

Factors Influencing Participation in Clinical Research

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Factors Influencing Participation in Clinical Research

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Abstract

Clinical research trials may benefit from attracting a sample population that accurately reflects the total population. Over 600 paper surveys have been administered to patients across several practices in the Lehigh Valley Health Network (LVHN). The surveys provide feedback on patients' past experiences and personal views towards clinical trials. They also include demographic information to show trends in the data. Another set of surveys will also be sent to research professionals across the nation in federally funded institutions. These surveys will provide insight on researchers' tendencies and beliefs when enrolling patients in clinical trials. The study will be open until 2015, but the data that has come out of the patient survey so far is not showing any significant difference of opinions towards participation in clinical research between English and non-English speaking patients nor between college educated and non-college educated patients.

Factors Influencing Participation in Clinical Research

Clinical research trials are a crucial piece of the healthcare field. In order to ensure productive trials for new drugs and other programs, the pilot studies should enroll patients who demographically represent the population that will ultimately benefit from the product. Recent studies have shown that the rates in which minority groups and women participate in research are much lower than those of Caucasians and males, respectively. This partially stems from the Food and Drug Administration's 1977 decision to prohibit the participation of fertile and pregnant women in Phase I drug trials. However, this demographic is important in clinical trials; they may respond to drugs differently, and this information is best obtained in the pilot stages of a medication or apparatus. This study aims to discover the attitudes of patients towards participation in clinical research. This will allow researchers adjust their methods accordingly, and ultimately, this can help diversify research participants.

Literature Review

As mentioned, women and minorities have a low turnout in clinical research trials. Women represented less than 40% of participants in cancer research, according to a review¹ conducted by Jagsi, Motomura, Amarnath, Jankovic, Sheets, and Ubel. Non-Caucasian women participate in less research than Caucasian women and have reported in higher numbers that they feel that doctors do not care about them². Studies have also indicated that non-Caucasian men similarly participate in fewer research trials, as well.

Not only do more males tend to participate in clinical research as patients, but also men tend to conduct research more frequently. A survey³ conducted by Lloyd, Phillips, and Aber discovered that out of a class of 428 graduates from Penn State College of Medicine, only 41 females had conducted research. Another study⁴, conducted by Waisbre, Bowles, Hasan, Zou, Emans, Goldberg, and Christou, showed that only 26% of researchers submitting grant requests were women.

Methods

This study is a multi-faceted investigation into the views of both patients and researchers towards clinical research. The data is being collected in the form of two surveys: one for patients, and one for research professionals. The survey for research professionals has not yet begun, and it will not be discussed in depth.

Patient Surveys

Paper surveys have been administered to patients in ten different Lehigh Valley Health Network facilities, focusing on three major divisions: Family Medicine, Women's Health, and Emergency Medicine. The research team was split up between Women's Health and Family Medicine, and emergency room surveys are beginning to be collected now. This paper focuses on data from Women's Health clinics. The surveys were translated into English, Spanish, and Traditional and Simplified Chinese in order to ensure minimal exclusion of demographics. A copy of the English survey is attached in Appendix A. By the end of the study, at least 400 completed surveys will be collected from each of the three divisions mentioned above for a statistically strong sample size. Selection criteria for participants simply dictate that they must be a patient of the clinic, and they must be eighteen or older.

Validity and Reliability

Pilot versions of both surveys were sent to thirty employees of the Lehigh Valley Health Network (fifteen for each survey) before the study began in full. To test the validity of the survey, a questionnaire was attached to the pilot surveys, in which participants were asked to write what they thought the purpose of the survey was. This ensured that survey was in fact addressing what it is supposed to address. To test the reliability, the same pilot survey was sent to the same thirty people in two waves, the second time being two weeks after the first. Pilot participants would complete the survey a second time, and the given responses would be cross-checked with their responses the first time they completed the survey. This tested to make sure participants did not change their answers significantly, ensuring survey reliability.

