The Diversity Study: Factors Influencing Clinical Research
A Focus on Women Participants

Adrian Paskey, Mentor: Anita Kurt, PhD, RN

ABSTRACT

The Diversity Study is a two-pronged study which evaluates both clinical research professionals and patient populations eligible to participate in studies. The focus of this paper is on patient populations. Specific aims regarding the patient population of this study seek to identify how widespread participation in clinical studies is within the Lehigh Valley Health Network (LVHN) community. Additionally, opinions regarding promotional tools which may more effectively entice women to participate in clinical research were evaluated in a 0-4 Likert scale. An overarching goal to improve diversity in research aligns with LVHN triple aim (better health, cost, and care) and touches on community involvement aspect of health. Outcomes indicate that women in Obstetrics clinics of all races and cultures are open to participation in clinical studies given the right approach and resources.

BACKGROUND

It was hypothesized that the interest in and significance of promotional tools (for example, video explanations, medical interpretation, and support groups) is high among women, providing the potential to lessen the disparity within clinical research. Education and socioeconomic status are thought to influence openness to participation. In addition, it was hypothesized that the majority of subjects who speak a language other than English at home will not have participated in clinical studies. What prevents these women from participating?

Disparity on the participant level was initiated in part by the Food and Drug Administration (FDA) more than 30 years ago when pregnant women were classified as unable to participate in Phase I drug trials. Generalization of this exclusion led to a noticeable absence of women participants in all phases of clinical studies.[1] In fact, a report reviewing 19 randomized and controlled cardiovascular clinical trials in 2009 revealed a low participation of 27% by females.[2] Previous clinical trial recruitment at the same location in which this study was conducted reported a 40% decline rate.[3] Through The Diversity Study it is hoped that factors influencing women's participation in clinical trials, or lack thereof, will be better understood. Furthermore, the deeper disparity including minority women is hoped to be better understood through this project. Presently, the demographics of the United States of America do not match accordingly to clinical research, even though studies have demonstrated that minorities are in fact *not* less willing overall to participate in clinical studies than are white subjects.[4] Literature suggests that mistrust of physicians and lack of participation is rooted in an overrepresentation of minorities in Phase I clinical trials and an underrepresentation of minorities in Phase III trials.[4]

Unfortunately, this dearth of women participants results in skewed conclusions from clinical trials due to physiological variability between men and women.[1] It is crucial to unravel the factors which will result in the inclusion of more women participants in clinical studies.

METHODS

The Diversity Study is a two-pronged study which evaluates disparity both on the level of research professionals and the participant pool. This paper refers only to the administration of surveys to patients in LVHN centers for women's medicine. Surveys were professionally translated into Spanish so that both English and Spanish copies were available. An eight-page consent combined with a survey was administered to 400 LVHN patients age 18 years and older over the course of five weeks. Research Scholars distributing surveys were able to describe the survey, consent participants, and answer questions regarding the survey to participants in both Spanish and English. Patients were informed of the voluntary nature of the survey and given an opportunity to ask questions. The survey was piloted and reviewed by 15 non-research and non-clinical staff of LVHN prior to its distribution in clinics. A screening log was kept of all individuals approached regarding the survey, and all changes and developments of this study have been approved by LVHN's Institutional Review Board. Data entry was performed by the Research Coordinator, Lauren Semler, and data analysis was completed by the author using Microsoft Excel.[5]

RESULTS

Participant Information	Average Response
Age	25-34
Percent with Children	76.80%
Previously Participated in Research Study	8.35%
Rating of Tools For Understanding Research Studies	3

Table 1: a sample of descriptive statistics of the 400 women who completed surveys.

More descriptive statistics referenced in Discussion.

