The Lazarex-MGH Cancer Care Equity Program

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Historically, accrual to cancer clinical trials (CTs) has been poor, with fewer than 7% of eligible patients enrolling into cancer CTs. Financial barriers likely play a role in lower enrollment rates among certain patient populations. Minorities, uninsured patients, and low socioeconomic status patients are underrepresented in clinical trials. Cancer care is associated with a higher financial burden when compared to other chronic conditions. Cancer patients have higher out-of-pocket expenses and are at greater risk for bankruptcy. In addition, patients with financial burden may adopt potentially harmful cost-coping strategies, such as delaying prescription refills and canceling follow-up appointments. Furthermore, clinical trial participants represent a population that may be especially vulnerable to financial toxicity due to the increased frequency of clinic visits, laboratory testing, and other procedures that may be beyond the scope of usual care. There is a need to address financial burden associated with CT participation. Most of the current literature about the costs of CTs focuses on costs to sponsors and payers, not the direct out-of-pocket costs to the patient. Trial participants endure added costs of more frequent clinical visits and travel to trial sites. The Affordable Care Act (ACA) seeks to ensure coverage of routine direct health care costs for patients enrolled on CTs, but patients must still pay their insurance premiums and co-pays, plus the costs of travel, lodging, and meals associated with CT participation.

In 2014, the Massachusetts General Hospital (MGH) partnered with the Lazarex Cancer Foundation to launch the Cancer Care Equity Program (CCEP) to help alleviate financial burden associated with trial participation. The CCEP includes 3 overarching components:

- Community outreach, including education to build awareness of available cancer care options, especially clinical trial participation
- Patient navigation support, to ensure appropriate cancer screening (e.g., mammography, colonoscopy) and follow-up of results
- Financial assistance, including reimbursement for trial participants struggling with travel and lodging costs

To access CCEP, patients must be enrolled or screened for a cancer CT. They are referred to the CCEP by members of their cancer care team, including their oncology provider, social worker, or nursing staff. Once referred to CCEP, the Lazarex Foundation determines the patient’s need for financial assistance and provides monthly reimbursement. The average monthly reimbursement per participant enrolled in the CCEP program varied for local residents ($185), regional (New England) residents ($300), and national (outside of New England) residents ($900). The CCEP collaborates with the Lazarex Foundation, the patient, and the cancer care team to track patient outcomes and conduct research.

The objectives of the current study were 3-fold: 1) to determine the impact of the CCEP on cancer CT enrollment at MGH; 2) to compare participant characteristics before and after implementation of the CCEP, and between CCEP vs non-CCEP participants; and 3) to assess patient-reported barriers to cancer CT participation. To achieve these objectives, the CCEP research team used an interrupted time series design to determine CT enrollment and patient characteristics in 2014 (after initiating the CCEP) to 2012 and 2013.

Adjusting for annual CT availability and the trends in accrual for prior years, we found that enrollment increased after CCEP implementation greater than expected (p<0.001). Following the launch of the CCEP program, several key features of patient demographics changed. Compared with the two years prior to the CCEP, patients enrolled the year after implementation of the CCEP were significantly less likely to have metastatic disease (74.2% vs. 70.0%; p=0.012) and significantly more likely to be enrolled in phase I clinical trials (46.9% vs. 56.5%; p=0.001).

The analysis of CCEP (n=153) vs. non-CCEP (n=1,064) patients enrolled in CTs in the year following implementation of the CCEP revealed interesting differences in these patient populations. Compared with non-CCEP patients,
CCEP participants were younger (mean age, 59.1 vs. 54.9 years; p<0.001) and had lower median annual incomes ($87,500 vs. $62,500; p=0.003). Compared with non-CCEP patients, a higher proportion of CCEP patients were female (50.8% vs. 66.7%; p<0.001), enrolled in phase I trials (53.6% vs. 77.1%; p<0.001), living farther away (>50 miles) from MGH (25.0% vs. 66.9%; p<0.001), and had metastatic disease (67.1% vs. 90.2%; p<0.001).

Additionally, the CCEP research team conducted a patient survey to assess barriers to clinical trial participation and financial concerns over past 3 months. Surveys were mailed to all living, English-speaking CCEP participants within 3 months of enrollment, and to a group of non-CCEP trial participants systematically matched by age, gender, and CT. Of 87 CT participants who completed the survey (63% response rate), 49 were CCEP participants and 38 were non-CCEP participants.

Survey results revealed several significant differences in baseline financial barriers between non-CCEP and CCEP participants. The survey asked CT participants to think back to when they were considering enrolling onto a CT and answer questions about their financial concerns. Compared with non-CCEP participants, a higher proportion of CCEP participants reported concerns regarding finances, medical costs, travel, lodging, and insurance coverage related to trial participation (Table 1).

**SUMMARY**
Costs represent a barrier to cancer CT participation and efforts to improve trial accrual should consider ways to alleviate the financial burden of trial participation. The CCEP represents a novel way to potentially improve trial participation by addressing some of the financial concerns associated with CTs, such as travel and lodging expenses. After implementation of the CCEP, cancer CT participation increased greater than what would have been expected in the absence of the program. Additionally, the CCEP served an underserved population in need of financial assistance, including younger patients, those with lower incomes, and those traveling farther. Survey results confirm the range of financial barriers and concerns among CCEP participants. Notably, patients assisted by the CCEP reported experiencing significantly greater financial concerns prior to enrolling onto their CT. These findings stress the need to recognize and address the financial burden of CT participation. Future directions include developing novel tools to identify patients most in need of financial assistance and encouraging key stakeholders to support efforts to remove financial barriers to trial participation.

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<tr>
<th>Table 1. Financial Barriers of Clinical Trial Participation</th>
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<td><strong>Bother by any financial concerns</strong></td>
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<td><strong>Concerned about travel costs for the trial</strong></td>
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<tr>
<td><strong>Concerned about lodging costs for the trial</strong></td>
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<tr>
<td><strong>Concerned about affording medical costs of trial</strong></td>
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<td><strong>Afraid health insurance would not pay for trial</strong></td>
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<td><strong>Concerned I would not be able to keep up with trial schedule</strong></td>
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<tr>
<td><strong>Concerned I would not be able to find transportation to trial center</strong></td>
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CCEP = Cancer Care Equity Program.

**References**

