

Examining and Enabling the Role of Health Care Providers as Patient Engagement Facilitators in Clinical Trials

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ABSTRACT

Purpose: The Tufts Center for the Study of Drug Development conducted a study among practicing physicians and nurses (health care providers) across multiple specialties to assess their attitudes and experiences with referring patients into clinical trials and to supplement the body of scholarly research focused primarily on referral practices among oncology-based health care providers.

Methods: A total of 755 physicians and 1255 nurses completed online surveys in late 2015 and early 2016.

Findings: The results of the study indicate that a high percentage of multispecialty nurses and physicians is interested in referring their patients to appropriate clinical trials, are familiar with the clinical trial process, and are comfortable providing clinical trial information to, and discussing clinical trial opportunities with, their patients. Study results also indicate, however, that health care providers refer only a small number of patients each year largely because of the inability to access clinical trial information and the lack of sufficient information and time to evaluate and confidently discuss clinical trial options with their patients.

Implications: Many reasons for choosing not to refer patients appear addressable, particularly through effective but presently underused communication leveraging social media communities and using liaisons who can act as a bridge between clinical care and clinical research. (*Clin Ther.* 2017;■:■■■-■■■) © 2017 Elsevier HS Journals, Inc. All rights reserved.

Key words: clinical trial referral practices, clinical trial referral rates, health care providers, patient engagement, social media and clinical trials.

clear indication that the clinical research enterprise is failing to attract a reasonable level of patient participation.¹⁻³ The statistic has also mobilized the cancer research community—and the broader clinical research enterprise—to understand more deeply and to address more effectively the barriers to participation.

Studies in the literature characterize a wide range of factors that hinder patient participation. To name a few, limited public and patient awareness and literacy have contributed to low response rates to recruitment efforts.⁴ Mixed patient attitudes and perceptions about clinical research have played a role in diminishing motivation to consider and participate in clinical trials.⁵ Complex clinical trial designs with stringent and high numbers of inclusion and exclusion criteria limit the number of eligible volunteers.⁶ Inconsistent and poorly executed study recruitment strategies, planning, and tactics, particularly when competing with other actively enrolling clinical trials, undermine the effectiveness of outreach and engagement initiatives.⁷

Another often cited barrier to participation has been low health care provider (practicing physician and nurse) familiarity with and access to clinical trials combined with limited interest in referring patients.² An increasing body of research, including the results of a new study conducted by the Tufts Center for the Study of Drug Development (CSDD), suggests that this barrier is more nuanced and has been mischaracterized.

Health care providers play an essential role advising, guiding, and influencing patient participation in clinical research. Studies have consistently found during the past 2 decades that physicians and nurses are

INTRODUCTION

Since the early 1990s, the ubiquitous and frequently cited statistic that only 3% to 5% of eligible patients participate in oncology clinical trials has served as a

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among the most trusted sources for health and medical information, including clinical trials.^{5,8,9} More than 8 of 10 patients (84%) state that they would consider participating in clinical trials if their physician recommended that they do so. A high percentage (71%) of global study volunteers confirms that they spoke with their physician before making the decision to participate in a clinical trial.¹⁰

Patients who receive information about clinical trials from their health care provider are significantly more likely to participate.¹¹ In addition, patients who engage in frequent quality interactions with and who receive an offer to enroll in a clinical trial from their health care providers are also significantly more willing to participate.¹² Albrecht et al,¹² for example, found that physician body language and understandable messages that convey support, reassurance, and alliance engender confidence among patients and increase their willingness to enroll in clinical trials.

An increasing body of literature, primarily focusing on physicians caring for oncology patients, indicates that general awareness about clinical research is high among health care providers as is their self-reported familiarity with the clinical research process and their high willingness and confidence to refer their patients.^{13,14}

With respect to referral practices and behaviors, Klabunde et al¹³ reported that 57% of specialty oncology physicians (eg, medical and radiation oncologist) referred at least one patient in cancer clinical trials within the previous year. Medical oncologists refer or enroll a mean of 17.9 patients annually; surgical and radiation oncologists refer or enroll a mean of 12.2 and 9.5 patients each year, respectively.¹³ Kaplan et al¹⁵ found that 71% of oncologists refer or recruit their patients to clinical trials administered by themselves or by others.

Many scholarly studies have assessed the barriers that prevent oncologists from referring and enrolling their patients. The strongest barriers include the lack of time to gather and evaluate clinical trial information and inadequate time to discuss clinical trial information with patients,¹⁶ lack of sufficient information about clinical trials,¹⁵ and overly stringent eligibility criteria and perceived participation burden for their patients.¹⁵ The weakest barrier among oncologists is the fear of losing their patient to the principal investigator or another specialist.¹⁵

Several factors increase the likelihood of oncologists referring their patients to clinical trials. Distance between clinical practice and the research center is inversely associated with patient referral rates, and physicians more involved in patient care are less likely to refer their patients.¹⁵

Although oncologist referral attitudes and practices have been studied extensively, few studies to our knowledge have looked at those of nurse practitioners. One study, conducted by Ulrich et al,¹⁷ found that nurse practitioners have positive perceptions of clinical research but substantially lower levels of confidence referring their patients into clinical trials. Most nurse practitioners (97%) said that they believe conducting clinical research is an important role for health care providers specializing in oncology, and 74% agreed that clinical research improves patient care.¹⁷

Only 30% of nurse practitioners caring for patients with cancer would recommend a clinical trial when conventional interventions had failed. This rate is half that observed among physician oncologists. More than half (53%) of nurse practitioners felt uncomfortable discussing clinical trials with their patients with cancer, and 87% of nurse practitioners reported that they leave the decision for clinical trial enrollment up to the oncologist.¹⁷ Among nurse practitioners, the reported barriers to referring patients with cancer to clinical trial are similar to those reported by physician oncologists.

Although insight into health care provider referral perceptions and practices, most notably those among physicians, has increased with the number of scholarly assessments published, to our knowledge there has been virtually no scholarly assessment across multiple therapeutic areas.¹⁸ As such, it is difficult to generalize the published findings despite the more than two-thirds of all investigational treatments that target diseases outside cancer-related illnesses. To address this opportunity, in late 2015, the Tufts CSDD conducted a study among physicians and nurses actively caring for patients across multiple disease conditions.

In addition, this new study is timely given increasing interest among clinical research professionals in optimizing patient engagement in clinical trials and the anticipated movement of clinical research into clinical care settings. This latter trend is unfolding in response to increasing demand for more targeted

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