Results

Although an extensive data analysis will be done upon completion of the study, only simple, small-scale analysis has been done on the data at this point. All data comes only from Women's Health clinics, which include the Maternal Fetal Medicine clinic (3900 Hamilton Boulevard, Suite 201, Allentown, PA 18103) and the Center for Women's Medicine (17th and Chew, PO Box 7017, Allentown, PA 18105). Responses in questions J-1 (Relationship with Doctor), J-2 (Doctor's Reputation in Community), K-1 (Distrust in Doctors), and K-2 (Time Commitment) have been compared between two demographic groups on two different axes: Language spoken at home (English vs. non-English) and Education (high school graduate or

less vs. college or more). The question codes (J-1, J-2, etc.) are displayed in Table 3 for easy reference.

On a Likert scale of 0 (least influence) to 4 (most influence), the mean rating for J-1 for the 392 English speakers surveyed was 3.22 with standard deviation 1.18. For the 322 non-English speakers, J-1 was 3.21 with standard dev. 1.26. Question J-2 received a score of 3.45 with standard dev. 1.06 for English speakers and 3.40 with standard dev. 1.14 for non-English speakers. Question K-1 received a score of 2.28 with standard dev. 1.59 for English speakers and 2.21 with standard dev. 1.58 for non-English speakers. Question K-2 received a 2.70 with standard dev. 1.26 for English speakers and 2.64 with standard dev. 1.25 for non-English speakers. This information can be viewed in Table 1 and Figure 1.

The same comparisons were made between those who reported having a high school diploma or GED, or less, as their highest degree of education, and those who reported having at least completed some college, or more. The results are as follows. J-1 scored 3.20 with standard deviation 1.24 for non-college participants and 3.21 with standard dev. 1.19 for college participants. J-2 scored 3.38 with standard dev. 1.13 for non-college participants and 3.44 with standard dev. 1.07 for college participants. K-1 scored 2.23 with standard dev. 1.59 for non-college participants and 2.28 with standard dev. 1.59 for college participants. K-2 scored 2.67 with standard dev. 1.30 for non-college participants and 2.71 with standard dev. 1.26 for college participants. These numbers are displayed in Table 2 and Figure 2.

No analysis has been done on the data from the research professionals' survey, as this survey has not yet been sent. The study will remain open through 2015.

Conclusions

For the four questions analyzed, results displayed no significant difference between either group on either of the two axes. In other words, responses between English and non-English speaking patients were not significantly different, nor were responses between college educated and non-college educated patients. This means that patients somewhat universally feel the same way towards these four criteria in terms of motivation for participating in clinical research. In terms of the goal of the study, the data from these questions will not mandate any change in the procedures of clinical research, as these factors do not seem to play a role in excluding non-English speakers. It is important to note that this data comes from only women's health clinics, so no results from any male participants were included in the data. Therefore, no conclusions can be drawn regarding a distinction in women's perceptions versus men's perceptions of these factors.

Limitations

Several limitations exist in this study. Most notably, for the patient survey, many patients have declined to complete the survey. This damages the data, as the people that will not complete the survey are also those that do not participate in clinical research. Of course, data from any patient is helpful, as the results have shown that beliefs amongst all patients tend to be similar (at least for certain questions, i.e. J-1, J-2, K-1, and K-2), but the study would benefit from learning the

beliefs of unwilling patients as well. This limitation is difficult to circumvent, however, because coercing patients to take the survey could skew the results.

Another limitation is that due to the nature of surveying, some patients have left some portions of the survey incomplete. Accordingly, these incomplete surveys have been left out of the main pool of data. The data that patients do supply in their incomplete surveys can be useful, but if a patient leaves certain information, such as demographics, blank, there is no way to tie their responses to anything. By collecting at least 400 *completed* surveys from each practice, this should not be a major problem.

