Studies Provide Insight on Factors in Clinical Trial Participation and Prospective Benefits

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ASCO Perspective

“It is our duty as oncologists to enroll our patients in clinical trials when appropriate,” said Merry-Jennifer Markham, MD, FACP, ASCO expert and chair of the Quality Care Symposium News Planning Team. “Research from this year’s meeting finds that participation in clinical trials is associated with longer overall survival in patients with advanced lung cancer. We also received insights on how our patients’ beliefs and perceptions on clinical trial participation may differ from our own. We must work to better understand factors associated with trial enrollment so that the prospective benefits can be made accessible to all who are eligible.”

ALEXANDRIA, Va. – Two studies examine different issues related to patient participation in clinical trials. One study investigates the relationship between participation in a clinical trial and overall survival in patients with advanced lung cancer. The second study discovers and explores a discrepancy between providers’ and patients’ perceived barriers to clinical trial participation. Authors will present their findings at the American Society of Clinical Oncology’s (ASCO) upcoming Quality Care Symposium, taking place September 6–7, at the Hilton San Diego Bayfront in San Diego.

Following is a summary of each of the two new studies on clinical trials. Additionally, listen to ASCO Experts Merry-Jennifer Markham, MD, FACP, and Neeraj Agarwal, MD, discuss these two studies on a Cancer.Net podcast.

Clinical Trial Enrollment is Associated with Lower Death Rate for Patients With Metastatic Non-Small Cell Lung Cancer

New research from the University of Washington (UW) and Fred Hutchinson Cancer Research
Center reports that patients with metastatic non-small cell lung cancer (NSCLC) enrolled in a clinical trial had a median survival that was nearly double that of those not enrolled, and patients enrolled in a clinical trial had an almost 50% lower risk of death.

The findings from this study are notable, as data on the benefits of enrollment in therapeutic trials for patients with advanced lung cancer have been inconsistent. To more conclusively answer the question, the researchers used a clinically enriched database that contained clinical and patient-level characteristics that are often are unavailable in larger registry-level studies or national databases.

“Our study accounts for some important clinical variables that other studies have not included, such as the molecular features of the cancer, and we also have some unique data regarding the study participants,” said lead author Cristina Merkhofer, MD, MHS, a Hematology-Oncology Fellow at Fred Hutch and UW. “For example, we have data on clinical trial phase, whether the trial was randomized or not, whether the agents studied were later approved by the Food and Drug Administration [FDA], and the classes of agents studied. This allows us to look at the survival difference that we found through some other lenses and see whether there were specific trial characteristics that may have contributed to it.”

Of a group of 371 patients who met eligibility criteria for clinical trials, 118 (32%) enrolled in at least one. The majority of patients (89%) were in phase I/II trials, which test the safety, side effects, and best dose of a new treatment, as well as the degree to which a certain type of cancer responds to a new treatment. For the patients who enrolled, 51% were in clinical trials for drugs that were later approved by the FDA. The researchers found that median survival in clinical trial enrollees was 838 days, as compared to 454 days for non-enrollees. After adjusting for sex, Eastern Cooperative Oncology Group (ECOG) score, smoking, histology, EGFR and ALK status, and presence of brain metastases, clinical trial enrollees had a 47% lower risk of death relative to non-enrollees.

While the authors hypothesize that both the access to new treatments and the enhanced supportive care offered through clinical trials are equally important, their data can only begin to examine the former by looking at the aspect of access to promising agents. However, the role of the enhanced supportive care received by trial patients is much more difficult to capture in a database.

This research is part of a larger study that investigates areas of uncertainty surrounding clinical trial participation. In upcoming subgroup analyses, the authors plan to evaluate whether specific trial design characteristics are associated with a survival benefit.

“The study can support research evaluating health care policies or research that looks at incentives...
for patient participation in trials, such as financing transportation or lodging,” said Dr. Merkhofer. “It can help with research that addresses some of these important barriers to trial participation.”

View the full abstract.

