EHR-based Clinical Trial Alert Effects on Recruitment to a Neurology Trial across Institutions: *Interim Analysis of a Randomized Controlled Study*

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**Abstract:** EHR-based, point-of-care, clinical trial alerts (CTAs) have shown promise in prior studies to improve subject recruitment rates, but those studies have had limitations of generalizability. We report here an interim analysis of a cluster randomized controlled trial of the CTA approach applied to a neurology study at a second institution to test the efficacy of the approach across institutions with a different EHR. During the first phase (4 months) of our study, the CTA significantly improved physician-generated referrals among intervention physicians vs. control physicians (35 vs. 0). Additional trends and information about the usage of CTA features have also been gleaned. These findings add to the limited evidence for the utility and generalizability of the CTA approach.

**Introduction:** Clinical trial success depends on the recruitment of an appropriate number of subjects in a timely manner, but difficulties achieving such goals are common. Despite their value, physicians tend not to contribute to recruitment efforts, and the majority of eligible patients are never offered the opportunity to participate in trials. To address this problem, the authors developed and previously tested an EHR-based Clinical Trial Alert (CTA) approach. (1) This approach has been associated with improved referral rates in a few prior studies, including one that applied to the same clinical trial used here but performed at the University of Cincinnati with another EHR (GE Centricity). With this current study we sought to explore CTA efficacy at a second institution using a different EHR system to assess test generalizability across systems.

**Methods:** We performed an IRB-approved, cluster-randomized controlled study of our CTA intervention across three physician specialties that share a common, commercial ambulatory EHR (Epic EMR). University-based physicians (n=231) were randomized by specialty (neurology, n=46; family medicine, n=81; and general internal medicine, n=104) into intervention (n=115) and control (n=116) groups. Prior to CTA activation, all physicians were encouraged via traditional means to recruit patients to the trial. Upon CTA activation, intervention physicians seeing eligible patients were presented with on-screen CTAs. We compared and tested differences in the number of physician-generated subject referrals (primary outcome) and enrollments (secondary outcome) between groups over a 4-month period (phase 1 of our cross-over study). CTA usage data were also analyzed. Phase 2, involving cross-over of physicians as well as stakeholder interviews is ongoing.

**Results:** Compared with the controls, intervention-group physicians referred significantly more subjects to the study coordinator during this study phase (35 vs 0 referrals, p<0.0001). Prior to activation of the CTAs, the only physician referrals for this study came from the trial’s PI, who was randomized into the intervention group for phase 1. At the time of this writing, two patients from intervention-group and none from the control group were enrolled. It is notable that enrollments to this study require additional studies and can lag referrals, hence we expect enrollments to increase by the time of presentation. Additional data including the increased number of physicians participating in recruitment from each setting, and their usage patterns for the CTA will also be presented.

**Discussion:** This study is the first to demonstrate with the same clinical trial that EHR-based CTAs can significantly increase physician-generated referral rates to a clinical trial across institutions and EHR systems. Given increasing adoption rates of EHRs capable of supporting it, the CTA approach may represent a much-needed solution to the major problem of inadequate recruitment rates facing clinical trials. Further study is ongoing and required to compare effects across types of trials as well as to optimize alert design and widespread deployment.

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**References**