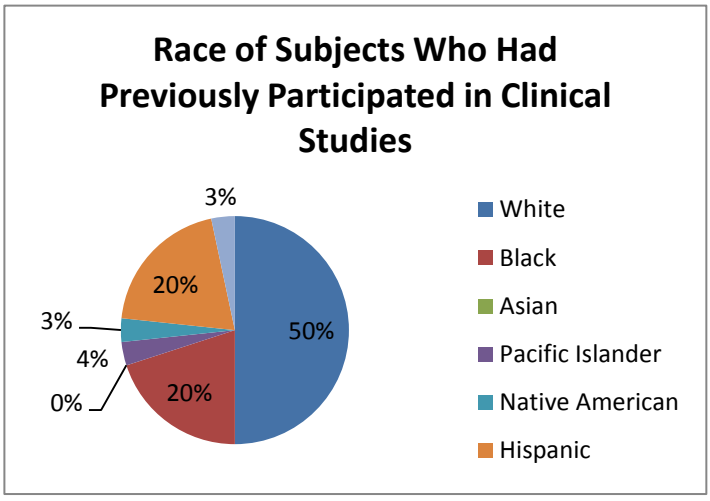

Figure 1 displays the percentage of respondents who had previously participated in clinical studies by race.

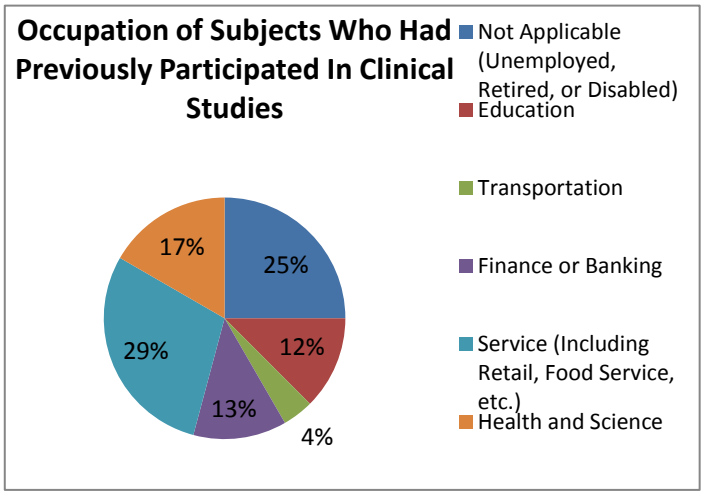

Figure 2 displays the percentage of participants who participated in clinical studies previously, stratified by occupation.

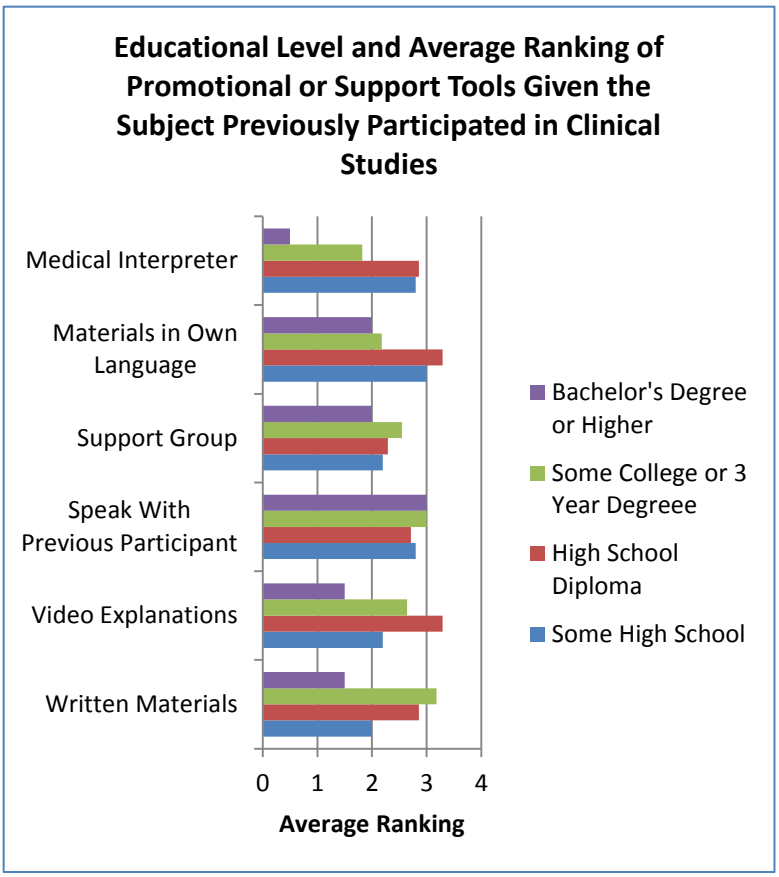

Figure 3 displays ratings of interest in support of subjects who had previously participated in clinical research, stratified by educational background.

