

The Cost of Cancer Care: Patient Navigation Challenges to Participation in Phase I Clinical Trials

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Abstract

Phase I trial participation for advanced cancer patients is often a “last resort” in an attempt to control progressive disease. It is also a necessary component mandated by our investigative community and FDA to characterize safety and mechanism via dose and schedule modulation of experimental therapeutics. Participation in phase I studies is difficult without support. The purpose of this assessment is to provide proof of principle mechanisms of support locally provided in Texas and established by nurse navigation to facilitate phase I trial patient participation. Specifically, extensive financial assistance programs exist to facilitate patient participation. Management of these opportunities through a nurse navigation program in coordination with the patient optimizes patient assistance.

Keywords: Navigator, cancer, cost, trial, phase I

Phase I clinical trials provide a unique opportunity to cancer patients who have failed standard of care (SOC) options, but the cost of treatment constitutes a significant patient concern. Patient Navigation programs are established to assist medical care management involving multi-specialty care and often include clinical research options (Ramsey et al., 2009; Thygesen et al., 2011). As Patient Navigation programs increase in prevalence, program models are evolving but often don't focus on the additional financial stress to the patient and family related to the more complicated care management required for clinical trials. This is particularly relevant to phase I clinical trial participation. While the sponsor of the clinical trial covers the cost of the study drug and research related expenses, other expenses are the responsibility of the patient or their insurance carriers. Uninsured patients have been shown less likely to participate in clinical trials (Sateren et al., 2002). However, insured patients also face financial obstacles to clinical trial participation. Some insurance plans do not cover standard non-research costs if patients participate in research. Medicare has a policy of covering standard costs for patients enrolled in research trials, and 29 states have enacted legislation mandating such coverage for all health insurance plans governed by their state (Klamerus et al., 2010). However, state laws do not impact plans governed by the federal Employee Retirement Income Security Act (ERISA). Certain employers can operate under a self-insurance scheme in which they are only governed by ERISA, and not by state law. This has proven a popular business decision to reduce costs for employers due to recent premium increases. On January 1, 2014, the minimum coverage mandated by the Patient Protection and Affordable Care Act will eliminate this loophole, and all plans will be required to cover non-research costs for patients enrolled in clinical trials (Klamerus et al., 2010). Until that time, clinical research centers must pre-certify all standard procedures before enrolling patients into a trial. Pre-certification can cause a delay of up to six weeks, a time period that can be fatal to a late stage cancer patient seeking to enroll on a trial and receive an investigational agent as a last hope, after standard therapies have failed.

Although insurance companies in most states are legally obligated to cover standard of care costs involved in clinical trials, coverage is limited by deductible and co-insurance amounts as well as benefit limits, which may have been exhausted by previous payment for standard of care treatments. Increasingly, managed care insurance plans limit the number of chemotherapy regimens allowed. The required precertification of all SOC costs, procedures and diagnostic imaging may create barriers to providers and patients from obtaining necessary payment for standard reimbursable costs. During precertification, it is essential to distinguish between SOC and

research costs and to follow insurance companies' guidelines, which often prove difficult to determine and variable in their application by insurance company staff. Failure to precertify may result in the loss of benefits, leaving the patient or the provider with an unpaid balance.

In the current economic climate Oncology Nurse Navigators can play an integral part in health care reform and cost containment. Addressing barriers to care leads to better compliance, potentially less treatment, improved quality of life, and earlier detection of complications – all of which save precious health care dollars (Beerman, 2010).

Clinical trial centers need processes to help individuals with financial assistance, and Patient Navigation programs can be designed to interface with the finance team. The team can include patient Financial Counselors to verify insurance coverage, discover coverage gaps, and explain the patient's financial responsibility before treatment begins. Patient consent should outline the patient's responsibility for SOC costs, including drugs, imaging, labs, so they are informed of this during the consent process. Patients should be given their estimated financial responsibility for a trial, up front. This will require an estimate of pre-certified insurance coverage and co-pay responsibility. Patient Navigators can identify additional financial needs, which include lodging and transportation as well as co-pays for treatment and diagnostic testing, and payment for supportive medications. For patients covered by 70/30 or 80/20 insurance plans, study-related SOC drug expense may represent a significant financial burden. Patient Navigation programs should incorporate communication of financial assistance program information at the time of consent for treatment. Identification of financial assistance programs may determine whether or not the patient is able to participate in a clinical trial.

Numerous well-documented barriers contribute to the under representation of lower income individuals in clinical trials. These include lack of adequate knowledge about available studies and lack of adequate insurance to allow participation. Cultural factors contribute to fears of cancer research and impede communication between patients and health care providers. Residential distance from the centers where research is conducted presents logistical barriers. Addressing logistical challenges such as transportation, child care, and difficult clinic scheduling can help to make clinical trials accessible to a wider demographic population (Holmes et al., 2012). Patient Navigation programs can be structured to guide and support patients through all of these logistical challenges.

