



Overcoming Financial Barriers to Clinical Trials Enrollment

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Participation in a clinical trial is free...or is it? While enrollees may receive medical care without charge, related expenses can mount. Few enrollees anticipate incidental expenses like parking, lodging, child care and meals away from home. Still fewer may understand the resources available to help cover those costs.

The Coalition for Clinical Trials Awareness hosted a Washington, DC policy panel discussion on May 14 to explore the issue. Held at the U.S. Capitol, the event fostered conversation about the importance of resources for clinical trials participants – and why related expenses shouldn't undermine enrollment and research on advanced treatments and new cures.



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Patient Expenses

Enrolling a clinical trial is no simple task. It's costly, often the most costly aspect of the trial, explained David Charles, MD, who conducts clinical research at Vanderbilt University. It's time consuming. And all too often, it fails. Eleven percent of trials cannot enroll even a single person, Laura Evans Manatos of the Lazarex Cancer Foundation explained.

So the prospect of losing enrollees or potential enrollees because of the burden of incidental costs deeply concerns researchers.

Expenses like parking, travel, child care or lost work income can be a serious deterrent to clinical trials participation. Manatos described a situation where a young girl fighting cancer needed treatment through a clinical trial but her mother couldn't afford gas to drive her to the trial site. With the help of Lazarex, Manatos explained, the girl enrolled in the trial and is now cancer free.

Clinical researcher Jan Brandes, MD, emphasized that "It's unfair to have a patient subsidize a trial." "What about patients with jobs that pay hourly?" Dr. Brandes queried. She noted that women, especially single mothers, might be "living on a thin margin" and trying to save for their children's college.

Expenses also intensify concerns about lack of diversity in clinical trials, noted Marsha Henderson, formerly of the FDA's Office of Women's Health. Women who might otherwise enroll may be asking themselves, "What am I going to do with my kids? Who's going to fix dinner?" Henderson explained.

Meanwhile, for minority populations an element of mistrust about clinical research lingers. Henderson emphasized the need to establish a positive narrative about clinical trials participation – one that minorities and populations traditionally underrepresented in trials could then share.





Solutions to Cost Challenges

The good news is that solutions exist. As Laura Evans Manatos explained, persistence among advocates like those at the Lazarex Cancer Foundation led the FDA to issue official guidance on reimbursement in January 2018. The agency explained that reimbursement for clinical trials expenses, as well as payment for participation, were legitimate practices – not “coercive” actions that could compromise a trial’s integrity or findings.

The question of compensation is a thorny one, but panelists were unanimous in their support of what Dr. Brandes called reasonable “stipends.” “Your body and your life are not worth a stipend?” Marsha Henderson exclaimed, “I think they are.”

While the FDA’s guidance was clear, substantive change has been gradual. To encourage more action to alleviate the financial burden on clinical trials participants, Lazarex worked with California legislators to make changes at the state

level. California passed the California Cancer Clinical Trials Program, which increases patient enrollment, retention, and minority participation in cancer clinical trials.



Pennsylvania passed similar legislation, while the U.S. Congress included language in 2018 appropriations legislation directing the National Cancer Institute to launch a pilot initiative that explores providing navigation and patient expense reimbursement for cancer clinical trials. Massachusetts and Texas have state bills currently under consideration.



Steps Forward

The panel discussion highlighted several key elements for increasing awareness about how patients can manage clinical trials-related expenses.



End misconceptions about reimbursement.

The idea that compensating patients for their time and reimbursing them for trials-related expenses is coercion is a myth. And it undermines efforts to enroll and retain clinical trials participants.

To maximize clinical trials' ability to enroll patients, stakeholders need to replace this message with a more accurate narrative: Stipends and reimbursement make participation possible for patients of all races, genders and socio-economic backgrounds who want to further medical research.



Continue legislative progress.

Celebrating California and Pennsylvania as trendsetters, advocates can encourage more state legislatures to turn their attention to the issue of reimbursement and access for clinical trials participants. Public policies can make good on the FDA's 2018 clarification, increasing access for those who want to enroll in clinical trials.



Improve patient guidance and support.

Patients considering clinical trials participation need frank, straightforward information about associated costs and available resources. Cooperation and coordination between clinical trials sites and support organizations can help to facilitate patients' access to aid and financial resources.

Learn more about Clinical Trials Awareness Week 2019 at CCTAwareness.org.



Coalition for
Clinical Trials
Awareness

The Coalition for Clinical Trials Awareness is a nonprofit group of health care providers, patient advocates, medical researchers and industry and government stakeholders working together to increase public awareness about the importance of clinical trials participation.