**Gap Exists Between Physician and Patient Perceptions on a Patient’s Enrollment in Cancer Clinical Trials**

Survey results show a gap between attitudes and beliefs held by physicians/staff about patients’ reasons for participating in cancer clinical trials—and what patients actually are thinking. The study is the first of its kind to survey both groups about clinical trial enrollment by asking similar questions about enrollment barriers and then comparing responses.

“We found that commonly held beliefs in the research community about why a patient joins or does not join a clinical trial are not in sync with barriers reported by our cancer patients,” said Assistant Professor of Epidemiology Grace Clarke Hillyer, EdD, MPH, of Columbia University’s Mailman School of Public Health. “Physicians and staff involved in cancer care and treatment may not be aware of barriers perceived by patients or hold misperceptions about reasons for cancer patients’ reluctance to join a clinical trial that could result in the lack of an offer of a trial to a patient or refusal to join by the patient.”

Clinical trials are essential to advancing cancer prevention, detection, and treatment. However, only about 8% of U.S. adult patients with cancer enroll in a clinical trial, and nearly one in five (18%) publicly funded cancer studies are unable to recruit enough participants. Closing trials due to low accrual ends the research before conclusions can be reached and wastes the substantial time and resources invested.

To assess the attitudes, perceptions, and beliefs of both groups, researchers at Columbia University Herbert Irving Comprehensive Cancer Center created surveys to assess perceived structural, clinical, provider- and patient-level barriers to clinical trial enrollment. In 2017, 120 physicians and research staff completed the survey; the following year, 150 cancer patients not currently enrolled in a trial completed the same survey. The differences in views among physicians, research staff, and patients were then examined.

The findings showed 27.3% of patients answered that clinical trials are only offered to people whose disease is hopeless, while only 8.7% of physicians and research staff thought patients believed this. The survey also found that physicians and research staff misunderstood patient concerns about many aspects of trials and the reasons they decline to participate, including:

- Lack of understanding about clinical trials (63.3% physicians/staff vs. 9.1% patients)
- Feeling overwhelmed physically or emotionally (64.2% physicians/staff vs. 18.2% patients)
- Mistrust of the medical system (69.2% physicians/staff vs. 36.4% patients)
- Concerns about invasive procedures (41.7% physicians/staff vs. 9.1% patients)
- Toxicity (60% physicians/staff vs. 18.2% patients)
- Reluctance to be randomized/receive a placebo (70.8% physicians/staff vs. 27.3% patients).

“We found that many patients have positive attitudes toward clinical trials, and most trust their doctors,” said Dr. Hillyer. “Awareness of the gaps in perceptions about why patients decline clinical trial enrollment between physicians and cancer patients can act as a catalyst to open up communication and resolve issues, which could potentially lead to increased enrollment in cancer clinical trials.”

Dr. Hillyer noted that the study was a comprehensive head-to-head barrier assessment conducted at a large urban minority underserved NCI Community Oncology Research Program site among a diverse patient population (29.3% Hispanic and 13.3% African American). Although potentially limited by the small sample size, findings are suggestive of an issue not previously investigated. She is exploring expanding the research to multiple sites and developing interventional materials to bridge the gaps uncovered in this study.

View the full abstract.

This year’s Quality Care Symposium will include more than 320 abstracts focusing on efforts to improve the quality of care for patients with cancer. On-site facilities for reporters will include a working newsroom and access to leading experts in quality care.

Information for Media: www.asco.org/QCSpresskit

Doctor-approved patient information for your readers from Cancer.Net:
- Deciding on a Cancer Clinical Trial? 4 Things to Ask
- Finding a Clinical Trial
- Getting Treatment in a Clinical Trial
- Questions to Ask About Clinical Trials
- Video: Cancer Clinical Trials as a Treatment Option, with Mary Lou Smith, JD

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- Chair: Merry-Jennifer Markham, MD, FACP, University of Florida
- Randall J. Kimple, MD, PhD, University of Wisconsin
- Neeraj Agarwal, MD, Huntsman Cancer Institute- University of Utah Health Care

View the disclosures for the News Planning Team.

View additional abstracts on the Tip Sheet.
ATTRIBUTION TO THE 2019 QUALITY CARE SYMPOSIUM IS REQUESTED IN ALL NEWS COVERAGE.

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References


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