CLINICAL INVESTIGATION

The importance of budgeting in clinical trials and how a budget can prevent billing errors

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Academic medical centers have paid millions of dollars in fines to the government over the past decade due to incorrect research billing. Combined with a decrease in federal funding, an increase in industry-sponsored studies and sites looking to cut costs, the financial management of clinical trials has been thrown into the spotlight, an area that historically has received little attention. Until recently, academic medical centers focused solely on the actual research taking place, with little thought placed on the financial aspects associated with the research. However, as medicine and research have become more complex, the financial processes to support that complexity have not kept pace. Many institutions do not have centralized offices to handle budgeting, billing and other administrative functions for clinical research, and many important responsibilities are not being prioritized as needed.

First, let us address research billing. We used to live in a very 'reactive' state. If billing was not done correctly, the error only became known when a patient called asking why he or she received a bill. Once a problem was identified, there was not always a clear process as to how to fix it. If a patient's insurance is billed incorrectly, the insurance needs to be refunded and the research grant needs to be charged. But unless a patient called multiple times or a study team followed up, no one knew if the problem had actually been fixed. There are patients who may not check their explanation of benefits (EOB), so they would not even be aware that their insurance had been billed incorrectly. Finally, even if a situation was corrected, a root cause analysis to discover what led to the error was not necessarily performed. Due to a lack of transparency, it was difficult to identify the problem to begin with, and it was just as difficult to identify whether the problem had, in fact, been resolved.

So how do we resolve this problem and not bill the research participants that we work so hard to recruit onto our studies?

The first step in getting accurate clinical trial billing is to prepare a budget prior to the commencement of the study. This budget serves two primary purposes: ensuring sufficient funds are available to perform the study from start to finish, and identifying those procedures that are research-related and must be billed to a specific grant account versus those considered to be standard of care and billable to a research participant or his or her insurance.

There is no doubt that ensuring sufficient funding is a critical step in preparing for a clinical trial. An investigator is required to complete the terms of a clinical trial agreement, even if it means operating at a loss. Successful budgeting requires a thorough understanding of the costs that will be incurred throughout the study. However, many people prepare a 'breakdown' budget, in which the funding offered by a sponsor is accepted at face value, and then they back into a detailed budget, which does not suffice. A sponsor offer of $30,000 may sound appealing; however, if it will cost $50,000 to conduct a clinical trial, that offer loses some of its appeal. No research group wants to find

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itself in a position where it only realizes in Year 4 of a 5-year study that it will not have sufficient funding to complete the study.

How does one know the true cost to perform a clinical trial? By preparing an internal budget, in which a protocol is reviewed and the individual services, procedures and tests needed to perform the study are identified. A spreadsheet or a clinical trial management system should be used, with each service required by the protocol appearing on its own line in the budget. In addition to reflecting the cost for each protocol requirement, each line item on the budget should also identify whether that cost will be charged to a research grant or to a participant as standard of care. Sponsors must pay for any services required by the protocol that are not standard of care [1]. This process will establish the true costs of the study and should be completed prior to consideration of a sponsor offer. This will also provide decision makers with the projected financial gain or loss from the study and an ability to make an informed financial decision in regard to proceeding with the study [1]. The Center for Cancer Care and Research in St. Louis confirms that developing a site budget to capture all costs associated with the trial and then using that budget to negotiate with the sponsor to ensure all costs are covered is critical to ensuring sufficient funding for the study [2].

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To successfully manage a site conducting a clinical trial, sufficient financial resources are required. Site performance is highly contingent on having sufficient resources; therefore, it is critical to accurately estimate the time and effort needed to conduct the trial [3]. This calculation is one of the most difficult components of the budget, as it requires an accurate assessment of the number of hours each study team member will spend on the study. Staff time is the primary factor contributing to the high cost of conducting a clinical trial [4], and this calculation is frequently underestimated, specifically in the areas of data monitoring, reporting of serious adverse events and patient follow-up [2]. The time required to screen patients, obtain a patient's consent, conduct patient visits, prepare case report forms and complete all regulatory documents must be included in the budget, and these costs should be reimbursed from the sponsor. If work will be performed during nights and weekends, overtime rates may need to be included [5]. Consideration must also be given to the time and effort needed to start a study prior to patient enrollment. The required time and effort to prepare for a study can cost several thousand dollars, and tying sponsor payments solely to participant visits when there is low participant enrollment could result in a financial loss to the site [6].

Insufficient funding is not an inherent reason to immediately reject a study, as potential options still exist. More aggressive negotiations may be necessary to persuade the sponsor to provide additional funding as needed. Private sponsors generally provide reimbursement to cover a site's costs; government sponsors, on the other hand, often do not fully cover the cost of conducting a clinical trial [7]. In addition to the primary sponsor, there may be other sources of funding that can be utilized – either internal or external funding sources. It is important to have these conversations and determine the proper path upfront to prevent misunderstandings down the road.

Another reason to prepare a budget prior to starting a clinical trial is that the budget, when done properly, should serve as a road map for billing. When you prepare an internal budget, identifying each procedure and test that will be required as part of the study will allow you to determine which procedures and tests are research and which are standard of care. This should be clearly noted on the budget and then provided to your institution's billing office to follow when charges are adjudicated. There must be clear communication channels between those who prepare the budget – either the study team or a centralized office – and the billing office to ensure that the billing office understands how to interpret the budget so as to make consistent and accurate allocations of expenses.

To facilitate consistent and accurate allocation of expenses, formal training should be implemented to enable the billing office to read and understand budgets. In addition, the formatting of clinical research budgets should be streamlined across an institution.

The registration process and the information technology infrastructure that supports the registration process are the most critical components of the research billing structure [8]. When a clinical trial management system and a centralized office are used to prepare clinical trial budgets, the registration process can be linked to the budget, so that when a participant arrives for a visit, there is visibility into what charges are expected to be generated by the billing office. If these options do not exist in your organization, create a budget template that includes key indicators to differentiate those services that are research-related and must be billed to a research grant and those services that are standard of care and may be billed to a participant's insurance.

In summary, preparing an internal budget prior to beginning a clinical trial, and prior to considering a sponsor's offer, can help identify potential shortfalls in funding and ensure that appropriate funding exists for the duration of a study. An accurate budget should also serve as a road map for billing, as it differentiates which costs will be paid by research and which will be billed as standard of care. Communication with your billing office is critical to ensuring that the budget is followed when performing the billing functions.

Preparing internal budgets is time-consuming and requires significant attention to detail while reading a protocol. But the time and effort invested upfront can ensure appropriate financial support for a study while facilitating accurate research billing. This will help prevent a difficult conversation either with a study team that was billed for standard of care charges or with a patient who was billed for research-related procedures.

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