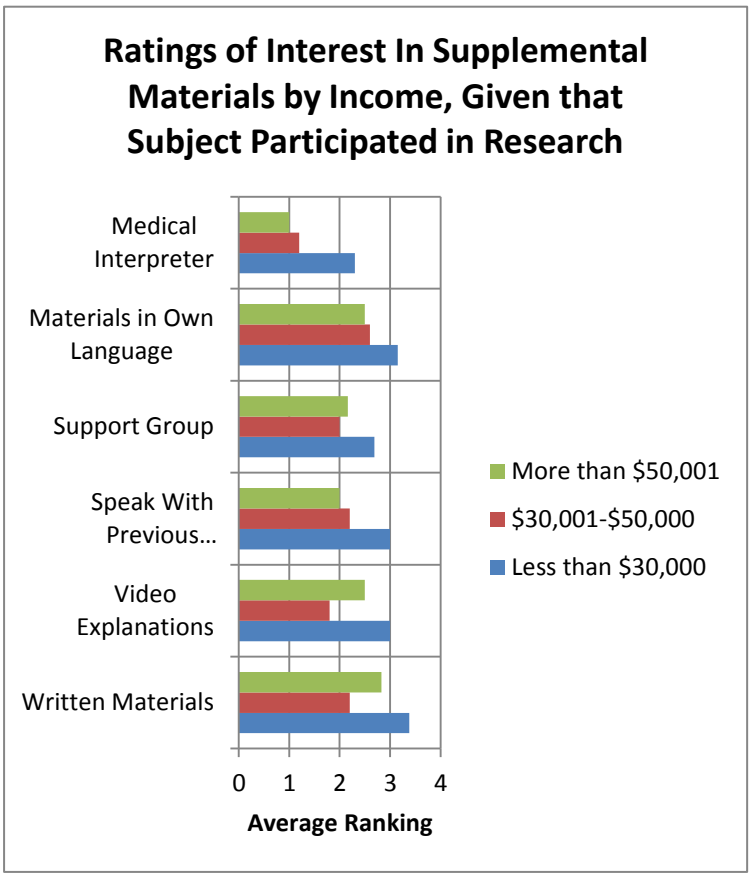

Figure 4 displays ratings of interest in support of subjects who had previously participated in clinical research, stratified by income.

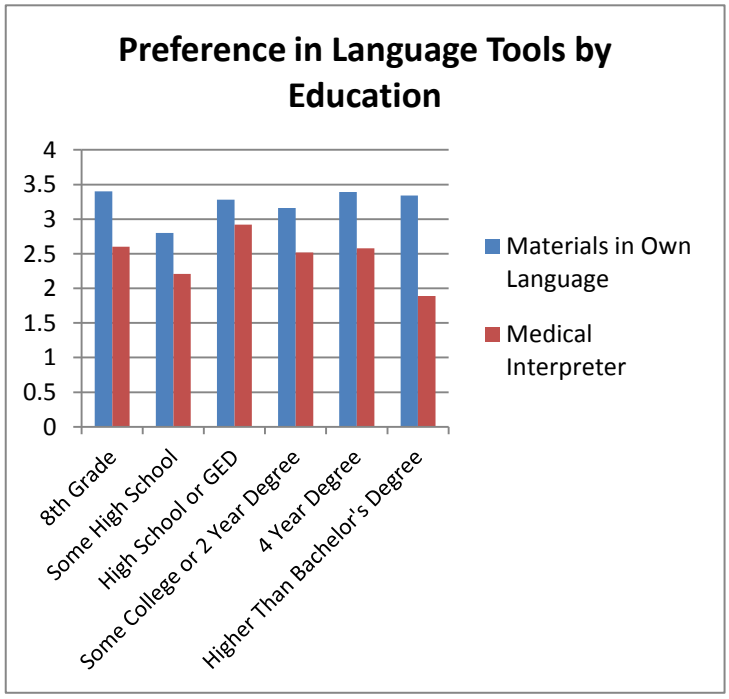

Figure 5 displays the average ratings of openness to language tools for all survey subjects, stratified by educational background.

