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E-screening Shows Promise for Clinical Trial Recruitment

Electronic screening tool saved 80 percent of research personnel burden

Electronic screening has the potential to significantly reduce the burden associated with clinical trial recruitment, according to a study published recently in the *Journal of the American Medical Informatics Association*.

Research suggests that 86 percent of clinical trials experience delays for anywhere between 1 and 6 months due to recruitment difficulties, and that the remaining 14 percent are delayed even longer. Use of electronic health records (EHRs) and other technologies have increased exponentially, but scientists have not studied their possible value for screening. A group of Columbia University researchers thus sought to investigate; they used the NIH-sponsored Action to

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Control Cardiovascular Risk in Diabetes (ACCORD) trial, as it was actively enrolling during the study period.

Columbia University Medical Center's clinical data warehouse is an electronic repository of sys-

tem-wide patient information from which potentially eligible subjects were selected. Only these patients were then reviewed by clinical research staff for a final determination of eligibility — saving 81 percent of the work normally required. To allow the warehouse to pull accurate data, the

study authors analyzed which criteria had corresponding EHR elements, where and how these data were stored, and which could be assessed automatically. Because the ACCORD trial had a complex set of inclusion and

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exclusion criteria — including at least age 40 years with type 2 diabetes determined by fasting plasma glucose, hemoglobin A1c, or certain medication use, as well as a lack of specific comorbidities — the authors surmised that their model would be applicable to many other trials, if successful.

When the clinical data warehouse performance was compared to an independent, manual eligibility evaluation, the sensitivity was found to be 100 percent and the specificity was found to be 84 percent. The authors point to the superb negative predictive accuracy as a large part of the model's success, as this translates into reliable effort savings without loss of eligible patients. Their main goal of avoiding unnecessary review of ineligible patients was attained. They conclude that eligibility cri-

teria to be included in e-screening should have corresponding data elements that can be automatically queried, and that more study is warranted to explore this promising recruitment tool.

Source: Thadani SR, Weng C, Bigger JT, et al. 2009. Electronic screening improves efficiency in clinical trial recruitment. *Journal of the American Medical Informatics Association* 16:869-873.

Intensive Medical Therapy Effective for Most Asymptomatic Carotid Stenosis

Revascularization should only be recommended if microemboli are visible on transcranial Doppler

Intensive medical therapy is an effective treatment for asymptomatic carotid stenosis and is the most appropriate strategy for the majority of patients, according to a study published recently in the *Archives of Neurology*. The data suggest that revascularization should only be considered in patients with microemboli appearing on transcranial Doppler.

Asymptomatic carotid stenosis (ACS) patients are at risk for cardiovascular events, but the literature does not support arterial stenting or endarterectomy due to increased likelihood of complications.

Microemboli detected via transcranial Doppler, however, raise stroke risk significantly, potentially making revascularization a more prudent treatment option. The authors of the current paper thus sought to further investigate the risks and benefits associated with ACS therapy.

The authors found that stroke risk has decreased from 15.6 to 10.3 percent in patients with microemboli, as the use of intensive medical therapy has risen, and that microemboli on transcranial Doppler are not as prevalent.

Four hundred sixty-eight patients with ACS of 60 percent or greater — assessed by Doppler peak velocity — were enrolled in the trial either between January 1, 2000 and December 31, 2002, or between January 1, 2003 and July 30, 2007, at an Ontario, Canada

teaching hospital.

All participants were evaluated at baseline for intracranial stenosis and total plaque area, and were checked annually. Any events that occurred, such as stroke, death, myocardial infarction, or carotid endarterectomy, were recorded in the study database. In patients with plaque progression, medical therapy was

intensified despite routine treatment. Intensification included lifestyle counseling, increasing statin dose, or adding one or more of ezetimibe, niacin, an angiotensin-converting enzyme inhibitor or angiotensin-receptor blocker, and metformin/pioglitazone.

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Analyses revealed that more than 34 percent of patients with ACS and microemboli (who were more likely to have intracranial stenosis, smoke, and have intermittent claudication) had a stroke, myocardial infarction, required carotid endarterectomy, or died in the study's first 2 years. Only 8.6 percent of those with ACS but not microemboli experienced these events. The authors also found that stroke risk has decreased from 15.6 to 10.3 percent in patients with microemboli, as the use of intensive medical therapy has risen, and that microemboli on transcranial Doppler are not as prevalent. They conclude: "Given our finding that intensive medical therapy has reduced the prevalence of microemboli to only 3.7 percent and

markedly reduced cardiovascular events, particularly stroke, we suggest that such intensive medical therapy be regarded as the first line of therapy for patients with ACS. Given that with intensive medical therapy, the risk of stroke in patients without microemboli is less than the risk of endarterectomy or stenting, we think that revascularization should be considered only for the rare patients with microemboli."

Source: Spence JD, Coates V, Li H, et al. 2009. Effects of intensive medical therapy on microemboli and cardiovascular risk in asymptomatic carotid stenosis. *Archives of Neurology* 67(2):doi:10.1001.

Hot Topic Highlights

Vascular Domain recently posted the following Hot Topics to your website:

'Healthy Obese' May Not Exist

A study published recently in *Circulation* refutes the notion that middle-aged men can be overweight or obese without increased cardiovascular risk. Negative outcomes like heart attack and stroke were more likely to occur even if overweight men did not have a condition called the metabolic syndrome, a cluster of risk factors previously thought to be responsible for the extra risk. The authors' analyses showed that overweight or obese men with the metabolic syndrome — as well as those without — had increased likelihood of cardiovascular events and death. In addition, obesity was associated with greater risk of death from non-cardiovascular factors and cancer.

Source:

Arnlov J, Ingelsson E, Sundstrom J, Lind L. 2010. Impact of body mass index and the metabolic syndrome on the risk of cardiovascular disease and death in middle-aged men. *Circulation* 121:230-236.

Vigorous Physical Activity May Protect Against Stroke and Cardiovascular Disease

Engaging in vigorous activity throughout life, especially during young adulthood, may prevent stiffness in the arteries of the neck, according to a study published recently in *Hypertension*. Arterial stiffness is a risk factor for many cardiovascular conditions. The authors found that adolescents and young adults with stiffer arteries spent significantly less time doing vigorous, but not light or moderate, physical activity. Consistent vigorous activity appeared to confer this positive effect by bringing about beneficial changes in other cardiovascular risk factors.

Source:

van de Laar RJ, Ferreira I, van Mechelen W, et al. 2009. Lifetime vigorous but not light-to-moderate habitual physical activity impacts favorably on carotid stiffness in young adults: the Amsterdam Growth and Health Longitudinal Study. *Hypertension* 55:33-39.