Medical History and Review of Medical Records

Over the more than two decades I have been conducting clinical pharmaceutical research as a physician investigator (PI), the total fees that research sites receive from sponsors for the work of obtaining and reviewing potential patients’ medical histories and medical records seems to diminish year by year. I suppose this is a result of the small amount of time that the “practically invisible” PI spends trying to request, review, abstract, and add to the subjects’ past medical histories.

How do the real PIs and the “practically invisible” PIs approach the critically important step of evaluating a prospective research patient’s medical history and obtaining medical records?

So, how do the real PIs and the practically invisible PIs approach the critically important step of evaluating a prospective research patient’s medical history and obtaining medical records? To answer the first part of this question, let’s look at what is standard operating procedure at the Memory Enhancement Center, where I work:

1. First, obtain written permission from the patient/legally authorized representative to request any/all medical records for the past five years.
2. Fax a copy of the signed informed consent forms to the primary care doctor.
3. Send a fax request to any/all of the doctors whose names are provided by the patient/family and to any hospitals that the patient has been discharged from in past five years, and any specialists seen by the patient in that period.
4. Obtain confirmation that the fax was received.
5. Wait one week for the records to arrive.
6. After one week, if no records have arrived, call and fax the request again.
7. After another week, if no records have arrived, notify the patient/family of the situation and ask them to call their family physician to obtain the records.
8. If all of these attempts fail, no further efforts are made to obtain records.
9. Upon receipt, I review all of the medical records, note the date of my review, and prepare an abstract of new information obtained that was not made apparent from the patient/legally authorized representative on the medical questionnaire completed at our facility.
10. Our research coordinator also abstracts all records and notes any additional past medical history, abnormal laboratory values, abnormal radiology reports, abnormal ECGs, or abnormal physical findings from prior physicians’ examinations.
11. All such information is then placed in the patient’s past medical history and signed off by the PI.

How would the practically invisible PI handle medical records for a prospective research patient? In all likelihood, he or she would simply use the information supplied by the patient and go no further.

Interpreting Abnormal Laboratory Values

As an example of the importance of studying a patient’s medical history, I can say from my work with mainly older patients (ages 60 and over) that it is very rare that a screening lab report or ECG is “within normal range.”

What does the real PI do when approaching any abnormal value? The proper approach is to determine first if the pertinent lab test being reported has been performed on the patient previously. If so, and the value in question is not significantly different from a prior (prescreening) value, I place a simple “NCS” (not clinically significant) next to it. However, the practically invisible PI might just check off NCS without any clue as to what a prior value may have been.

When does the lab value that is out of range become clinically signifi-
When does an abnormal lab test become an adverse event (AE)?

If the PI does anything more than simply putting an NCS at the value, it should be made an AE. The severity, of course, depends on what impact such an abnormal lab test has on the patient’s well-being. If there is no, or minimal, impact on the welfare of the patient, it should be coded as “mild.” If there is a measurable impact on the patient’s quality of life, it can be labeled “moderate”; but if there is a major effect, the PI must code it as “severe.” This determination should not be made by the research coordinator, which is a favorite move of the practically invisible PI—that is, to have the coordinator decide the severity of an AE.

Remember, an AE can be coded as “severe” and not be a serious AE (SAE). For example, if a patient’s screening hemoglobin is 11 grams (the normal level at our lab is 13.5) and a repeat level is drawn to confirm it, then it must be reported as a new past medical history of anemia. If it was present on prior records, but at similar levels, it can still be noted as NCS, but by redrawing, it becomes an AE.

An abnormal ECG, which might show a right bundle branch block at screening, if present on prescreen records, is simply part of past medical history and should be coded as NCS on the ECG, and nothing further. If no such old ECG is obtained, and a right bundle branch block is found, it can be coded as an AE if found on screening, although some monitors and auditors have told me that it can be added to past medical history if the subject has not yet been dosed. I could not find any statute from the Food and Drug Administration website to help resolve this issue in a more “official” manner. When in doubt, make it an AE, or use your best discretion.

Coordinators should not let their PIs become disinterested or nonchalant about reviewing prior records, old lab reports, and consultation reports. They should ensure that the PI notes every abnormal lab test reported. However, as research coordinators, they should never rate the AEs, as that is the job of the person who signs the 1572. If the PI has delegated the rating of an AE, it should be to a qualified healthcare professional who has been trained well in this field (usually a sub-PI with an MD or DO degree, or a nurse practitioner/physician assistant who is experienced in such research).

Thus, the fee that a true PI deserves for obtaining records, reviewing them, abstracting them, and discussing them with his/her coordinator is usually five times the going rate. Show this article to sponsors who offer a small amount for this critically important part of being a research PI, and let me know what they have to say.

Joel S. Ross, MD, FACP, AGSF, CMD, CPI, LLC, is founder, chairman, and president of the Memory Enhancement Center of America, Inc, a Phase I, II, and III Alzheimer’s disease evaluation and treatment center, and the medical director of Iberica USA’s Phase I research center, both located in Eatontown, N.J. He received his geriatric fellowship training at Mt. Sinai Medical Center in New York City, where he holds a clinical adjunct professorship in the Department of Geriatrics. He also was the first board-certified, fellowship-trained geriatrician in the state of New Jersey. He can be reached at jrossmd@memorycenternj.com.