden similar to other oncology patients, with an average pain score of 5.3 (0–10 scale) and a fatigue score of 5.7 on a 0–10 scale (Hui et al., 2010). The prevalence of symptoms in Phase 1 patients ranged from 93/104 patients (90%) for fatigue, with vomiting in only 25/104 patients (24%) (Parsons, Baracos, Dhillon, Hong, & Kurzrock, 2012). In a study at the University of Pennsylvania, Phase 1 patients had a symptom burden similar to non-enrolled patients, but after adjustments for ECOG performance status scores, the Phase 1 patients were more likely to have 5 of the 10 symptoms assessed with the Memorial Symptom Assessment Scale, with greater severity for 6 of 10 symptoms (Finlay, Lu, Henderson, O'Dwyer, & Casarett, 2009).

In addition to a baseline symptom burden, Phase 1 trials are known to increase patient symptoms. As patients progress on the cancer trajectory, performance status worsens and symptoms increase. Clinical trial drugs may have toxicities causing side effects, multiple clinic visits, time away from family, and increased diagnostic tests. Targeted therapy may cause additional side effects, in addition to existing disease and medication side effects (Cassel et al., 2016). Phase 1 trials can increase symptom burden and decrease quality of life.

Early research revealed Phase 1 patients to be a highly motivated group willing to take treatment chances. In one report, 90% of Phase 1 patients would risk an unproven drug with a 10% chance of mortality (Agrawal et al., 2006). In this same report, 84% of patients were aware of hospice and palliative care options, but only 6% had considered these options. Recent research, however, reflects patients' unwillingness to participate in clinical trials, with only 35 percent of Americans likely to enroll in a trial. New data shows that only 40% of Americans view clinical trials favorably, citing such barriers to clinical trial enrollment as side effects, safety, insurance coverage, inconvenience, feeling like "guinea pigs", and general skepticism (Memorial Sloan Kettering Cancer Center [MSKCC], May 23, 2016). This negative public view is occurring at a time when the oncology community is calling for increased clinical trial participation.

Prior reviews have documented patients' failure to understand treatment intent or Phase 1 trial alternatives; realistic benefit and risk expectations; and the right to withdraw or not enter the trial (Cox, Fallowfield, & Jenkins, 2006). Despite a patient's terminal illness and average survival of just several months, oncologists rarely discuss prognosis during Phase 1 trial discussions (Jenkins, Anderson, & Fallowfield, 2010; Jenkins et al., 2011). A recent national poll of 600 respondents found that physicians see clinical trials "as a treatment of

last resort”, even though they are available in early treatment phases (MSKCC, May 23, 2016). The study suggests that providers consider clinical trials for patients across the cancer spectrum and communicate these opportunities. The authors of this report concluded that “Failing to consider clinical trials at every stage of cancer diagnosis and treatment can represent a significant missed opportunity, primarily for patients, as well as for doctors and researchers trying to develop better therapies” (MSKCC, May 23, 2016). Targeted therapies and many trials with reduced toxicities are decreasing patient burden.

Recent data has shown that education can increase patients’ willingness to enter clinical trials, with patients’ “positive impression” improving from 40 to 60 percent when the trial was briefly explained (MSKCC, May 23, 2016). Fallowfield and colleagues tested a provider intervention that appears to improve communication about Phase 1 trials (Fallowfield, Solis-Trapala, & Jenkins, 2012). Similarly, Kass and colleagues researched ways to increase patients’ understanding of Phase 1 trial participation (Kass et al., 2009), but there are no data showing better understanding of treatment goals and options, as has been repeatedly observed with concurrent palliative care consultation (Smith et al., Mar. 10, 2012; Temel et al., 2011).

Recent work has shown that African-Americans are at least as likely as whites to be referred for inpatient palliative care consultation, live longer than whites after consultation (25 vs 17 days) and have rates of hospice use that exceeded that of whites (59% vs 51%) (Sharma et al., 2015). Palliative care consultation appeared to allow providers to bring up Advance Directives and “DNR” status, for example with 98% of African Americans at one hospital, 65% agreed to DNR orders (Sacco, Carr, & Viola, 2013; Zaide et al., 2013). In addition, palliative care consultation with specific emphasis on goals of care discussion appeared to “level the playing field” with the same number of African-Americans electing hospice as white patients; those who discussed code status had twice the rate of referral to hospice (OR 2.14) (Enguidanos, Vesper, & Goldstein, 2013).