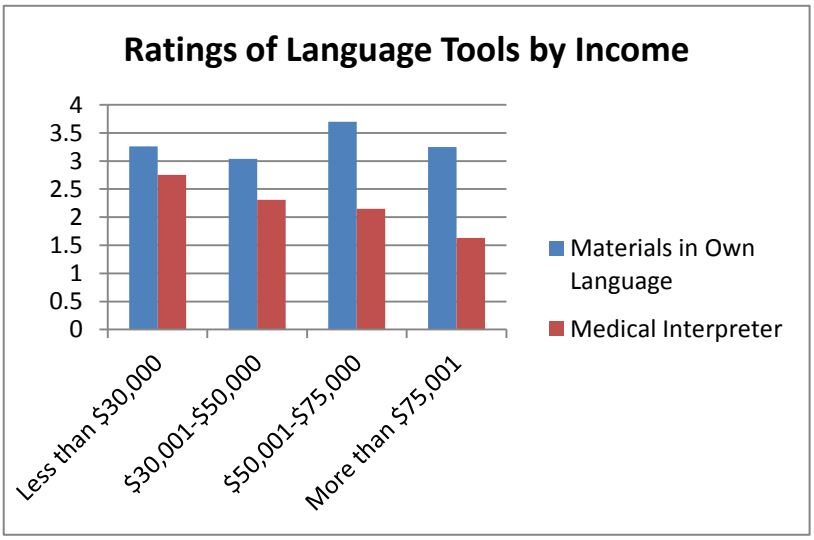

Figure 6 displays average rating of language tools for all survey subjects, stratified by income.

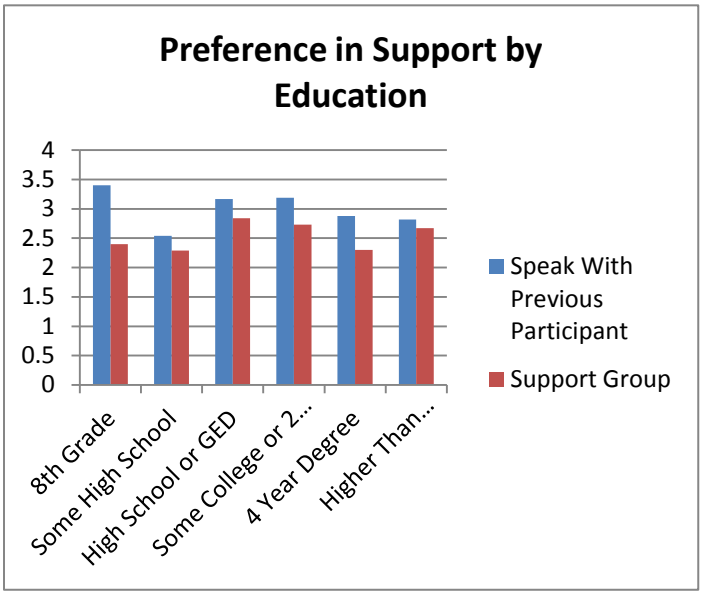

Figure 7 displays average rating of support tools for all survey subjects, stratified by education.

