

Subject Illnesses Found at Screening

By Joél Marie Barra

When screening a potential subject for a clinical study, we sometimes discover an illness unknown to the person. The illness can then be treated, regardless of whether the person enrolls in the study. Our research facility is associated with an internal medicine practice, so we can refer these people either to appropriate healthcare providers or to our internist. In many cases, they can still enroll in the study.

Such discoveries are more likely if the person has inadequate medical care, but, with the comprehensive histories, physicals and tests typical of clinical research, we sometimes discover illnesses that normal clinical care has not detected. As a side benefit, diagnosing an infectious disease reinforces the need to use universal precautions with all subjects.

Over the past six years, we have discovered unknown illnesses in about 40 potential subjects, about 1 in 30 screened. We were able to enroll more than half of them in the same or a different trial. Here are four examples:

- Person A was interested in a hypertension study. His lab results showed a fasting HbA1c of 12%, leading to a diagnosis of diabetes. We referred him to his regular primary care physician.
- Person B was interested in a diabetes study. Based on his ECG report, we diagnosed atrial fibrillation. We referred him to a cardiologist.
- Person C was interested in a hypertension study. Based on his lab results, we diagnosed Hepatitis C. We referred him to a hepatologist.
- Person D was interested in a resistant hypertension study. Based on her lab results, we diagnosed HIV. We referred her to HIVLA, a comprehensive directory of services in Los Angeles County and AIDS Project Los Angeles (APLA).

Although it takes years for clinical research to improve public health, it is satisfying to know that we can sometimes make a difference to people's health in the short term. These stories propagate through the local community, making it easier to recruit subjects for clinical trials.

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