Financial assistance programs include co-pay assistance, drug assistance or replacement programs by pharmaceutical companies for SOC drugs needed on a trial, but not covered by the research sponsor. For example, organizations providing financial assistance with medications include: Rx Assist; Patient Advocate Foundation Co-Pay Relief; NeedyMeds; and Partnership for Prescription Assistance. Other organizations assisting with patient's financial and emotional needs include Cancer Care, which provides one time payments for any patient need including medication, transportation or living expenses, supported in part by a grant from the Hirshberg Foundation; and Patient Advocate Foundation. See Table 1 for website and phone numbers for these organizations and others discussed below.

Table 1. Patient assistance organizations

Name of Organization	Website Address	Phone Number
Rx Assist	www.rxassist.org	401-729-3284
Patient Advocate Foundation Co-Pay Relief	www.copays.org	866-512-3861
NeedyMeds	www.needymeds.org	978-281-6666
Partnership for Prescription Assistance	www.pparx.org	888-477-2669
Cancer Care	www.cancercare.org	800-813-4673
Patient Advocate Foundation	www.patientadvocatefoundation.org	800-532-5274
Bridge of Blessings	www.bridgeofblessings.org	214-714-1077
National Pancreatic Cancer Foundation	http://pancreaticcancerfoundation.com/	800-859-6723
Susan G. Komen for the Cure	http://www5.komen.org/	877-465-6636
Careity® Foundation	www.careity.org	817-882-4100
American Cancer Society	www.cancer.org	800-227-2345
Cancer Care Services	www.cancercareservices.org	817-921-0653
Cancer Care, Inc.	www.carecare.org	800-813-4673
Lance Armstrong Foundation	www.livestrong.org	877-236-8820
Kids Connected	http://kidsconnected.org/	800-899-2866
Angel Flight	www.angelflight.com	888-426-2643
Wings of Hope	www.wings-of-hope.org	800-448-9487
Mary Crowley* Benevolence Program	www.marycrowley.org	866-902-2623
Ark House	www.arkhouse.net	972-671-7144
Meals On Wheels, Inc. of Tarrant County	www.mealsonwheels.org	817-336-0912

* Applicable only for Mary Crowley study patient participants

In addition, disease-specific organizations exist, for example, the Bridge Breast Network in Dallas, Texas, serves uninsured and underinsured women with breast cancer. Another example is Bridge of Blessings in Richardson, Texas, which helps breast and ovarian patients with rent, utilities, and gas. The National Pancreatic Cancer Foundation benefits patients with a pancreatic cancer diagnosis.

Patient Navigators should keep current with all local programs that serve cancer patients in their vicinity. This includes local hospital/clinic general patient assistance programs. Each year the Cancer Assistance Fund of North Texas provides financial assistance to help with a portion of COBRA payments. A limited amount of funds are available to assist cancer patients in Tarrant, Johnson, Wise and Parker counties who are in serious financial need with the cost of their cancer treatment programs. For those patients in financial need with minimal (e.g., Medicaid) or no health insurance the fund may be able to make direct payments to oncology care providers. Support is provided by generous gifts from the Susan G. Komen Greater Fort Worth Affiliate and Careity® Foundation.

The American Cancer Society provides education services and serves as a resource for identifying community assistance. Though ACS is limited in the amount of funds provided to each individual, programs assist with lodging and gasoline expenses. Many patients receive vouchers for travel expenses. The Road to Recovery program depends on volunteers to provide transportation to treatment. Other examples of agencies providing assistance with transportation costs include Cancer Care Services, which offers travel and prescription assistance for patients receiving radiation. Cancer Care, Inc. in New York can help with a one-time grant of \$100 for transportation.

The Lance Armstrong Foundation offers a wide range of services, including Oncology Nurse Navigators who provide education information, as well as assistance in identifying resources for financial assistance. Licensed professional counselors are available free of charge for patients and family members dealing with a cancer diagnosis.

Kids Konected offers free programs for children that have a parent with cancer and may be a good resource for kids especially for emotional support.

Nonprofit charitable organizations of pilots, volunteers, and friends provide air transportation for medically related needs. One such organization, Angel Flight, primarily services patients needing transportation to or from the heartland region. However, by coordinating with other organizations, they may arrange transportation for patients on longer flights or to other parts of the country. Angel Flight is supported primarily by volunteer pilots who fly the missions and donate the use of their airplanes and operating expenses, and by contributions from individuals, service clubs, social and religious groups and corporations. In 2003, Wings of Hope established the St. Louis based Medical Relief and Air Transport Program, referred to as the MAT. Volunteer pilot and volunteers provide medical transportation free of charge.

Clinical Trial Centers may use philanthropy to maintain institution-specific financial assistance programs. For example, the Mary Crowley Benevolence Program was established to provide assistance with travel and medical expenses, including flights, gas, lodging, prescriptions, imaging and other underinsured medical expenses for patients participating in clinical trials at Mary Crowley Cancer Research Centers (Mary Crowley) in Dallas, Texas. The Mary Crowley Patient Navigation Program in collaboration with Medical City Dallas Hospital and Baylor Regional Medical Center at Plano provides cancer patients a continuum of care including early phase clinical trials, with program design including financial aspects as well as multi-disciplinary medical care.

