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Clinical Research Terminology Codes: What We Do and How Much It Costs

By Norman M. Goldfarb

When physicians bill their patients' insurance companies, they use Current Procedural Terminology (CPT) codes to specify the precise activities – endoscopies, EKGs, etc. – they perform in treating patients. Most activities in clinical research study protocols and budgets, however, do not have CPT codes. Neither do the large number of research activities – "hidden costs" – that do not appear in protocols or budgets.

A new system of Clinical Research Terminology (CRT) codes fills this gap by defining codes for over 240 study activities.[1] With a combination of CPT and CRT codes, study sponsors can specify exactly what activities study sites are to perform. Sites can also use the codes to understand their costs by determining how study personnel use their time.

The Study Budget Problem

There is a general consensus among research sites that most study budgets are too low to provide adequate – or any – profitability. However, most research sites have little or no understanding of their clinical research costs. Research personnel at academic medical centers, hospitals, clinics and physician offices often participate in clinical care activities, making it very difficult to distinguish the total direct costs of clinical research vs. clinical care – to say nothing of specific studies. Accurate overhead allocation presents additional challenges. Because only a fraction of research time is billable, the true cost of a billable study coordinator hour can be several times the salary cost.[2] An additional challenge is posed by physicians, scientists and academics who may not cooperate enthusiastically in cost measurement and management programs. Nevertheless, if sites want sponsors to take their budgetary concerns seriously, sites must know their costs.

There is also an unfortunate dynamic at play: Sponsors do not invent study budgets out of thin air; they rely on their experience, consultants, and commercial databases such as GrantPlan and Grants Manager to set budgets. Sponsors then propose these budgets to sites. Unsophisticated sites, that do not know their costs, willingly accept low budgets and quickly sign clinical trial agreements. Many of these sites also do not know how to enroll subjects or generate high-quality data. Sophisticated sites, that know more about their costs, enter into time-consuming negotiations. Sponsors have only so much time and resources for study start-up, so cannot afford too many of these negotiations. As a result, the population of study sites is disproportionately unsophisticated. One result is that 30% of the sites in a typical study enroll zero subjects.[3] Unsophisticated sites also increase sponsor costs for training, monitoring and data cleaning. The low prices accepted by the unsophisticated sites feed back into sponsor experience and the pricing databases, propagating low budgets to future studies.

Sponsors, in general, think their study budgets are fair; after all, most sites accept them with little or no negotiation. Site, in general, think budgets are not fair, but accept them anyway. However, in the absence of site refusals or accurate information on site costs, there is little motivation to increase budgets. Sponsors also generally define "fair" pricing as paying about the same prices to all sites, as opposed to paying more for the higher value delivered by better sites. As a result, sites that incur extra costs to train their personnel and

review their data for quality, seldom see a direct return in the form of higher study budgets. Sponsors may not remember that the sites conducted previous studies at all.

Sites can obtain incrementally higher study budgets by communicating their costs with CPT and CRT codes, but this strategy is vulnerable when competitors with much lower costs arrive in the market. Exactly that is now happening with the accelerating globalization of clinical research. It is very difficult for a U.S. site to justify a study budget increase when sites in Asia, Eastern Europe, and Latin America – that enroll faster and generate data of equal or better quality – are delighted with budgets 10-50% lower. Fortunately for the U.S. clinical research industry, some percentage of clinical research will always be performed in the United States –principally at sites that meet their enrollment commitments and produce high quality data at relatively low cost. The future for unreliable, low-quality, expensive suppliers is limited in any market.

Cost Reduction Opportunities

The use of CRT codes to understand costs pays real dividends when sites use this information to reduce costs. Cost reductions can occur in several ways:

- Simply measuring costs has the effect of lowering them. This "Hawthorne Effect" is well-documented in other industries.
- Cost variations within an organization are very common. Different study coordinators do things differently. Inevitably, some approaches are more efficient than others. With accurate data, management can promote best practices within the organization.
- Cost variations between organizations are also very common. With cost data from multiple organizations, each organization can benchmark its costs and identify best practices from other organizations.
- When costs are not understood, there often appears to be a tradeoff between cost and quality. When costs are understood, the cost implications of poor quality become apparent, and management can focus on the right places to reduce overall costs by improving quality.

Informed Consent Best Practice?

Over two million clinical research subjects will sign informed consent forms this year. Mailing informed consent forms to potential subjects prior to the initial visit may:

- Scare off qualified subjects.
- Prevent wasting time with reluctant participants.
- Increase retention rates.

Without data, all we have is opinion.

Industry leaders such as Toyota and General Electric form "preferred provider" relationships with their suppliers. In these relationships, customers and suppliers work together to streamline processes and share in the benefits. With the resulting efficiencies, suppliers simultaneously reduce prices and increase profits.