Tables and Figures

Table 1. Comparison of English and non-English Speaking Patients' Responses for Various Questions

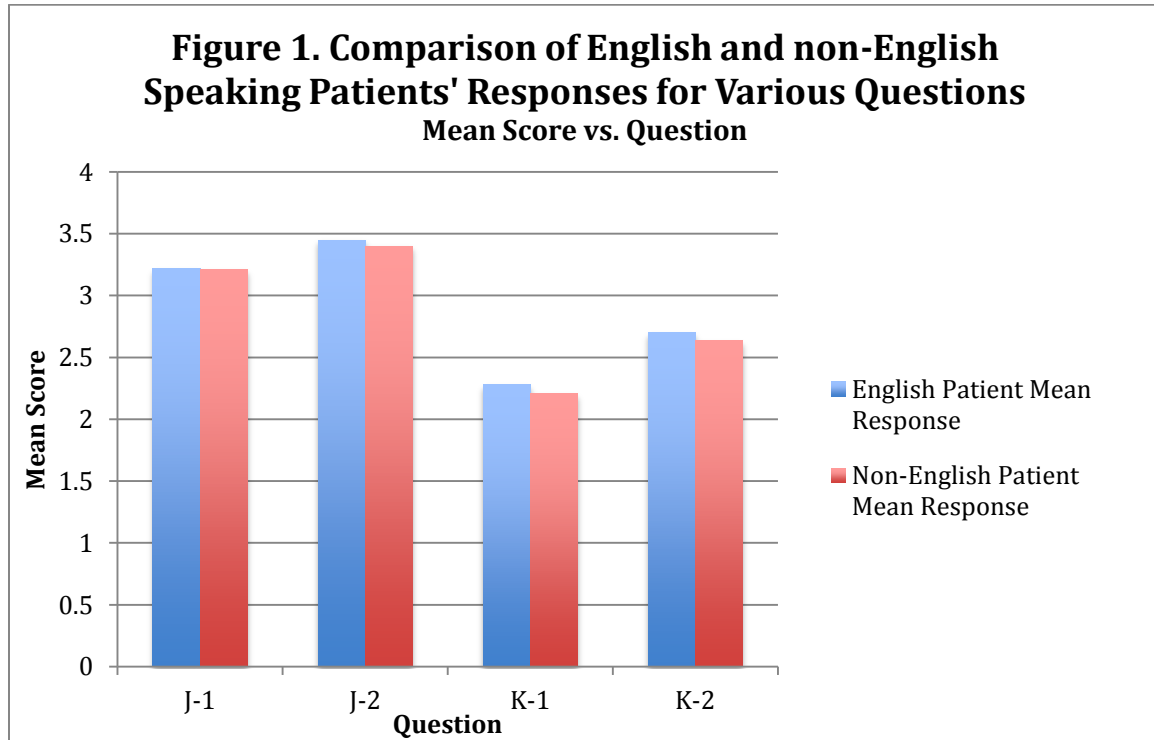
Question	English Patient Mean Response	Non-English Patient Mean Response
J-1	3.22	3.21
J-2	3.45	3.40
K-1	2.28	2.21
K-2	2.70	2.64

