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Personal physicians as study investigators: Impact on patients' willingness to participate in clinical trials

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ABSTRACT

Background: We asked whether patients are more willing to participate (WTP) in a cardiovascular drug trial if their personal rather than an unfamiliar physician were engaged as the study investigator.

Methods: We approached 1440 randomly selected patients from 13 Maryland-based outpatient cardiology and general medicine clinics to complete an 86-item self-administered questionnaire. We then asked respondents their WTP if their personal rather than an unfamiliar physician were the study investigator, as well as their trust in physicians and quality of their health care experiences.

Results: Of 1132 patients eligible, 789 (70%) patients responded and 666 had complete data. Patients were "very likely/likely" to participate in the study 56% of the time if conducted by their personal compared to only 36% if by an unfamiliar physician ($p<0.0001$). After adjusting for age, race, gender, and socioeconomic and health status, only the presence of a family member or friend in health care was positively associated with "very likely/likely" WTP with unfamiliar physician (OR, 95% CI = 1.42, 0.99–2.03). If by a personal physician, however, trust in physician (1.57, 1.16–2.11, per 1/5 unit increase), rating of health care quality (1.18, 1.06–1.31 per 1/10 unit increase), and having a family member or friend in health care (1.57, 1.16–2.11) were important predictors of WTP.

Conclusion: Patients are much more likely to enroll in a clinical trial if their personal physician is engaged as a study investigator, which could relate to the importance of communication, trust, and familiarity with the health care system.

1. Introduction

Clinical trials are the major impetus for health care improvement in the practice of evidence-based medicine. Increased enrollment in clinical trials not only advances the best practices in medicine, but it also affords patients the opportunity to access the latest treatments and to participate in health care innovation. Limited enrollment in clinical trials dilutes, or worse, obscures significant findings, wastes scarce economic resources and time, and unnecessarily exposes those patients who do participate to the potential harm of experimental treatments without opportunity to arrive at any conclusions about treatment efficacy.

Attempts to enhance recruitment into clinical trials have employed a number of strategies including, but not limited to, the use of full time clinical research associates [1], culturally targeted mass mailings and media presentations, [2], and occupational screenings and patient registries [3]. Another strategy to possibly enhance recruitment is through greater use of personal physicians as study investigators. Fisher et al. [4] demonstrated that the number of patients recruited per month into cancer clinical trials could be doubled through the use of community oncologists [5] and showed that among 360 high-risk women considering enrollment in the Breast Cancer Prevention Trial, patients were 13 times more likely to

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enroll when their personal physician encouraged joining versus discouraged joining. While informative, these studies were limited by their smaller sample sizes, focus on cancer clinical trials at the exclusion of other fields of clinical investigation and failure to elucidate those factors that may explain why personal physician engagement in clinical trials enhances participation.

Trust may be one of the major mechanisms through which patients are more likely to participate in a clinical trial with personal physician engagement, and several prior studies have demonstrated trust toward "researchers" and the "medical community" to be important determinants of enrollment, particularly among populations traditionally underrepresented in clinical trials [6].

We performed a study to investigate whether patients are more likely to participate in a cardiovascular drug prevention trial if their personal physician rather than an unfamiliar physician is acting as the study investigator and what related factors, such as the strength and quality of the patient–physician relationship, are most influential to a preference for participating in a clinical trial with a personal physician rather than unfamiliar physician as study investigator.

2. Methods

2.1. Study design

We performed a cross-sectional study on a randomly selected sample of adults (≥18 years old) presenting to 13 academic and community-based internal medicine and cardiology clinics in Maryland between May and October 2002. Participation required completion of an 86-item self-administered questionnaire either in clinic or at home. Based on clinical volume, trained recruiters solicited individuals in either consecutive or random (using a computerized random numbering scheme) fashion. To be eligible, individuals had to have a scheduled clinic visit with a physician or nurse practitioner, be English-speaking or have an English interpreter available for survey translation, and have the cognitive capacity for survey comprehension. To assess potential non-responder bias, we gathered from individuals declining participation their age, race, gender, site of care, and "reason for refusal". The institutional research review boards at the Johns Hopkins Hospital and associated with each site approved the study protocol and permitted use of a standardized oral consent procedure.

2.2. Questionnaire development and content

Recruiters informed participants that the study's general purpose was to understand individuals' attitudes about medical research and physicians who perform research, and to understand factors important to patients when considering joining clinical trials. Participants were blinded to all study hypotheses. Participants began the survey by reading a 1-page description of a hypothetical double-blinded, placebo-controlled cardiovascular drug prevention trial. The description read at a Flesh-Kincaid Grade Level of 7.2 (Microsoft Word 2000, Redmond, Washington) and was akin to a typical consent document used in cardiac clinical trials. Elements disclosed were: the experimental nature of the study; study objectives; adverse drug event risk and type; potential benefits to joining; voluntary nature of the study; study requirements with regard to length and type of follow-up; alternative treatment options; right to withdrawal; the study sponsor; the presence of potential investigator financial conflicts of interest; and rewards for joining, which included free trial-related health care and monetary compensation. Patients were asked "How likely are [they] to join the study?", and from the responses to this question, willingness to participate (WTP) in the trial was scored on a 5-point scale (very likely, likely, moderately, unlikely, very unlikely).

The remainder of the questionnaire constructs measured attitudes toward specific elements of the described clinical trial, medical researchers and the health system. We also collected data on self-reported conditions, health status, prior trial and health care experience, and socio-demographic indicators.

An expert panel of cardiovascular clinical trialists carefully reviewed the hypothetical CVD drug prevention trial to assure it closely simulated reality, and a panel of expert survey methodologists face- and content-validated all other measures used in the instrument. We pilot tested the survey instrument at one recruitment site in approximately 20 individuals. Since the survey did not undergo subsequent material revision, however, we retained these individuals in the analysis.

2.3. Outcome variables

The primary outcome for this analysis was WTP, as measured by a 5-point Likert response scale (very likely/likely/moderately/unlikely/very unlikely). We subsequently asked respondents how likely they would be to join the study if their personal physician were performing the study rather than a heart specialist not currently involved in their care, and again measured responses by a 5-point Likert WTP response scale.

2.4. Independent variables

The major independent variables for this analysis were respondents' experience with and their rating of health care quality, and trust in their personal physician, health plan, and hospitals. Experiences and ratings of health care were adapted from the Consumer Assessments of Health Plans Study 2.0 (CAHPS) (Agency for Health Research and Quality, Rockville, MD) [7]. We asked individuals the duration of their relationship with their personal physician (or nurse) (categorically defined as <1 year, 1–5 years, or more than 5 years), how often in the past year they visited the emergency room or were hospitalized (excluding childbirth) (did not visit the emergency room or get hospitalized in the past year, 1–3 times, 4 or more times, don't know) and their rating of all of their health care in the past year from all doctors and other health providers (measured on a 0 (worst)–10 (best) scale). Trust in personal physician, health plan, and hospital were measured based on four questions from the Trust in Physician Scale [8]. All four questions measure trust on a 5-point Likert response scale (not at all/a little/somewhat/mostly/completely). We also asked individuals to report whether they had any close friends or family members who work in the health care field