A Preferred Provider Relationship in Action

Toyota and General Motors jointly operate the New United Motor Manufacturing, Inc. (NUMMI) automobile manufacturing plant in Fremont California. If you supply axles to NUMMI, you electronically notify NUMMI when you send a shipment. NUMMI does not inspect the axles; it does not count them; it does not even wait to receive them before it wires payment to your bank account. As an exercise, compare this process to the equivalent process in clinical research.

Pharmaceutical companies are beginning to experiment with preferred provider relationships with contract research organizations (CROs) and other service providers, but, as yet, very little with research sites. If the U.S. clinical research industry has a role to play in the era of globalization, streamlining research processes serves everyone's

interests. For example, imagine the impact on site monitoring and data cleaning costs if sites were to produce 100% clean data. What can sites do to accomplish this objective? What can sponsors do? What can we do together?

Time Study Produces Hard Data

In November and December 2005, all study personnel at three research sites kept detailed time logs for one week each. Using CRT codes, they recorded a total of 2,047 activities over 528 hours. Completing the time logs took about 30 minutes per day, which may have been offset by improved productivity from knowing the time was being recorded.

This time study generated useful data, and can be refined in future versions. The high number and variety of activities require care in recording, classification and analysis. An unknown percentage of activities were miscoded because of code ambiguity, participant error, transcription error, or the correct code did not exist until the timelogs were analyzed. For example, there were no codes available during the study for "other" activities within a category such as "Between-visit." A much larger sample is required to measure infrequent activities. More detailed comments on "other" activities would have helped define these better.

Although detailed results from the time study are confidential to the participants, the following results can be shared:

- The median activity took 9 minutes. In other words, an eight-hour day for a study coordinator typically includes over 50 different activities.
- As shown in Table 1, study visit activities, the major component of study budgets, comprise about 20% of study personnel time. This percentage may be understated because of activities classified in the "Other Study" category, but the importance of hidden costs is clearly supported.
- Table 2 presents data for four relatively common activities, with 31 to 55 occurrences each. This data demonstrates various levels of consistency across sites. R1250: Dispense or Administer Study Drug shows a high level of consistency, with an average of only about 5 minutes per activity. R1290: Wrap-up Visit (after Subject Leaves) shows much more variability, which may reflect more-or-less efficient practices or simply different studies; a discussion between the sites could be informative.

Table 1. Time by Category

Activity	**Time**
Pre-Study	8.0%
Recruiting & Prescreening	5.4%
Study Visit	20.4%
Between-visit	18.3%
Adverse Event	0.4%
Regulatory	0.5%
Study Records	0.0%
Sponsor-Related	2.8%
Other Study	23.0%
Non-study	21.3%
Total	100.0%

The last column shows average estimates, which are all high. Given all the hidden time not included in stuffy budgets, there is probably a natural upward bias in these estimates.

Table 2. Minutes/Activity

		Minutes/Activity				
Code	**Activity**	**Average**	**Site 1**	**Site 2**	**Site 3**	**Estimate**
R1200	Prepare for Visit	12.2	9.3	11.6	16.1	15.0
R1227	Interview for Previous & Concomitant Medications	4.4	5.8	3.8	6.2	11.7
R1250	Dispense or Administer Study Drug	5.1	6.0	5.0	5.0	7.3
R1290	Wrap-up Visit (after Subject Leaves)	12.6	12.4	16.7	6.7	15.0

- No single activity type consumed over 5% of total time, so efficiencies will be found in small increments. Table 3 lists the ten most time-consuming activities in descending order. The list is not definitive, but these activities are probably good places to look for efficiencies. Unfortunately, the adoption of eCRFs appears to decrease site productivity. On the other hand, there are probably ways to eliminate or streamline correspondence between sites and sponsors. Sites with electronic medical records (EMR) have an obvious cost advantage.

Table 3. Ten Most Time-consuming Activities

Code	**Activity**
R1300	Complete CRF
R1901	Receive, Read & Process Correspondence (Mail, Fax, Email)
R1900	Write & Send Correspondence (Mail, Fax, Email)
R1143	Review Charts for Potential Subjects
R1200	Prepare for Visit
R1370	Data Clarification Request, Handle
R1290	Wrap-up Visit (after Subject Leaves)
R1091	Clinical Supplies, Order
R1209	Screen & Recruit Subject
R1021	Investigator Meeting, Coordinator Attend

Future Time Studies

Future time studies will generate more data of higher quality, shedding light on clinical research costs and pinpointing opportunities to improve efficiency. Sites interested in participating should contact the author.

References

1. Available at http://www.firstclinical.com/resources/codes
2. "The True Cost of a Study Coordinator Hour", Norman M. Goldfarb, Journal of Clinical Research Best Practices, November 2005
3. Private communication with major CRO, September 2005

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