JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 3, No. 9, September 2007 "Can You Handle the Truth?"

Good Clinical Practice Q&A: Focus on Subject Histories & Physicals

In documenting a patient's eligibility for a study, must the investigator obtain the prospective subject's previous medical records, or are history forms completed at the start of a study considered adequate?

Some studies are so complex and have so many complicated inclusion/exclusion criteria that a review of previous medical records is a necessity. A well-written clinical summary prepared by the subject's primary physician, along with relevant lab reports and related documents, would suffice; photocopies of reams of prior medical records are not required.

In more straightforward studies that have few inclusion/exclusion criteria, the completion of a history form alone may be adequate (i.e., without the need to obtain prior medical records). The caveat here is that the history taker must be clinically knowledgeable in order to ask the appropriate questions and adequately probe the study candidate for additional information when needed.[1]

Physical exams of study subjects are important in the context of several aspects of clinical studies. Is there a difference between a physical exam and a physical assessment? If so, under what circumstances? Must the protocol state which is required?

There is a definite difference between a physical exam and a physical assessment. A physical exam is conducted by a physician, a physician's assistant, or a nurse practitioner. The procedure involves an examination of all or certain body systems (e.g., genito-urinary). The examiner uses auscultation, palpitation, percussion, as well as visual, auditory, and olfactory means, to evaluate the individual. In most states, a registered nurse who performs a physical exam is operating outside his or her scope of practice.

On the other hand, a physical assessment is an abbreviated evaluation, typically performed by a registered nurse. Percussion and palpitation are not routinely employed. The examiner may auscultate heart and lungs, measure vital signs, check pupil size and reaction, and assess skin turgor.

For clinical studies, the protocol should define which of the two procedures will be required. In many cases, protocols are ambiguous and physical assessments are performed in lieu of physical examinations—sometimes to the surprise of the sponsor. There have been studies in which a physical exam was required, but the physical exam source document forms created for the study were actually titled "Physical Assessments." Of course, this creates a conflict between the protocol and study source documents. In other studies, the physical exam source document form was correctly titled, but physical assessments were performed.

In simple studies, nursing assessments may suffice and protocols should reflect this specification. For complex studies, the physical exam is an important activity necessary to demonstrate that the patient's safety is ensured.

Unless specified in a protocol, a physical assessment cannot be submitted for a physical exam.[2]

Reference

1. “Good Clinical Practice: A Question & Answer Reference Guide”, Barnett International, 2007 p. 56
2. Ibid., pp. 61-62

Source

“Good Clinical Practice: A Question & Answer Reference Guide 2007,” is available for $39.95 at http://www.barnettinternational.com/