

January 2010



Please add newsletters@npdinc.com to your address book to ensure future delivery of NorthPoint Domain newsletters to your inbox (not bulk or junk folders).

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 corresponding EHR elements, where and how these data were stored, and which could be assessed automatically. Because the ACCORD trial had

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.

continued on page 2

... E-screening Shows Promise for Clinical Trial Recruitment
continued from page 1

a complex set of inclusion and 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 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.

Men on Statins Have Lower Pre-Op PSA: Study

Further study is necessary to elucidate the role of statins in prostate cancer development

Men who took preoperative statins presented for radical prostatectomy with lower prostate-specific antigen (PSA) levels, according to the results of a study published in the January 2010 issue of *The Journal of Urology*.

Among the most widely prescribed medications in the United States, statins have demonstrated a complex interaction with the prostate, PSA, and the development of prostate cancer, according to the authors. In two studies, PSA decreased in patients who had been prescribed statins — and in vitro, statins have demonstrated antitumor effects. For the current study, the authors compared pathological features of men on statins with men who did not take statins. They determined the effect of preoperative statin use on total preoperative PSA and the risk of biochemical recurrence in patients with prostate cancer presenting for radical prostatectomy.

The authors compared 3,828 men (1,031 on statins and 2,797 who were not) who underwent radical prostatectomy between January 2001 and July 2008, evaluating the differences in PSA overall and

Overall median serum PSA was lower in patients on preoperative statins (5.0 ng/ml compared to 5.2 ng/ml).

when patients were stratified by age-specific groups, body mass index, and Gleason grades on final pathology. In addition, they investigated differences in biochemical recurrence rates. Overall median serum PSA was lower in patients on preoperative statins (5.0 ng/ml compared to 5.2 ng/ml). Median PSA was lower in men on statins with Gleason grades 7 or 8/9. Statin therapy was associated with a 4.7 percent decrease in PSA. Statin therapy was not, however, associated with an overall decreased risk of

biochemical recurrence at a mean follow-up of 26 months.

The authors write that the results suggest that “patients on statin medications may require a lower threshold for PSA screening.” However, “Further study is warranted to ensure that patients on statin medications are being appropriately screened for prostate cancer,” they conclude.

Source: Krane LS, Kaul SA, Stricker HJ, et al. 2010.

Men presenting for radical prostatectomy on preoperative statin therapy have reduced serum prostate specific antigen. *Journal of Urology* 183:118-125.

Hot Topic Highlights

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

Fesoterodine Effective for Overactive Bladder

The overactive bladder medication fesoterodine (trade name Toviaz) is more effective than tolterodine extended release (ER, trade name Detrol LA), according to a study published recently in *BJU International*. Both of these common drugs were well tolerated by patients. The authors found fesoterodine to be significantly better at reducing episodes of urinary urgency and increasing bladder capacity than tolterodine ER. Fesoterodine was also more effective at keeping patients dry and at reducing bothersome symptoms and social impact during the 12 weeks of treatment.

Source:

Herschorn S, Swift S, Guan Z, et al. 2009. Comparison of fesoterodine and tolterodine extended release for the treatment of overactive bladder: a head-to-head placebo-controlled trial. *BJU International* 105:58-66.

Brachytherapy Effective Treatment for Early Prostate Cancer

Brachytherapy achieves high cure rates in men with low- and medium-risk prostate cancer, according to a study published recently in the *International Journal of Radiation Oncology*Biography*Physics*. Brachytherapy (BT) was more effective than external beam radiation therapy (EBRT). The authors found that, although both treatments were quite effective, cancer in the BT-treated men was better controlled than cancer in the EBRT-treated men (95 versus 85 percent). The failure rate beyond 5 years was also significantly less in the BT group. BT was associated with greater toxicity than EBRT, however. More specifically, BT men had more urinary problems after treatment, especially in the period immediately afterward, than did those receiving EBRT.

Source:

Pickles T, Keyes M, Morris WJ. 2009. Brachytherapy or conformal external radiotherapy for prostate cancer: a single-institution matched-pair analysis. *International Journal of Radiation Oncology*Biography*Physics* 76(1):43-49.