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NorthPoint Domain Inc.
One Joy Street
Boston, MA
02108-1403 USA

(800) 603-1420

www.northpointdomain.com
memberservices@npdinc.com

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 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 system-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 corre-

sponding 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 exclusion criteria — including at least age 40 years

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.

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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 criteria 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.

Catheter Ablation Before ICD Implantation Improves Outcomes

Physicians should consider performing the procedure prophylactically

A study published in the January 2 issue of *The Lancet* found that prophylactic catheter ablation before defibrillator implantation seemed to prolong time to recurrence of ventricular tachycardia (VT) in patients with stable VT, previous myocardial infarction (MI), and reduced left ventricular ejection fraction (LVEF). The authors state that physicians should consider prophylactic catheter ablation before placement of an implantable cardioverter defibrillator (ICD).

Patients with VT and a history of MI are considered high-risk for recurrent VT, ventricular fibrillation (VF), and sudden death. Placement of an ICD can prevent sudden cardiac death and reduce total mortality. However, ICD shocks are painful and do not provide complete protection against sudden cardiac death. The Ventricular Tachycardia Ablation in Coronary Heart Disease (VTACH) study was designed to assess prophylactic VT ablation

followed by ICD placement in patients with a previous MI, first episode of stable VT, and reduced LVEF.

The researchers conducted the prospective, open, randomized controlled trial at 16 European centers. Eligible patients were aged 18 to 80 years, had stable VT, previous MI, and reduced LVEF (less than 50 percent). A total of 107 patients were randomly assigned to receive catheter ablation and ICD placement (52) or

to a control group who received ICD placement alone (55). The primary endpoint was the time to first recurrence of VT or VF. Mean follow-up was 22.5 months. Time to recurrence of VT or VF was longer in the

Time to recurrence of VT or VF was longer in the ablation group, a median of 18.6 months compared to 5.9 months for the control group.

ablation group, a median of 18.6 months compared to 5.9 months for the control group. At 2 years, estimates for survival free from VT or VF were 47 percent in the ablation group compared to 29 percent in the control group. In addition, patients in the ablation

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group had fewer appropriate ICD shocks, and fewer hospital admissions for cardiac reasons than the control group.

The authors write that, although the study has limitations, “prophylactic catheter ablation in patients with haemodynamically stable VT, previous myocardial infarction, and reduced left-ventricular function should be strongly considered before implantation of a cardioverter defibrillator, especially in patients with an LVEF of more than 30 percent.”

Source: Kuck K-H, Schaumann A, Eckardt L, et al. 2010. Catheter ablation of stable ventricular tachycardia before defibrillator implantation in patients with coronary heart disease (VTACH): a multicentre randomised controlled trial. *The Lancet* 375:31-40.

Hot Topic Highlights

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

More Cardiac Rehabilitation Is Better

Cardiac rehabilitation programs are effective at lowering the risk of cardiovascular events, such as heart attack, among older people. A study published in *Circulation*, however, found that too few people who would benefit from these programs participate in them. The study also found, perhaps unsurprisingly, that among people who participated in cardiac rehabilitation programs, those who attended the most sessions gained the most benefits. People who attended 36 sessions had a 14 percent lower risk of death and a 12 percent lower risk of heart attack than those who attended 24 sessions; 22 percent lower risk of death and 23 percent lower risk of heart attack compared to those who attended 12 sessions; and 47 percent lower risk of death and 31 percent lower risk of heart attack compared to those who attended only one session.

Source: Hammill BG, Curtis LH, Schulman KA, Whellan DJ. Relationship between cardiac rehabilitation and long-term risks of death and myocardial infarction among elderly Medicare beneficiaries. *Circulation* 121:63-70.

Modest Weight Loss Can Change Your Heart

Obese people who lost a moderate amount of weight through diet and exercise improved their cardiovascular health, according to the results of a small study published in the December 15, 2009 issue of the *Journal of the American College of Cardiology*. Participants lost an average of 9 percent of their body weight during an average of 6 months. The authors noted decreased heart muscle thickness, improved pumping and relaxation, and decreased carotid artery wall thickness. The cardiovascular benefit occurred after the weight loss, and the greatest benefit occurred 9 to 12 months after the study began.

Source:

de las Fuentes L, Waggoner AD, Mohammed BS, et al. 2009. Effect of moderate diet-induced weight loss and weight regain on cardiovascular structure and function. *Journal of the American College of Cardiology* 54(25):2376-2381.