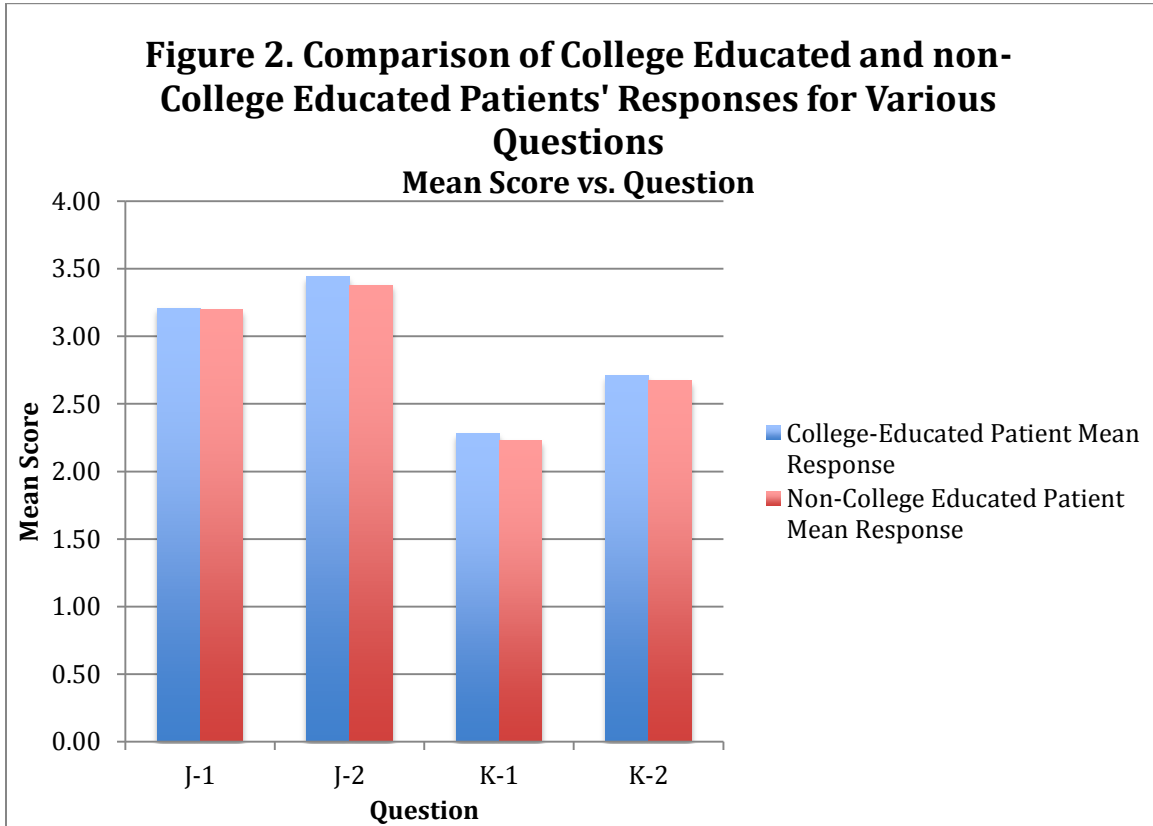
Table 2. Comparison of College-Educated and Non-College Educated Patients' Responses for Various Questions

Question	College-Educated Patient Mean Response	Non-College Educated Patient Mean Response
J-1	3.21	3.20
J-2	3.44	3.38
K-1	2.28	2.23
K-2	2.71	2.67

Table 3. Questions Being Analyzed

Code	Question
J-1	Relationship with Doctor
J-2	Doctor's Reputation in Community
K-1	Distrust in Doctors
K-2	Time Commitment





References

1. Jagsi, R., Motomura, A., Amarnath, S., Jankovic, A., Sheets, N., & Ubel, P. (2009). Under-representation of women in high-impact published clinical cancer research. *Cancer*, 115(14), 3293-3301.
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3. Lloyd, T., Phillips, B., & Aber, R. (2004). Factors that influence doctors' participation in clinical research. *Medical Education*, 38(8), 848-851.
4. Waisbren, S., Bowles, H., Hasan, T., Zou, K., Emans, S., Goldberg, C., & ... Christou, H. (2008). Gender differences in research grant applications and funding outcomes for medical school faculty. *Journal of Women's Health (2002)*, 17(2), 207-214.

