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Short Report

Predictors of patient's intentions to participate in pragmatic clinical trials: An initial exploration

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ABSTRACT

The Veterans Health Administration is implementing a pragmatic trial research program, called Point of Care Research (POC-R). The purpose of this telephone survey in which respondents were randomized to different framing conditions of the purpose of POC-R was to determine the impact of differing frames of the purpose of POC-R on attitudes towards the program and intentions to participate; and the relative importance of different beliefs and attitudes in discriminating low vs. high intenders to participate in POC-R. The survey addressed veterans' perceptions and attitudes towards POC-R, and their willingness to participate in a pragmatic trial. Overall, respondents felt positively towards POC-R and intended to participate. Differing frames of the purpose of POC-R were not associated with either attitudes (towards the program) or intentions to participate. However, specific beliefs and attitudes toward POC-R program were predictive of intentions to participate.

Introduction

The Institute of Medicine (IOM) defines a Learning Health System as "one in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and health care." (IOM, 2012). Pragmatic randomized clinical trials have been proposed as one mechanism to support a Learning Health System and improve the evidence base of clinical practice.

Pragmatic clinical trials are research studies that are conducted during the process of care under situations of clinical equipoise (in which the evidence regarding the risk/benefits of competing treatments is approximately equal) (Elwyn, Edwards, Kinnersley, & Grol, 2000; Little et al., 2001) The goal of pragmatic trials is to ameliorate limitations to the generalizability of research findings by using: (1) typical clinical settings, (2) clinical populations that are representative of the targeted population (as opposed to the highly selected populations commonly enrolled in clinical trials), and (3) clinicians who practice in the situations where the intervention would be implemented (Chalkidou, Tunis, Whicher, Fowler, & Zwarenstein, 2012; Thorpe et al., 2009; Zwarenstein et al., 2008).

The Veterans Healthcare Administration (VA) is considering a new research program, called Point of Care Research (POC-R), which is based on the concept of pragmatic trials. The POC-R program would support research conducted during the process of care; randomization would be a part of regular clinical care decisions. To the degree that the treatment arms of a study are judged to have equipoise, specific POC-R trials may not require consent or additional oversight.

A pragmatic trial program highlights the tension between two perspectives of clinical research. In the traditional view, all clinical research puts patients at risk and therefore they must be protected through informed consent. In the pragmatic triallist's view, the fact that both treatment arms represent accepted practice suggests that no differential harm is expected. In this latter view, it is thought to be both practical and ethical to allow lower levels of oversight and monitoring and to allow modification to the usual informed consent process (Vickers, & Scardino, 2009). This difference reflects the purpose of these different forms of research: traditional research is intended to develop new knowledge, while pragmatic trials are intended to compare efficacious interventions to identify the one that is most efficient and effective across a range of outcomes.

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The frame that is used to explain the purpose of pragmatic trials to potential participants may be an important predictor of individuals' willingness to participate, however this question has not yet been addressed. In this study, the question we sought to address is not whether one particular explanation of the purpose of point of care research would be better or worse than others but the more general question of whether framing effects would impact people's attitudes and intentions towards POC research. In summary of the goals of this study were to determine: (1) whether differing frames regarding the purpose of POC-R were associated with attitudes towards the program and intentions to participate; and (2) the relative importance of different beliefs and attitudes in discriminating low vs. high intenders to participate in POC-R. Finally, since consent models are an important implementation issue in POC-R, our third exploratory aim was to assess the relationship between individual's beliefs about POC-R and their willingness to engage in yearly consent for the program.

Prior work

As part of an internal evaluation of the POC-R program, a series of focus groups were conducted across 7 VA medical centers with 48 patients (Weir, Butler, Barrus, & Lewis, 2013). Qualitative analysis of the transcripts from these focus groups found 6 different thematic areas: (1) concern over the *potential burden* of participating, (2) concern over the impact of the program on the *provider–patient relationship*, (3) the *value* of the research to the VA; (4) belief that it would *improve care*, (5) belief that, as veterans, they had a *personal responsibility or duty* to participate in research that might help other veterans, and (6) concern regarding differing models of *consent*. These themes were used for item construction in the development the survey.

