

Cancer Policy Institute at the Cancer Support Community Moonshot Submission Idea

Introduction and Organization Background:

On behalf of the Cancer Support Community (CSC) and the thousands of patients we touch each year, thank you in advance for the opportunity to submit our cancer research ideas for the Vice President's Moonshot Blue Ribbon Panel.

In 2009, The Wellness Community and Gilda's Club joined forces to become the Cancer Support Community. CSC is the largest, nonprofit provider of social and emotional support for people with cancer and their families, reaching nearly one million people through our telephone helpline, our vibrant online community and our 170 locations across the country. Serving people with all types of cancers, it is our mission to ensure that all people impacted by cancer are empowered by knowledge, strengthened by action and sustained by community.

In addition to our direct services, CSC also works tirelessly to make sure that the voices of patients, families, caregivers, friends and colleagues are heard through the research we perform. One example, our Research and Training Institute's Cancer Experience Registry®, is a place where nearly 10,000 individual and collective voices of people impacted by cancer can be heard and measured. The goal of the Cancer Experience Registry is to better understand the full impact of the cancer journey on patients, families and caregivers and leverage those lessons to create new programs and services and inform policymakers.

Given the complexities of the cancer patient experience throughout each step of the patient journey, policy decisions must be made with some level of consideration to the impact such decisions will have on those most vulnerable. In today's environment, as seen in CSC's Cancer Experience Registry and other published data, patients are experiencing significant challenges accessing treatment and accessing health care professionals. There remains a deficit in the provision of comprehensive care due to these challenges and the lack of reimbursement for current services. And, finally, patients are living with chronic and long-term collateral damage (biomedical and psychosocial), which are often not addressed.

Again, thank you in advance for your attention to the following idea.

The Research Problem:

Clinical trials are one of the most important tools available for improving comprehensive quality cancer care. Unfortunately, only 3 percent of eligible patients enroll in oncology clinical trials and the retention rates continue to decline. Despite data which demonstrates improved patient outcomes and reduced cost, patients with cancer are not guaranteed comprehensive care when enrolled in a clinical trial. Further, enrollment and retention rates remain low leading to inefficiency and delay in reaching meaningful answers to challenging health questions.

The 2008 Institute of Medicine (IOM) report entitled, "Cancer Care for the Whole Patient" notes that up to 43 percent of people with cancer experience psychosocial distress, which negatively impacts both their overall quality of life and long-term survivorship. Further, a 2010 study by Barbara Andersen, PhD, demonstrated that when patients participated in a bi-weekly support group for one year, they experienced a reduced risk for breast cancer recurrence and a reduced risk of dying from breast cancer if they did have a recurrence. Most impressive, however, is that those participating in a support group lived a full 1.5 years longer than their counterparts who did not participate.

This compelling body of data led the American College of Surgeons Commission on Cancer (CoC) to require its 1,500 hospitals and cancer centers, which treat up to 70% of all newly diagnosed patients with cancer, to screen patients for distress and provide follow up care. Distress screening and follow up care are becoming the gold standard in cancer care. However, patients who enroll in a clinical trial, including those funded by the NIH or one developed by a drug or device manufacturer, are not necessarily guaranteed the same level of care.

Proposed Solution:

To help ensure the highest level of care is being provided to cancer patients, and to further reduce the cost to the already strained healthcare system, CSC requests that the National Cancer Institute consider the following options:

1. Funding a pilot study at the NCI, in coordination with the Office of Research on Women's Health and the FDA, which measures the value of providing distress screening and follow up care to cancer patients in clinical trials, both in terms of improving health outcomes and clinical trial participation and retention.
2. Urges NIH to screen patients for distress at the NIH Clinical Center and in all NCI-funded clinical trials.

3. Direct the Office for Human Research Protection to develop guidance specific to addressing the psychosocial needs of patients in clinical trials research.

How the Solution Will Make a Difference:

Unfortunately, the Department of Health and Human Services (HHS) has not kept pace with the IOM's recommendations nor the private sector's activities in ensuring that the psychosocial needs of patients are being met, particularly in the area of clinical research. Despite advances made by the CoC, there is still much work to be done. The challenges facing researchers related to trial retention and recruitment should not be minimized. The Tufts Center for the Study of Drug Development notes several indicators of concern related to trends in clinical trials. In particular, the study identified:

- An increased burden of procedures per trial protocol of 65%*
- An increased length of clinical trial days of 70%*
- A decrease in clinical trial enrollment rate by 21%*
- A decrease in clinical trial retention rate by 30%*

Many of the reasons patients do not enroll in or abandon trials can be addressed if those reasons are identified early in the care continuum. For example, a recent report published by the NIH's Office of Women's Health Research found that potential trial participants declined to enroll due to logistical barriers. According to the report:

- In determining postmenopausal breast cancer patients' willingness to participate in an acupuncture trial for pain relief, investigators found that among women who declined to enroll, white women were more likely to report that they would not participate because of concerns about transportation.

The report also points out that potential patients would be willing to participate if their concerns were addressed:

- Although minority populations express greater mistrust of research, they are not necessarily less willing than white populations to participate in research once these barriers are addressed.

Moreover, a study presented by the Cancer Support Community in December 2014 explored the attitudes and beliefs of patients with metastatic breast cancer regarding clinical trials. In addition to having significant misperceptions about clinical trials generally (e.g., fear of being assigned to a placebo, fear of side effects, etc.), a full 22 percent of patients indicated that they would not be able to fulfill trial requirements due to logistical barriers such as transportation—barriers that would be addressed and managed through distress screening. In cancer research, where only 3 percent of eligible patients enter a clinical trial, the loss of 22 percent at the beginning of the process is a

significant issue. By addressing these issues through distress screening and support services, there will be dramatic improvements in our ability to recruit and retain patients in trials.

Conclusion:

Thank you again for your consideration of our research idea. We would be happy to discuss this with you in further detail. This is an exciting time to be working in the cancer field and we look forward to leveraging our resources and networks in order to make the Cancer Moonshot a success.

References:

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