There are no randomized controlled trials of palliative care concurrent with Phase 1 care. However, two trials show preliminary evidence of benefit. The first study was a quasi-randomized study with 44 patients on Phase 1 or 2 trials, assigned to “simultaneous care” (SC), a home care program focused on supportive care needs, or usual care (UC) (Meyers et al., 2004). The SC patients had a palliative care- and chemotherapy-trained nurse and a social worker with hospice experience, who developed a written plan of care. The number of chemotherapy cycles did not differ between SC and UC patients. More SC patients than UC patients were referred to hospice (35/44), compared to the UC group (8/15) ($P=0.034$). The median length of hospice stay was the same for both cohorts, but the mean stay was greater in the SC cohort (54 days), compared to the UC cohort (37 days). The investigators concluded that SC may enhance care coordination and facilitate patients’ explicit transition from curative to palliative intent.

In the second trial, Meyers and colleagues studied 476 patient and caregiver dyads, the patients undergoing Phase 1, 2, or 3 cancer treatment at three cancer centers. They were randomized to UC, or UC plus COPE (Creativity, Optimism, Planning, and Expert information), labeled the “Simultaneous Care Educational Intervention (SCEI)” (Meyers et

al., 2011). The primary end point of the trial was global quality of life (QOL), with patients' or caregivers' problem-solving abilities as a secondary end point. There was no difference in the rate of change of patient QOL between groups. Caregiver QOL scores declined but at a lesser rate in the intervention group, which was statistically significant ($p=0.02$). In planned secondary analyses, the SCEI caregivers had significantly less decline in psychological, social, and spiritual QOL scores. Over time, the impact of COPE increased and allowed caregiver QOL to remain stable.

Researchers continue to refine palliative care methods to provide quality care throughout the disease trajectory. Dr. Sydney Dy and colleagues identified key aspects of cancer end-of-life care in an academic medical center, targeting areas for quality improvement and measuring progress (Dy et al., 2011). They emphasize the importance of integrating palliative care across the trajectory of cancer.

Hui and colleagues (2014) conducted a retrospective study of 366 adult outpatients who died of advanced cancer over a 6-month period. Early palliative care referrals (>3 months before death) were associated with fewer emergency room visits ($p<.001$), hospitalizations ($p<.001$), hospital deaths ($p=.001$), ICU admissions ($p=.001$), and shorter hospital stays ($p=.002$). These patients also had improved quality of care compared to inpatients with late referrals (<3 months before death) (Hui et al., 2014).

Palliative care is cited as providing better communication, symptom control, treatment options, and improved QOL. The American Society of Clinical Oncology (ASCO) has recently updated recommendations that all seriously ill cancer patients be given concurrent palliative and oncology care (Ferrell et al., 2016). There is also increasing evidence that palliative care can lengthen patient survival, perhaps because palliative care goals include avoiding futile treatment and controlling symptoms, leading to improved survival with both psychological and physical benefits of care.

Phase 1 clinical trial patients may benefit from interdisciplinary palliative care that provides symptom relief, psychosocial support, and a better understanding of illness goals and treatment options, while concurrently receiving disease-directed therapies. With the rapid growth of palliative care, randomized trials have documented improved clinical outcomes (Cassel et al., 2016). If palliative care enables patients to stay on clinical trials longer, with better management of treatment toxicities, decreased symptom burden, and improved quality of life, palliative care may help advance cancer science.⁴ A recent article in the *New England Journal of Medicine*, "Bending the cost curve in cancer" (Smith & Hillner, 2011), has documented the financial savings associated with palliative care.

Study in Progress

This National Cancer Institute funded study is in year 3 of a 5 year project and has accrued 180 patients thus far.

Conceptual Framework

This study utilizes the National Consensus Project (NCP) *Clinical Practice Guidelines for Quality Palliative Care* to guide study design and intervention content (NCP, 2013). The NCP Guidelines recognize that multidimensional patient support is essential in quality palliative care, and such support promotes the integration of palliative care as part of the cancer care continuum. The application of NCP Guideline domains to this study of palliative care integration into Phase I clinical trial is presented in Table 1.

This randomized clinical trial tests a Palliative Care Intervention (PCI) administered concurrently to cancer patients with solid tumors who are participating in a Phase I clinical trial. It is being conducted at two Comprehensive Cancer Centers, one on the east coast and one on the west coast. This multi-site, randomized PCI clinical trial evaluates key outcomes and hopefully will provide a model for other cancer settings where Phase I trials are conducted. This innovative design brings together leading palliative care clinicians, researchers, and medical oncologists to test an interdisciplinary intervention that will provide optimum palliative care to support patients through clinical trials.