In these focus groups, we found that nearly all patients had difficulty understanding the purpose of POC-R. We explored different explanations and purposes with the focus group participants in order to maximize their understanding of the program. Explanations that emphasized how POC-R might improve the quality of care, reduce costs and improve efficiency, and/or lead to improved scientific knowledge were all tried with these groups. However, we were not sure how these different explanations might impact attitudes and intentions to participate. Given that prior research has demonstrated that small differences in how programs or interventions are described may lead to significant impacts on perceptions of value, and on behavioral choice (Kühberger, 1998), we felt it was necessary to directly test these differing explanations of the purpose behind POC-R on attitudes or intentions to participate.

Methods

Design

The study was a randomized experiment embedded in a telephone survey. Participants were randomized to one of three frames describing the purpose of POC-R:

1) Improving clinical quality ("The goal of POC-R studies is to improve the quality of care by determining which options for care are safe, appropriate and meet performance standards");
2) Reduce costs ("The goal of POC-R studies is to improve the efficiency of healthcare delivery by determining which options for care are the least costly and the most efficient. In POC-R studies, the treatment options being compared are both effective, but vary in terms of the ease and feasibility of implementation");
3) Improve science ("The goal of POC-R studies is to enhance scientific knowledge by comparing treatments using large numbers of patients across diverse geographical areas and in a variety of natural care settings").

Construction of the survey

The survey items were based on the themes identified in the focus groups and were constructed using an adapted Likert format, scored on a 1–7 scale. Survey items were created to assess individuals' general attitude toward POC-R as well as to reflect the specific attitudes expressed in the focus groups. Finally, items to capture intentions to participate were created. Piloting of sample items was conducted with 5 veterans. The telephone survey used in this study is listed in Appendix 1.

Participants/setting

The study was conducted at *HOSPITAL*, this center includes a 113-bed hospital and 5 Community based outpatient clinics. The study was given IRB approval by both the University and VA Boards.

A sample of 496 English-speaking veterans without dementia who had been seen in a primary care clinic in the previous 3 years were selected at random from the VA's clinical data warehouse and contacted by phone. Of this initial sample 333 did not respond to phone messages left asking them to call back regarding a survey, and 13 refused participation. 150 individuals agreed to participate and 141 provided complete answers to all survey questions.

Creation of outcome scales

We created and tested two scales from the raw survey data to measure our two outcomes of interest: Attitudes towards POC-R and Intentions to participate in POC-R. Finally, since consent models are an important aspect of pragmatic trials, we created a Consent scale to reflect participants' willingness to engage in blanket consent.

The Attitude scale combined individual's responses to 3 questions: (1) "Should POC-R be implemented in the VA" (question 7); (2) "You think POC-R is – not important/very important" (question 9) and (3) "You believe that the POC-R research program will improve the quality of care in the VA" – not at all/a great deal (question 10).

The Intention scale combined individual's responses to 3 questions. The first question asked the likelihood they would agree to participate (question 4). The second question asked for the probability they would participate (question 8); this response was originally scored as 0–100% and was normalized to 0–7 prior to calculation of this scale. The third question asked for their willingness to participate in POC-R (question 11).

The Consent scale was the mean of the individuals response to two questions: "Based on what you know today, would you be willing to give a blanket consent, (covers all studies) yearly to be part of any local ongoing POC-R studies?" – very unlikely/very likely (Question 12), and "If you could consent only once for all ongoing POC-R studies in your VA for a year, you would be?" – Not at all willing/willing, (question 18).

Analysis

Several analyses were conducted, using R statistical computing software for all analyses (The R Project for Statistical Computing, 2012). First, we tested the internal reliability (Cronbach's alpha) of the scales for *attitudes* toward the program, *intention* to participate