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## Financial Toxicity in Early Phase Clinical Trials: How Advanced Practice Providers Can Help



By [Amanda Brink](#) posted 49 minutes ago

Financial stressors pose significant obstacles to initial enrollment and sustained participation in early phase clinical trials. The factors contributing to this issue are multifaceted. Many early phase clinical trials are conducted at major academic medical centers situated in urban areas, rather than small community cancer centers. Consequently, patients often must travel for clinic visits, treatment appointments, and re-staging scans. Clinical trials require intensive monitoring, even if patients are undergoing oral medication regimens. This monitoring might entail extended periods of observation and the collection of pharmacokinetic research data at specific intervals. As a result, even a routine appointment can span multiple days. Furthermore, patients might need to travel for mid-cycle monitoring visits to assess labs and address treatment-related side effects, even when treatment is not due mid-cycle. Unanticipated expenses, such as unplanned hospitalizations due to medical complications like treatment-related side effects or uncontrolled symptoms from progressive disease, also arise.

While certain clinical trials offer reimbursement for enrolled patients, many studies do not provide this benefit. Even in trials that offer reimbursement, patients typically bear the upfront expense, submit receipts, and endure waiting periods for reimbursement, which might not always be prompt.

Most of the clinical trial requirements are delineated in the protocol, and advanced practice providers (APPs) do not have significant flexibility to modify these protocol stipulations. Nevertheless, there are steps that APPs can take to ease the financial burden for patients during their participation in clinical trials.

### **Multistate Licensure**

During the COVID-19 pandemic, many health-care providers, including oncology providers, became well versed in using telemedicine to meet with patients. While patients receiving intravenous therapy still needed to attend infusion appointments in person, those receiving oral medications could receive a substantial portion of their care remotely. As the national emergency designation for COVID-19 has concluded, many of the temporary licenses permitting cross-state practice for providers have lapsed.

One strategy for APPs to mitigate some of the financial stressors on patients is to collaborate with their institution to secure out-of-state licenses. Identifying the states where patients predominantly reside and obtaining licenses in one or more of those states can be beneficial. Even if the clinical trial requires that patients travel for appointments and monitoring, an initial consultation could potentially be conducted virtually. Some mid-cycle visits that only require routine labs that can be obtained locally may also be candidates for virtual visits.

### **Initiate the Conversation About Financial Aid**

Another proactive approach APPs can adopt is not waiting for patients to inquire about financial resources. Patients might feel reluctant to ask their providers about financial aid, fearing that they may not be able to participate in the clinical trial. By consulting with the clinic's social worker, APPs can initiate

early referrals for a comprehensive needs assessment and financial resources, assuaging patient's concerns. Informing patients of your willingness to facilitate any necessary paperwork to secure the assistance they require is crucial.

### Support Transfer to Closer Trial Sites

Patients often travel to large cancer institutions based on reputation and the desire to have access to a robust clinical trial program. Occasionally, after selecting a specific clinical trial, patients discover that another institution closer to their residence offers the same trial. While patients might initially opt to start the trial at the original site to expedite enrollment, they could consider transitioning to another site after completing a few treatment cycles. APPs can support their patients by remaining well-informed about alternative sites conducting the same clinical trial.

These suggestions represent just some methods to try to reduce the financial burden for patients and enhance participation on early phase clinical trials. APPs often possess a heightened awareness of their patients' psychosocial needs, including financial concerns. If we make the process of participating in a clinical trial even a little bit easier for patients, APPs can potentially initiate a positive cascade effect for future patients.

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