For the experimental PCI group, the study is initiated at the time of accrual to a Phase I trial, but prior to administration of the first Phase I treatment dose. It is a randomized trial with randomization assigned through the statistical center. The intervention includes completion of baseline evaluation using quantitative surveys, comprehensive palliative care assessment by a Research Nurse based on patient baseline evaluation, and goals of care discussion. Goals of care are discussed by the treating oncologist or the PC team if the oncologist defers, guided by a standard protocol (Table 2).

The PCI's second component is initiated following the first dose of Phase I treatment and completed within one month of the first treatment. This component includes an interdisciplinary team (IDT) meeting, where Palliative Care recommendations are made. Two patient educational sessions (Table 3) follow, covering QOL-related domains: physical, social, psychological, and spiritual well-being. Based on IDT recommendations, supportive care referrals to social work, nutrition, and psychology services are made. Patients in the UC group receive the usual care and each group is re-evaluated at 4, 8, 12, 16, 20, and 24 weeks following treatment initiation. As the 12 week time point is designated as the key outcome point, patients in the usual care group are offered the intervention after completing the 12 week data collection. Additionally, a chart audit is conducted at the conclusion of the study to document variables such as the patient's ability to complete the trial, referrals to supportive care services, advanced directive completion, hospitalizations and other aspects of resource utilization.

Case Example

The following case example is included to illustrate a patient receiving the PC intervention.

Elizabeth is a 49-year-old married female, native Californian, mother of one daughter and one son, ages 29 and 27, respectively. She and her spouse were self-employed at the time of diagnosis. Approximately six months prior, Elizabeth was suffering low back pain, pelvic

cramping, along with a 20-pound weight loss over a 3 month period. More recently, she had been experiencing severe abdominal pain, abdominal bloating, and anorexia. An ultrasound showed abdominal ascites. A paracentesis was performed and yielded two-and-a-half liters of fluid. Cytology revealed adenocarcinoma considered to be an ovarian primary. Further diagnostics done with a CT scan found an adenexal mass with enlarged abdominal lymph nodes.

She was evaluated at the cancer center in surgical gynecology and medical oncology, where a debulking surgery with a TAH/BSO followed by chemotherapy was recommended with further testing for tumor markers to ascertain the most appropriate treatment regimen. The surgery was completed and the final pathology revealed a stage IIIC high grade serous adenocarcinoma. Her pre-op CA-125 was 1289, which eventually decreased to 21, postoperatively.

Upon recovery, Elizabeth was admitted to the hospital to receive the chemotherapy regimen of IP cisplatin and paclitaxel for the planned six cycles. Eight months later, imaging revealed a recurrence in her abdomen and regional lymph nodes. She also suffered bilateral hydronephrosis, mandating stent placement. After stent placement, she began carboplatin and doxil and completed 4 of the planned 6 cycles. Nausea, vomiting, and the need for bilateral stent replacements necessitated hospital readmission. Further work-up showed disease progression.

Due to the disease's progressive nature and available treatment, she consented to a Phase I clinical trial of P53MVA vaccine in combination with gemcitabine. The oncologist discussed the goals of care with Elizabeth and her spouse. Upon consent for the Phase I clinical trial, the patient agreed to participate in the Palliative Care study. Two teaching sessions in four QOL domains were conducted. After the sessions, the APRN advised the physician there was not an advance directive (AD) in place and the patient was consulted regarding the need for an AD, which she tearfully agreed to implement, given her advanced disease. Clinical Social Work assisted and the AD was notarized and placed in the electronic medical record.

The APRN referred Elizabeth to the Pain and Palliative Care Team who evaluated her increased abdominal and back pain. She was placed on a 72-hour Fentanyl patch, along with Oxycodone 5 mg every four hours for breakthrough pain and Senekot to prevent constipation. The new pain care plan reduced her pain from 6/10 to 2/10 and her anxiety.

Elizabeth did well initially on the Phase I trial, completing 4 cycles, but was readmitted for intractable nausea and vomiting along with hydronephrosis. She was to be on study for an indeterminate number of cycles, or until she progressed. Her nausea was brought under control with IV Zofran and hydration. She also had another bilateral stent replacement. While she was admitted, the APN contacted the Chaplaincy Department, and a priest visited. The APN asked for a nutritional consult due to Elizabeth's worsening anorexia. Her oncologists advised Elizabeth that her disease had once again progressed and there was no further anti-cancer treatment but that palliative care should be continued.