APPENDIX A: Survey for Patients**PARTICIPANT INFORMED CONSENT, AUTHORIZATION AND SURVEY**

Title of Study: Factors Influencing Participation in Clinical Research

Principal Investigator: Anita Kurt, PhD, RN

Address: Lehigh Valley Health Network
1240 South Cedar Crest Boulevard, Suite #212
Allentown, Pennsylvania 18103

Telephone: 610-402-7666

You are being asked to participate in a survey which will help us understand the factors that influence participation in clinical research (for example: doctors testing a new medication or device and collecting data to see whether the new medication or device is working).

If you are 18 years of age or older, you are eligible to take the survey. This survey is completely anonymous; in other words, any personal identifying information or your signature will not be collected. Also, your participation in this survey is completely voluntary; it is up to you to decide whether or not you want to participate.

Completing the survey should take no more than 8 to 10 minutes of your time. If you start the survey and change your mind about participating, you may stop at any time. If any of the questions make you uncomfortable, feel free to skip them.

This project is funded by the Anne and Carl Anderson Trust, a non-profit philanthropic trust. If you would like to discuss any issues, have complaints, and/or address concerns or questions, you may contact the Research Participant Protection Office at Lehigh Valley Health Network, 1255 South Cedar Crest Boulevard, Suite #3500, Allentown, Pennsylvania, 18103, telephone, 610-402-2760.

If you were asked to participate before and completed this survey at another location, please do not fill out another survey. If you wish to know the results of this survey after the data are analyzed (likely by the end of 2016), please call Anita Kurt, PhD, Principal Investigator, at 610-402-7666.

Please take this page with you for future inquiries.

Thank you for taking the time to complete this survey.

Section 1: General questions about your health and previous participation in clinical research studies:

- A. Are you here today as a *patient*?
- A1. Yes
- A2. No
- B. In general, compared to other people your age, how would you *rate your overall health*?
- B1. Excellent
- B2. Very Good
- B3. Good
- B4. Fair
- B5. Poor
- C. About *how often* would you say *you make decisions* about obtaining the medical care you need (as opposed to someone else making the decision for you)?
- C1. All of the time
- C2. Most of the time
- C3. Some of the time
- C4. Rarely
- C5. Never
- D. Have you *ever participated in a clinical research study* (a study where a doctor tests a new medication or device to see how it improves your health)?
- D1. Yes
- D2. No
- E. Which *family member would play the MOST important role* in deciding whether another member of your family can participate in a clinical research study? **(Please select one)**
- E1. My mother
- E2. My father
- E3. My spouse or significant other
- E4. My brother
- E5. My sister
- E6. Other; please specify_____

F. *How many clinical research studies* have you participated in within the ***last FIVE*** years?

F1. None

F2. One

F3. More than one

G. Please ***list the health condition*** that was the focus of the **MOST RECENT** study you participated in.

G1. _____

G2. ____ I did not participate in any.

H. Using any number from 0 to 10, where 0 was the worst experience possible and 10 was the **best experience possible** what number would you use to rate the **MOST RECENT** study you participated in?

H1. _____

H2. ____ I did not participate in any.

I. Some studies are able to offer participants money to participate. Would you prefer to participate if you are paid?

I1. Yes

I2. No

I3. Does not matter

Section 2: Factors that relate to participating in clinical research studies:

- J.** What **factors would motivate you** to participate in a clinical research study?
Please rate the following from **NO MOTIVATION (0)** to **MOST (4)** motivating factor.

Motivating factors	0	1	2	3	4
My relationship with my doctor	0	1	2	3	4
Doctor's reputation in the community	0	1	2	3	4
How well the research study is explained to me	0	1	2	3	4
My desire to please the doctor	0	1	2	3	4
Money offered for my participation	0	1	2	3	4
A friend or family member participating in the same study	0	1	2	3	4

The doctor conducting the research is the same gender (sex) as me	0	1	2	3	4
The doctor conducting the research is the same race/ethnicity as me	0	1	2	3	4
The doctor conducting the research speaks the same language as I do	0	1	2	3	4
Knowledge learned from my participation will benefit someone in the future	0	1	2	3	4

K. What *factors would prevent you* from participating in a clinical research study? Please rate the following from **NO BARRIER (0)** to **GREATEST (4)** barrier.

