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Opinion

Pre-Screening Cancer Patients for Clinical Trial Eligibility: Research or Implement?

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Abstract

A low level of patient accrual to clinical trials in oncology is well documented [1], but the complexity of patient recruitment precludes an obvious simple singular solution to drive dramatic improvements. The steps in the recruitment process are numerous, and detailed outcomes of each aspect have been poorly reported historically [2,3]. But a higher proportion of cancer patients could be recruited to clinical trials if; more trials were available; inclusion criteria were broadened; more restrictive exclusion criteria were minimized; all eligible patients were identified and informed of their clinical trial options; and when a patient's decision is solicited, the ratio of affirmative responses is maximized [4,5]. While many strategies to improve accrual seem worthy to pursue, few broadly applicable interventions have been successfully evaluated prospectively.

Keywords: Screening; Patient Eligibility; Trial Recruitment; Clinical Trials

Introduction

In the past, like many sites, we have reviewed the patient and physician factors thought to influence clinical trials recruitment, and while individual physicians were not significant factors in predicting whether an individual patient consented to enter a clinical trial, there were large differences in the rates of identifying eligible patients [6]. This suggested that some physicians were more thorough in their identification of eligibility, which increased the likelihood of approaching a patient to consider the clinical trial option. This observation supported a screening intervention to identify patients for clinical trial eligibility that would assist physicians with clinical trial accrual. Since that time, there have been many reports of both strategies to screen patients for specific trials, and to identify a list of trial options for patients. Ni et al, referred to these strategies respectively as trial centered patient cohort identification vs. patient centered trial recommendations [7]. Many search tools are available for motivated patients, and in the province of Ontario, Canada this includes the websites of many local hospitals, Clinical Trials Ontario, The Canadian Cancer Society, the Canadian Cancer Trials Group, and Health Canada. But all these sites require various levels of health data and disease status input from the patient, and none have direct links to any of their own personal level health data.

Alternatively, limited evaluations of automated processes have been reported for over twenty years [8,9], and newer approaches using Artificial Intelligence (AI) and tools evaluating the matching of traditional approaches vs automated approaches show great promise. Not only do they appear to have excellent levels of agreement, but automated approaches are also substantially faster [10]. A recent scoping review by Cascini et al., highlights the availability of AI based applications in clinical trials and suggests studies are needed to both further validate the tools, and to facilitate their adoption [11]. But as Electronic Health Records evolve, and functionality improves is there really a need to think of screening as either trial based, or patient based? We need both. Specifically, we require a systems approach that pulls relevant details from the individual medical record to concurrently inform

both patients and providers of the relevant clinical trials options. While real world evaluations of this technology would be welcome, it is clear that given the dearth of such research to this point that this type of research is difficult. The downside to limited evaluation is clearly the consumption of resources without measurable benefit, a problem shared with technology in general. But already many organizations have committed to providing a less tailored approach, and increased awareness seems a good investment regardless of the outcome. We don't need another twenty years to complete robust evaluations, we just need to implement what we already know we can do. Accrual to clinical trials needs to improve.

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