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Improving clinical trial accrual by streamlining the referral process

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ABSTRACT

Objective: Poor accrual rates impede clinical trial efficiency and significantly contribute to development costs for new interventions. Many providers recognize investigational treatments are their patients' best opportunities for improvement, but operational clinical burdens impede providers' awareness of, and ability to leverage, such opportunities. We aimed to develop a new workflow for non-intrusively apprising providers of trial opportunities for their patients and enabling providers to efficiently refer potential trial candidates to study teams for preliminary eligibility review.

Materials and methods: We developed a small information system to monitor institutional systems, identify patients potentially eligible for ongoing clinical trials, and give providers a non-intrusive, one-click method to refer such patients to study teams for preliminary eligibility vetting.

Results: In 18 months of pilot experience, providers invited study teams to vet 11% of 1844 patients found potentially eligible for 38 trials registered with the system. Seventy-nine patients were conservatively estimated to be accrued. Accrual rates were boosted for several trials. Results of a survey indicated most users were satisfied with the system.

Discussion: Providers' time constraints impede their pursuit of investigational opportunities for their patients. In pilot experience, our novel approach to facilitating such pursuits yielded improved accrual, benefiting trials and presumably patients, too. Our approach may bear particular fruit for cross-disciplinary referrals for screening.

Conclusion: Systems for assisting providers in making investigational opportunities available to their patients may benefit from careful attention to provider workflow and time constraints. Our system might further benefit from improved patient/trial matching and shorter messages.

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1. Introduction

Poor accrual rates impede clinical trial efficiency [1] and significantly increase research costs. Development costs of new pharmaceuticals have been estimated over the last decade to average $1B [2–6], and re-estimated recently at $4–12B [7,8], roughly half attributable to clinical development [4].

Most studies of accrual have focused in oncology. Despite public willingness to participate (32% of American adults), or at least consider enrolling (38%), in cancer clinical trials [9], only about 3% of newly diagnosed adult cancer patients enroll [1,10,11] (10–20% at academic institutions [12–14]). This rate has not improved despite increased resources such as mass media campaigns [12] and third-party payer funding of trial participation [12,15,16]. Accrual rates to non-oncology trials may not be much higher [17].

Many factors contribute to poor accrual, but providers missing opportunities for their patients is key [15,18,19]. Studies report 18–50% of newly diagnosed adult cancer patients at both community and academic cancer centers were not considered by their oncologists for clinical trials [10,16,20]. Many providers recognize investigational treatments offer their patients the best opportunities for improvement, but operational clinical burdens impede providers' awareness of, and ability to leverage, such opportunities [15,19,21,22]. In one study more than half (53%) of the patients approached to enter a cancer treatment trial reported the provider or coordinator spent 16–30 min presenting the trial [23]. In times of increasing pressure for clinical productivity [24,25], such allocation of time for research is challenging and sometimes outright infeasible. Another reported accrual challenge is the referring physician's fear of loss of involvement with the patient.

Furthermore, as the population ages and medical science advances, patient acuity and complexity inevitably increase [26–28], but providers' awareness of trials, especially in disciplines other than their own, is decreasingly likely. Poor cross-disciplinary trial awareness particularly impedes trials requiring accrual soon after diagnosis.

Automated systems for alerting providers to trial opportunities for their patients have been developed [29,30]. Barriers to wider use included custom programming effort not scalable to multiple trials [29] and perceived excessive alert intrusiveness [31].

We developed a new workflow to address these problems, supported by a small custom-developed information system interfaced with existing institutional systems, and easily scalable to the full range of an institution's trials. Our goal was to non-intrusively apprise providers of trial opportunities for their patients and to enable providers, at their discretion, to access trial information and refer candidates to study teams for preliminary eligibility review. We report 18-month pilot phase experience.

2. Materials and methods

Deriving from a central premise that providers' time (especially their in-clinic time) is sacrosanct, we conceived a new workflow, modified from Embi et al. [30], to address the above-noted goals. The system we developed – Medical University System for Accelerating Clinical Trials (MUSACT) – is illustrated in Fig. 1. A web-based application, with access secured by institutional credentials, allows study teams at the Medical University of South Carolina (MUSC) to register their studies with MUSACT. Information entered for each trial includes title, study team members, diagnoses of interest (by ICD-9 code, as presently used by the billing system), and, optionally, a link to a web-based resource providing information about the trial. Each morning, a query runs on MUSC's enterprise data warehouse to review providers' bills submitted in the last day and build a table identifying patients newly assigned any of the registered diagnoses of interest. Shortly, another application e-mails these patients' providers, informing them of the relevant trial opportunities (Fig. 2). If a provider has more than one patient in a given day's run who may be eligible for registered trials, all such patients are listed so that the provider never receives more than one e-mail per day from MUSACT. Each trial listed in the e-mail is hyperlinked to descriptive trial information if such a link was provided when the study was registered with MUSACT. "Inquire" links are provided in the e-mail for the provider to invite eligibility vetting across all listed patients and studies or just specific patients, or even just a specific study for a specific patient.

MUSACT's e-mails to providers also explain the system's workflow, describing how clicking "Inquire" causes MUSACT to send e-mails to the study team (Fig. 3), inviting their review of the patient's chart to preliminary vet eligibility. Providers are assured that study teams are cautioned in these invitations to not contact the patients and instead contact the providers to

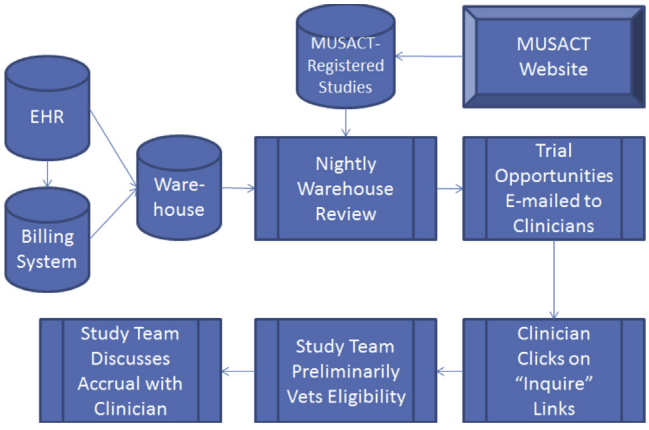

Fig. 1 – MUSACT Workflow. Study teams use the MUSACT website to register their studies, listing diagnoses of interest. Enterprise data warehouse receives nightly updates of clinical and billing data. Warehouse is then reviewed nightly to identify patients newly assigned diagnoses of interest to MUSACT-registered studies. Clinicians who assigned new diagnoses are notified by e-mail of trial opportunities and can click on "Inquire" links to invite study teams to access charts and preliminarily vet eligibility. Study team contacts clinician to discuss how a potentially eligible patient will be approached. MUSACT cannot be used by study teams to "trawl" through the EHR looking for trial candidates.