Clinical Social Work supported the patient and a family meeting was held for the patient and her loved ones to consider the patient's and family's goals of care. A referral for initial

palliative care home intervention, with transition to hospice care was made. The patient died peacefully, free of pain, her family at her bedside, and hospice provided bereavement support.

Summary

The intent of this study is to test the provision of quality palliative care for solid tumor patients participating in Phase I clinical trials. The integration of palliative care into clinical trial care should improve the patients' quality of life by addressing symptoms and psychological distress. Additionally, the patient educational sessions cover the QOL domains, including physical, social, psychological, and spiritual well-being. Supportive care referrals to social work, nutrition, and psychology are designed to improve patients' quality of life. This palliative care intervention study builds on our prior work which showed positive outcomes for patients and family caregivers in an NCI-supported study, Palliative Care for Quality of Life and Symptom Concerns in Lung Cancer (Ferrell et al., 2015; Sun, Grant et al., 2015; Sun, Kim et al., 2015). This study will hopefully serve as a model for the benefit of providing palliative care concurrent with clinical trials, so vital to preventing, treating, and curing cancer.

References

- Agrawal M, Grady C, Fairclough DL, Meropol NJ, Maynard K, Emanuel EJ. Patients' decision-making process regarding participation in phase I oncology research. *Journal of Clinical Oncology*. 2006; 24:4479–4484. [PubMed: 16983117]
- Cassel JB, Del Fabbro E, Arkenau T, Higginson IJ, Hurst S, Jansen LA, ... Miller FG. Phase I Cancer Trials and Palliative Care: Antagonism, Irrelevance, or Synergy? *Journal of Pain and Symptom Management*. 2016; doi: 10.1016/j.jpainsymman.2016.02.014
- Cox AC, Fallowfield LJ, Jenkins VA. Communication and informed consent in phase I trials: A review of the literature. *Supportive Care in Cancer*. 2006; 14:303–309. [PubMed: 16633840]
- Dy SM, Asch SM, Lorenz KA, Weeks K, Sharma RK, Wolff AC, Malin JL. Quality of end-of-life care for patients with advanced cancer in an academic medical center. *Journal of Palliative Medicine*. 2011; 14(4):451–457. [PubMed: 21391819]
- Enguidanos S, Vesper E, Goldstein R. Ethnic differences in hospice enrollment following inpatient palliative care consultation. *Journal of Hospital Medicine*. 2013; 8(10):598–600. [PubMed: 24022871]
- Fallowfield LJ, Solis-Trapala I, Jenkins VA. Evaluation of an educational program to improve communication with patients about early-phase trial participation. *Oncologist*. 2012; 17:377–383. [PubMed: 22382459]
- Ferrell B, Sun V, Hurria A, Cristea M, Raz D, Kim J, ... Koczywas M. Interdisciplinary Palliative Care for Patients with Lung Cancer. *Journal of Pain and Symptom Management*. 2015; 50(6):758–767. [PubMed: 26296261]
- Ferrell B, , Temel J, , Temin S, , Alesi E, , Balboni T, , Basch E, , Firn J, , Paive J, , Peppercorn J, , Phillips T, , Stovall E, , Zimmermann C, , Smith T. Integration of Palliative Care Into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline Update; *J Clin Oncol* 2016 34 <http://ascopubs.org/doi/abs/10.1200/JCO.2016.70.1474>
- Finlay E, Lu HL, Henderson H, O'Dwyer PJ, Casarett DJ. Do phase I patients have greater needs for palliative care compared with other cancer patients? *Cancer*. 2009; 115:446–453. [PubMed: 19107769]
- Hui D, Parsons H, Nguyen L, Palla SL, Yennurajalingam S, Kurzrock R, Bruera E. Timing of palliative care referral and symptom burden in Phase I cancer patients. *Cancer*. 2010; 116:4402–4409. [PubMed: 20564164]