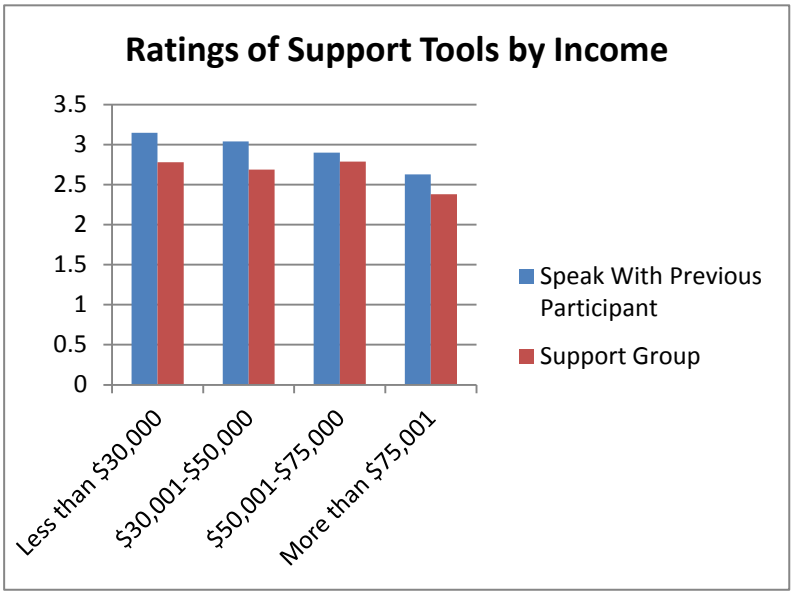

Figure 8 displays average rating of support tools for all survey subjects, stratified by income.

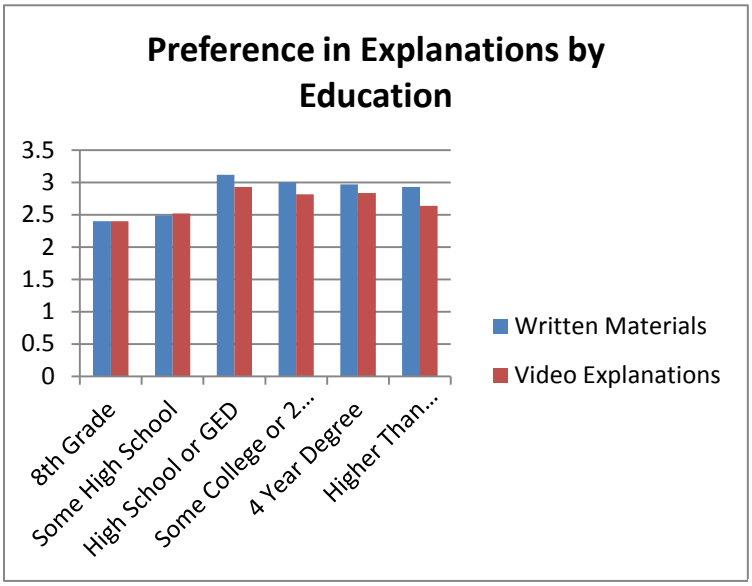

Figure 9 displays average ratings of helpfulness of explanations for all subjects, stratified by education.

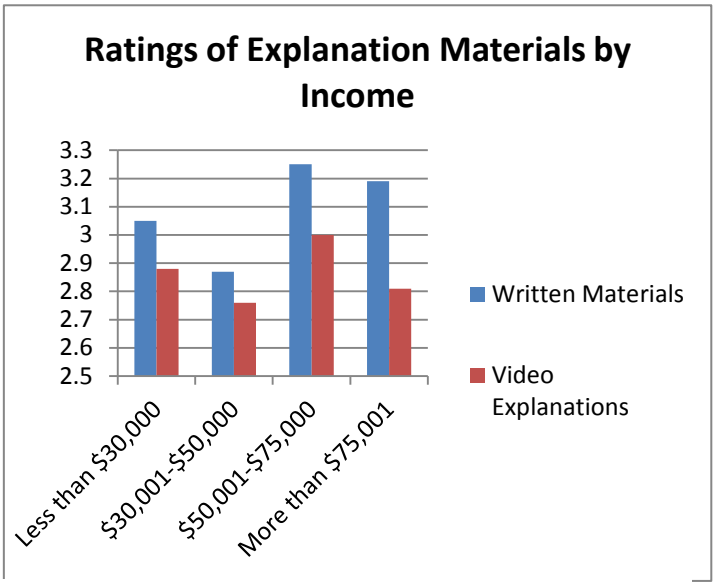

Figure 10 displays average ratings of helpfulness of explanations by subjects, stratified by income.