Potential barriers	0	1	2	3	4

My distrust in doctors	0	1	2	3	4
Time commitment	0	1	2	3	4
My family's concern	0	1	2	3	4
My religious beliefs	0	1	2	3	4
Clinical research studies are too hard to understand	0	1	2	3	4
Study related phone calls for follow-ups	0	1	2	3	4
Multiple follow-up visits related to the study	0	1	2	3	4
Risk of unknown side effects	0	1	2	3	4
Access to transportation	0	1	2	3	4

- L. What **would help you decide** whether to or not to participate in a clinical research study? Please rate the following from **NO HELP (0)** to **MOST (4)** helpful resource.

Helpful Resources	0	1	2	3	4
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Written material explaining the research study	0	1	2	3	4
DVDs or electronic material explaining the research study	0	1	2	3	4
Having opportunity to speak to a patient who has participated in a clinical research study	0	1	2	3	4
Having access to a support group of patients who have participated in clinical research	0	1	2	3	4
Having all material provided in my own language	0	1	2	3	4
Having access to a medical interpreter throughout the study	0	1	2	3	4

Section 3: Information about you:

M. What is your age?

- M1. 18-24
- M2. 25 to 34
- M3. 35 to 44
- M4. 45 to 54
- M5. 55 to 64
- M6. 65 to 74
- M7 75 or older

N. What is your gender? _____Male _____Female

O. Do you have any children? _____Yes _____No

P. What is the highest grade or level of school you completed?

P1. 8th grade or less

P2. Some high school, but did not graduate

P3. High school graduate or GED

P4. Some college or 2 year degree

P5. 4 year college graduate

P6. More than a 4 year college degree

P7. Masters degree (for example, MA, MS, MSN, MEng, Med, MBA)

P8. Professional degree (for example, RN, MSW, MD, DDS, DVN, LLB, JD)

P9. Doctoral Degree (for example, Ph.D, EdD, DSW, DNP)

Q. Are you of Hispanic or Latino origin or descent?

Q1. Yes

Q2. No

R. What is your race (circle all that apply)?

R1. White or Caucasian

R2. Black or African American

R3. Asian

R4. Native Hawaiian or Other Pacific Islander

R5. American Indian or Alaska Native

R6. Other: Please specify: _____

S. What is your religious preference?

- S1. Buddhist
- S2. Catholic
- S3. Christian
- S4. Evangelical/Pentecostal
- S5. Hindu
- S6. Jehovah's Witness
- S7. Jewish
- S8. Muslim
- S9. Not religious/None
- S10. Protestant
- S11. Other; please specify: _____

T. What language do you speak at home?

- T1. English _____
- T2. Spanish
- T3. Other: please specify: _____

U. How well do you speak and understand English?

- U1. Very well
- U2. Pretty good
- U3. Can understand English, but have a hard time speaking it
- U4. Cannot speak English

V. What category best describes your CURRENT employment status.

- V1. Employed Full-Time
- V2. Employed Part-Time
- V3. Unemployed and looking for work
- V4. Unemployed but not looking for work
- V5. Student
- V6. Retired

V7. Other; please specify: _____

W. If you said you are employed, what category best describes the industry you work in?

W1. Not applicable (I am either unemployed or retired)

W2. Military.

W3. Education.

W4. Transportation.

W5. finance/banking

W6. Service industry (for example, food services, retail, sales).

W7. Health care/science.

W8. Construction.

W9. I work in another industry (please list here
:_____)

X. What category best describes your TOTAL income in 2013?

X1. Less than \$30,000

X2. \$30,001-\$50,000

X3. \$50,001-\$75,000

X4. \$75,001-\$100,000

X5. \$100,001 or more

X6. I'd rather not answer.

Thank you!!