- Hui D, Kim SH, Roquemore J, Dev R, Chisholm G, Bruera E. Impact of timing and setting of palliative care referral on quality of end-of-life care in cancer patients. *Cancer*. 2014; 120(11): 1743–1749. [PubMed: 24967463]
- Jenkins VA, Anderson JL, Fallowfield LJ. Communication and informed consent in phase 1 trials: A review of the literature from January 2005 to July 2009. *Supportive Care in Cancer*. 2010; 18:1115–1121. [PubMed: 20204418]
- Jenkins V, Solis-Trapala I, Langridge C, Catt S, Talbot DC, Fallowfield LJ. What oncologists believe they said and what patients believe they heard: An analysis of phase i trial discussions. *Journal of Clinical Oncology*. 2011; 29:61–68. [PubMed: 21098322]
- Kass NE, Sugarman J, Medley AM, Fogarty LA, Taylor HA, Daugherty, ... Goodwin-Landher A. An intervention to improve cancer patients' understanding of early-phase clinical trials. *Irb*. 2009; 31(3):1–10.
- Memorial Sloan Kettering Cancer Center. Despite Pressing Need, Survey Finds Most Americans Unlikely to Enroll in Clinical Trials May 23, 2016 press release, <https://www.mskcc.org/press-releases/despite-pressing-need-survey-finds-most-americans-unlikely-enroll-clinical-trials>
- Meyers FJ, Linder J, Beckett L, Christensen S, Blais J, Gandara DR. Simultaneous care: a model approach to the perceived conflict between investigational therapy and palliative care. *Journal of Pain and Symptom Management*. 2004; 28(6):548–556. [PubMed: 15589080]
- Meyers FJ, Carducci M, Loscalzo MJ, Linder J, Greasby T, Beckett LA. Effects of a problem-solving intervention (COPE) on quality of life for patients with advanced cancer on clinical trials and their caregivers: simultaneous care educational intervention (SCEI): linking palliation and clinical trials. *Journal of Palliative Medicine*. 2011; 14(4):465–473. [PubMed: 21413846]
- National Consensus Project for Quality Palliative Care Clinical Practice Guidelines for Quality Palliative Care 3. Pittsburgh, PA: National Consensus Project for Quality Palliative Care; 2013
- Parsons HA, Baracos VE, Dhillon N, Hong DS, Kurzrock R. Body composition, symptoms, and survival in advanced cancer patients referred to a phase i service. *PLoS One*. 2012; 7(1):e29330. [PubMed: 22235285]
- Sacco J, Carr DRD, Viola D. The effects of the palliative medicine consultation on the DNR status of African Americans in a safety-net hospital. *American Journal of Hospice & Palliative Medicine*. 2013; 30(4):363–369. [PubMed: 22777405]
- Sharma RK, Cameron KA, Chmiel JS, Von Roenn JH, Szmuiłowicz E, Prigerson HG, Penedo FJ. Racial/Ethnic Differences in Inpatient Palliative Care Consultation for Patients With Advanced Cancer. *Journal of Clinical Oncology*. 2015; 33:3802–3808. [PubMed: 26324373]
- Smith TJ, Hillner BE. Bending the cost curve in cancer care. *The New England Journal of Medicine*. 2011; 364:2060–2065. [PubMed: 21612477]
- Sun V, Grant M, Koczywas M, Freeman B, Zachariah F, Fujinami R, ... Ferrell B. Effectiveness of an interdisciplinary palliative care intervention for family caregivers in lung cancer. *Cancer*. 2015; 121(20):3737–3745. DOI: 10.1002/cncr.29567 [PubMed: 26150131]
- Sun V, Kim J, Irish T, Borneman T, Sidhu R, Klein L, Ferrell B. Palliative care and spiritual well-being in lung cancer patients and family caregivers. *Psycho-Oncology*. 2015
- Temel JS, Greer JA, Admane S, Gallagher ER, Jackson VA, Lynch TJ, ... WF. Longitudinal perceptions of prognosis and goals of therapy in patients with metastatic non-small-cell lung cancer: Results of a randomized study of early palliative care. *Journal of Clinical Oncology*. 2011; 29:2319–2326. [PubMed: 21555700]
- Zaide GB, Pekmezaris R, Nouryan CN, Tanveer PM, Sison CP, Liberman T, ... Wolf-Klein GP. Ethnicity, race, and advance directives in an inpatient palliative care consultation service. *Palliative and Supportive Care*. 2013; 11:5–11. [PubMed: 22874132]

Implications for practice

- Phase 1 clinical trial patients may benefit from interdisciplinary palliative care that supports symptom relief, provides psychosocial support, and promotes better understanding of illness goals and treatment options, while patients concurrently receive disease-directed therapies.
- Palliative care may enable patients to stay on clinical trials longer, with better management of treatment toxicities, decreased symptom burden, and improved quality of life.
- Oncology nurses play a vital role in assessment of QOL concerns, coordination of interdisciplinary care, and patient teaching to support patients on clinical trials.