DISCUSSION AND CONCLUSION

The average age range of the women surveyed was 25-34 ($p=0.0029$), 76.75% of patients had children, and the education level of this population is "some college or 2 year degree" ($p=0.01421$). Of the 395 participants who responded to the question asking about heritage, 42.27% were of Hispanic descent (*Table 1*). However, given that the subject had participated in a clinical trial previously, 84.85% of subjects spoke a language other than English at home. This is indicative of a population which participates in clinical studies and has not been barred from participation in trials due to cultural or language differences.

The average language spoken at home was Spanish ($p=0.014264$), and subjects responded on average that they speak and understand English "very well" ($p=0.016$). The majority of subjects self-reported good health (median response, "Very Good," $p<0.05$) and that overall health decisions are on average made by themselves "all" or "most of the time" (median response, "All of the time," $p<0.05$). This may suggest that language, illness, or lack of autonomy in decision making does not minimize the average subject's openness to participation in surveys.

While one of the locations in which the study was conducted boasts bilingual physicians and staff in addition to heavy involvement in research, only 8.35% of survey subjects indicated participation in a research study previously. Of the participants who had previously been part of clinical studies, only one woman had participated in more than one study in the past five years. Average ratings by women who had previously participated in clinical studies of support tools were overall lower compared to the whole population of women who took the survey (*Figures 3 and 4).* There was high variation in veteran participant responses (not statistically significant to a 95% confidence interval), indicating that decision-making regarding study participation may be

more autonomous given prior exposure to clinical studies. One additional piece of information which may add to this project is how many times the survey population had been asked to participate in a study over the past year.

In rating tools by helpfulness in terms of deciding whether or not to participate in clinical studies, more personal options such as support groups and opportunities to speak with prior participants were rated slightly higher than written explanations or video support by the whole survey population. The median for each tool was rated at 3 on a 0-4 Likert scale, with 4 being the most helpful. The highest rating median of 4 was given to "Having material provided in my own language," however; the average rating was 3.21 (similar to other option responses) with a p-value of 0.0547, which is not statistically significant (*Figures 5-10).*

Given that the subject had previously participated in clinical studies, 17% of those subjects were employed in health care or science fields. The women who had previously participated in clinical studies identified as 20% Hispanic, 50% white/Caucasian, and 20% black or African American and the average education was "some high school" (*Figures 1 and 2).* It could be said that the group which previously participated was somewhat diverse in educational, ethnic, and socioeconomic background. The trend based on education follows that the subjects with the most and least education rated less importance on supportive tools to improve openness to clinical studies than those in the middle of the educational spectrum (high school or some college). The average respondent was of an income $30,000 or less, which is reflective of the area in which the study was conducted. The highest importance of promotional tools was rated by the lowest income subjects who had previously participated in clinical studies (*Figures 3, 4).*

Limitations to this study include several confounders and logistical challenges. The survey was available in English for more days during the study than Spanish. Confounding factors of incompleteness due to a lack of comfort with the question type or the subject's English fluency could have influenced responses. A final confounder could lie in the responses in English surveys versus Spanish surveys given the subject's English fluency.

Outcomes of this study suggest that women are in fact open to educational and supportive resources which may increase openness to participation in clinical studies. It can be said that the hypothesis regarding interest and openness to promotional tools and clinical studies is high among women was correct. Education and socioeconomic status relatively influenced openness to participation. Between video and written explanation ratings, written was rated higher overall. Between the option to speak with a prior participant of the study and to have a support group, the option to speak with a prior participant was rated higher. Between the option for materials in the subject's own language and access to a medical interpreter, materials in the subject's own language were the highest and clearest preference. These three preferred tools would make for a good base in further testing.

The final hypothesis that the majority of subjects who speak a language other than English at home would not have participated in clinical studies was not accepted. Results indicate that over 80% of the participants of clinical studies did in fact speak a language other than English at home. The largest factor which may improve openness to clinical studies may lie in the approach and provision of support to participants.

Further research directions include identifying a consensus of openness to materials of reference and in-person support which is positive and able to be implemented. Utilization of discrete

materials at various enrollment sites and comparison between outcomes given the support tool as a sole variable could help better identify which tool is best for the women and minority population within LVHN.

Works Cited

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