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Commentary: Improving Participant Recruitment in Clinical and Translational Research

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Abstract

In this issue of *Academic Medicine,* Kitterman and colleagues report the results of an evaluation of the prevalence and cost of low-enrolling studies (zero or one participant enrolled) conducted at Oregon Health & Science University (OHSU). They found that one third of all studies terminated between 2005 and 2009 at OHSU had low enrollment and that these low-enrolling studies cost the institution almost $1 million annually. The recruitment of research participants is critical to conducting clinical and translational research. Failure to recruit research participants has a negative financial impact, but, more importantly, under-enrolled studies do not contribute to scientific or clinical knowledge. In this commentary, the authors describe four areas in which academic medical centers (AMCs) could invest more effort and resources to improve the recruitment of research participants. First, more planning and resources should be put into determining the feasibility of participant recruitment. Second, studies that are under-enrolling should be terminated early to prevent unethical research, to save financial and other resources, and to allow these resources to be applied to successful research. Third, AMCs should professionalize, centralize, and automate participant recruitment. Fourth, AMCs should take a leadership role in partnering with the public to improve participation in clinical research. Participant recruitment must be improved if clinical and translational research is to meet its promise of improving health.

Keywords

participant recruitment; clinical research; academic medical center

The recruitment of research participants is critical to conducting clinical and translational research. If we cannot recruit adequately, we simply cannot carry out successful clinical research. In this issue of *Academic Medicine,* Kitterman and colleagues[1] report the results of

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an evaluation of the prevalence and cost of low-enrolling studies (zero or one participant enrolled) at Oregon Health & Science University (OHSU). They found that one third of all studies terminated between 2005 and 2009 at OHSU had low enrollment and that these low-enrolling studies cost the institution almost $1 million annually, using a conservative estimate. Failure to recruit research participants has a negative financial impact, but, more importantly, under-enrolled studies are underpowered and often do not contribute to scientific or clinical knowledge. Such studies are unethical—at a minimum, they waste participant time and effort, and many put participants at risk without producing scientific or clinical benefit.

The problem of low enrollment is clearly not unique to OHSU. With some variation, similar dismal recruitment rates apply to all academic medical centers (AMCs). Using the same strict definition of low enrollment as Kitterman and colleagues,[1] Pierre reported in 2006 that 50% of independent inpatient and outpatient sites enrolled one or no patients into the studies initiated at these facilities.[2] This supports the theory that the challenge of recruiting into clinical studies is neither new nor exclusive to AMCs. According to CenterWatch, more than 81% of clinical trials are delayed due to participant recruitment that is inadequate to achieve statistically valid results.[3] Despite this serious and widespread problem, little attention has been given to developing innovative methods or implementing best practices for achieving successful participant recruitment.

Improving the Recruitment of Research Participants

We believe that there are at least four areas in which AMCs could invest more effort and resources to improve recruitment of research participants. First, while enormous effort is placed on developing clinical research protocols that are likely to have scientific and community health impact, very little planning and few resources are put into determining the feasibility of participant recruitment. Feasibility of recruitment depends on access to an adequate number of persons who fit the study inclusion criteria, as well as on the willingness of these persons to enroll in the study. This willingness often depends on the attractiveness of the research question, the burden of study visits and measures, the invasiveness of study procedures, and the potential risks and benefits associated with the intervention. Much greater attention should be given to designing study protocols that maximize the ability to recruit participants, especially since nearly one third of the entire cost of a study is invested in the recruitment phase.[4] The feasibility of recruitment should also be a major criterion assessed during peer review.

Second, as suggested by Kitterman and colleagues,[1] studies that are under-enrolling should be terminated early to prevent unethical research, to save financial and other resources, and to allow these resources to be applied to successful research. Annual reports required by most institutional review boards (IRBs) collect data on enrollment, but, to our knowledge, under-enrollment generally does not result in IRB requests for new plans to address this issue, and marked under-enrollment does not result in the termination of a study. Since under-enrollment is one of the main reasons that clinical research studies do not provide good scientific data, and thus may be unethical, institutions and IRBs should pay more attention to this issue.

Third, AMCs need to professionalize, centralize, and automate the recruitment process. Most investigators still rely on study staff to recruit participants, staff who often have little experience in recruitment and no infrastructure to support their efforts. Professional, full-time, experienced participant recruiters should be available to help investigators optimize protocols for maximal recruitment, estimate resources needed for recruitment, develop recruitment plans and materials, and carry out these plans. Today, recruitment efforts across

academic units are uncoordinated and do not take advantage of efficiencies of scale. Centralized recruitment services can improve efficiency and avoid overlap but, more importantly, can lead the development of key recruitment infrastructure, such as websites, call centers, databases, and well-coordinated recruitment campaigns that can sustain participant recruitment efforts across the AMC. Automated recruitment services might include searching clinical and patient databases for eligible participants; maintaining a participant-friendly, web-based listing of studies actively enrolling at the AMC along with online prescreening tools; and developing a cadre of persons in the community interested in research who can be contacted using popular communications methods such as text messaging and social media.

Fourth, AMCs need to take a leadership role in partnering with the public to increase participation in clinical research. AMCs should play a major role in improving public education about the clinical study design, safeguards, potential scientific and clinical impact, and the critical role of research participants. Finally, AMCs should work much more closely with patient advocacy groups to design and implement clinical research of importance to these groups.

Going Forward

How should we pay for professional, centralized, and automated participant recruitment services? We believe that this cost should be shared by the AMC and the study sponsor. As demonstrated by Kitterman and colleagues,[1] reducing the number of studies that under-enroll or are low enrollers can save an AMC a significant amount of wasted funds, suggesting that institutions should bear some of the cost of developing recruitment services. On the other hand, efficient, cost-effective and successful recruitment is very valuable to all types of sponsors. A professional, centralized, and automated recruitment service should be supported by appropriately charging the study sponsor and will likely cost no more than current recruitment efforts.

Participant recruitment must be improved if clinical and translational research is to meet its promise of improving health. In this commentary, we offer several suggestions for attaining this goal, and we encourage others to join the conversation.

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