Table 1

Conceptual Framework

National Consensus Project Guidelines Domains	Application of Guidelines to Phase I Clinical Trials
1. The Structure & Process of Care	Palliative care assessment and intervention will be concurrently provided with Phase I clinical trials.
2. Physical Aspects of Care	Focus on symptom concerns common to advanced cancer and the type of investigational agent used for treatment.
3. Psychosocial & Psychiatric Aspects of Care	Focus on psychosocial issues common in advanced cancer and address issues that are specific to patients participating in a Phase I clinical trial.
4. Social Aspects of Care	Address family distress, social support and financial burden associated with advanced cancer and participation in Phase I clinical trials.
5. Spiritual, Religious & Existential Aspects of Care	Assessment of spiritual needs and living with a poor prognosis.
6. Cultural Aspects of Care	Assessment of cultural factors in diverse populations.
7. Care of the Imminently Dying Patient	Initiate goals of care and prognosis discussions for advance care planning while receiving Phase I clinical trial treatment.
8. Ethical & Legal Aspects of Care	Initiate advance directives for care following participation on a Phase I clinical trial (i.e. hospice referrals).

Table 2**Suggested Components for Goals of Care Discussion (with suggested phrases)**

<p><u>Illness Understanding</u></p> <p>Inquire about how people like to get medical information. “Are you the sort of person who wants to know all the details, or not? How about discussion of what might happen in the future?”</p> <p>Inquire about illness and prognostic understanding.</p> <p><i>“What do you want to know about your illness? What do you know about your situation?”</i></p> <p>Offer clarification of treatment goals including Phase I treatment:</p> <p>Always check with the treating oncologist first about realistic prognosis and future options</p> <p>Patient perception, family perception, and reality</p> <p>Understanding after discussion of reality</p> <p>Address adapting to changed goals and likely death from cancer. Offer clarification of adaptation to changed goals and foreseeable death on several visits.</p>
<p><u>Symptom Management</u></p> <p>We start with the symptoms first as these are considered “safe” and allow us to establish trust.</p> <p>Always use a Symptom Assessment Tool such as Edmonton or Memorial Symptom Assessment Scales.</p> <p>Inquire about uncontrolled symptoms with a focus on:</p> <p>Pain</p> <p>Pulmonary symptoms (cough, dyspnea)</p> <p>Fatigue and sleep disturbance</p> <p>Mood (depression and anxiety)</p> <p>Gastrointestinal (anorexia, weight loss, nausea & vomiting, constipation)</p> <p>Other symptoms expected from the Phase I treatment</p> <p>Focus on symptom management as a part of the goals of care.</p> <p>Inquire about spirituality and religion. We ask, as routine, “Is religion or spirituality important to you?” and unless there is active disinterest, “Would you like to see a chaplain?”</p>
<p><u>Decision-Making</u></p> <p>Inquire about mode of decision making.</p> <p>Assist with treatment decision-making, if necessary</p> <p>Assess coping with life-threatening illness by patient and family</p> <p><i>“This must be hard on you and your family. How are you coping with this illness?”</i></p>
<p><u>Other</u></p> <p>Referrals and note new prescriptions Identify care plan for future appointments</p> <p>Indicate referrals to other care providers, and communicate directly by fax, email, or electronic medical record</p>

Table 3

PC 1 Teaching Sessions Table

Session I:	
<i>Physical Well-Being</i>	<i>Social Well-Being</i>
Pain	Communication
Constipation	Social and family support
Breathing problems	Healthcare planning
Cough	
Fatigue	
Lack of sleep	
Nausea and vomiting	
Side effects of Phase I treatment	
Session II	
<i>Emotional Well-Being</i>	<i>Spiritual Well-Being</i>
Anxiety	Spirituality, purpose and meaning
Depression	Uncertainty
	Hope

Table 4

Available Patient Resources

Name	Link
American Cancer Society	www.cancer.org
National Cancer Institute	www.cancer.gov
American Society of Clinical Oncology	www.asco.org
American Institute for Cancer Research	www.aicr.org
Cancer.Net	www.cancer.net
CancerCare	www.cancercare.org
National Comprehensive Cancer Network	www.nccn.org/patients
OncoLink	www.oncolink.org
Cancer Financial Assistance Coalition	www.cancerfac.org
Cancer Research Institute	www.cancerresearch.org