Some phase I clinical trials require the patient to be present for treatment or follow-up on a weekly or daily basis. Additional out-of-pocket costs related to travel to the phase I study site, housing at the site of treatment, combined with time off work lead many patients to hesitate when considering phase I clinical trial participation. At Mary Crowley, the Patient Navigation Program has incorporated several sources of assistance to reduce patient travel and lodging burden. For patients who live outside the clinical research center's area, lodging can be a challenge. One excellent resource available in Dallas, Texas, is the Ark House. A local church leases twenty units at an apartment complex near the Mary Crowley clinic, and subleases the units to families requiring lodging for more than seven days. Each one bedroom unit is fully furnished with everything except toiletries and food. Patients pay a refundable deposit of \$100 and \$15 per night, and can stay as long as they continue medical treatment.

Several clinical trial sponsors (pharmaceutical corporations) offer reimbursement for lodging to patients enrolled in specific studies. When this option is available, Mary Crowley has established direct billing to reduce the patient burden. In situations where the sponsor does not cover the cost of lodging it is possible for the treatment center to negotiate a lower rate with local facilities to defray some of the expense. Residence Inn (www.marriott.com/residence-inn) is one such hotel that offers amenities to meet the unique needs of guests undergoing medical treatment, including simple services such as hotel staff stocking the refrigerator with unique patient food/drink needs. American Cancer Society's guest room program may provide short term lodging to patients, caregivers, or advocates. This lodging can be free or at a special medical rate at local hotels, depending on availability. Arrangements must be made through the local American Cancer Society office. Texas Medicaid recipients may be eligible for lodging at participating hotels, when they are traveling more than 100 miles for medical treatment.

Other resources used to identify services for patients and their families include but are not limited to chaplains, social workers, and home health agencies. Social services providing food include local churches and local food banks. Elderly patients may qualify for home delivery of food. Meals on Wheels is a program that deliver meals to individuals at home or hotel room who are unable to purchase or prepare their own meals. Because they are housebound, many of the recipients are elderly, and many of the volunteers are also elderly but able to drive and serve. The program guarantees that the recipient will have contact with the volunteer who delivers one hot meal per day.

Patients may apply for financial assistance in a number of ways. Some providers establish their own application process. Other providers may have specific guidelines which allow them to offer deep discounts or even write off entire balances to patients who qualify. Many foundations exist for the purpose of assisting with the costs of cancer care. It is essential that the patient or family member provide required documentation of financial need. The application can be stressful and confusing for a patient who is facing treatment decisions. A knowledgeable patient advocate can assist with the process and help to ease the burden. Patient Navigation programs can incorporate the financial aspect of care and provide the interface and guidance to serve this critical patient need. Models that can be developed to optimize support of the Patient Navigation program should involve social services interaction, financial advisor support, family counseling and an established policy with the research program business

department to be interactive or provide assistance to the various outside financial assistance support which may be unique to individual patients.

Thus the proof of principle provided in this assessment largely involving Texas related assistance will likely be an opportunity that can be established throughout the USA. Providing assistance with the cost of cancer care requires a team approach. Programs addressing assistance with pre-certification, co-pays, non-experimental drugs, and imaging are critical. When an individual's needs are identified, financial counselors, coordinators, doctors and nurse navigators need to utilize every resource available to meet those needs. This is especially true when participating in phase I trials, which involve significantly more time and commitment by the patient and family.

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References

- Beerman, T. (2010). The Nurse Navigator's Role in Health Care Reform and Cost Containment. http://www.hcplive.com/publications/oncng-oncologynursing/2009/june2009/nurse_navigator_role_in_health_care_reform_0909
- Holmes, D. R., Major, J., Lyonga, D. E., Alleyne, R. S., & Clayton, S. M. (2012). Increasing minority patient participation in cancer clinical trials using oncology nurse navigation. *Am J Surg*, *203*, 415-22. <http://dx.doi.org/10.1016/j.amjsurg.2011.02.005>
- Klamerus, J. F., Bruinooge, S. S., Ye, X., Klamerus, M. L., Damron, D., Lansey, D., ... Rudin, C. M. (2010). The impact of insurance on access to cancer clinical trials at a comprehensive cancer center. *Clin Cancer Res*, *16*, 5997-6003. <http://dx.doi.org/10.1158/1078-0432.CCR-10-1451>
- Ramsey, S., Whitley, E., Mears, V. W., McKoy, J. M., Everhart, R. M., Caswell, R. J., ... Mandelblatt, J., Patient Navigation Research Program Group. (2009). Evaluating the cost-effectiveness of cancer patient navigation programs: conceptual and practical issues. *Cancer*, *115*, 5394-403. <http://dx.doi.org/10.1002/cncr.24603>
- Sateren, W. B., Trimble, E. L., Abrams, J., Brawley, O., Breen, N., Ford, L., ... Christian, M. C. (2002). How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *J Clin Oncol*, *20*, 2109-17. <http://dx.doi.org/10.1200/JCO.2002.08.056>
- Thygesen, M. K., Pedersen, B. D., Kragstrup, J., Wagner, L., & Mogensen, O. (2011). Benefits and challenges perceived by patients with cancer when offered a nurse navigator. *Int J Integr Care*, *11*, e130.