A Multicenter Study Investigating the Factors that Influence Female Participation in Clinical Research: A Focus on the Mindsets of Pregnant and Fertile Women

Meredith Kalberer
Columbia University

Published In/Presented At
Kalberer, M. (2015, July 31) *A Multicenter Study Investigating the Factors that Influence Female Participation in Clinical Research: A Focus on the Mindsets of Pregnant and Fertile Women.* Poster presented at LVHN Research Scholar Program Poster Session, Lehigh Valley Health Network, Allentown, PA.

A Multicenter Study Investigating the Factors the Influence Participation in Clinical Research: A Focus on the Mindsets of Pregnant and Fertile Women

Meredith Kalberer; Anita Kurt, PhD, RN
Lehigh Valley Health Network, Allentown, Pennsylvania

OVERVIEW

The Multi-center Study focuses on investigating factors that influence female participation in clinical research. The goal is to understand female patient's perspectives about research that lead to the gender disparity and **to gain enough insight to overcome potential barriers**.

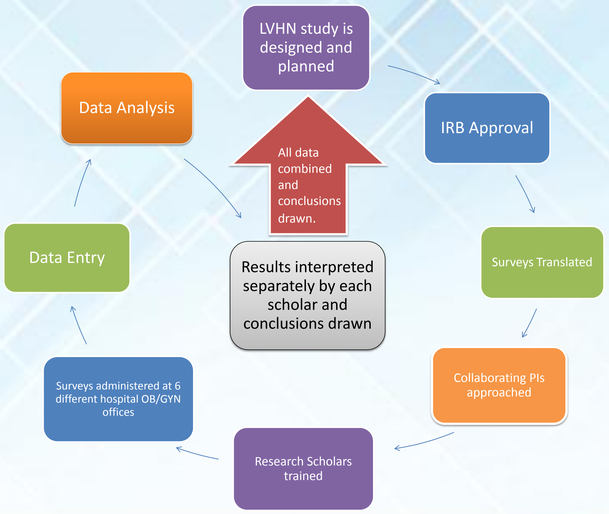
GOALS:

- Investigate female patient's overall mindset about clinical research
- Recognize factors and resources that can help influence participation using a 0-4 Ascending Scale. (0=No motivation, 1= Very little motivation, 2=Some motivation, 3=Significant motivation, 4=Most motivation)
- Begin to bridge gaps in clinical research concerning gender

The results of this specific research will aim to identity any differences between pregnant and fertile women's barriers concerning clinical research.

Outcomes indicate that a stigma may be influencing fertile women's decision making and that pregnant and fertile women have different factors that influence their participation. Overall, women are open to participating in clinical research, if approached correctly.

METHODS



SUSPECTED INFLUENCES

1. *In 1977, the FDA banned all women of child bearing potential from participating in clinical research.*[1]
   -This could have cause a continuing **stigma concerning participation**.
2. *Women with child bearing capabilities or who are already pregnant may view risks to their health differently than those women who can no longer have children.*
   - Different **resources** may influence each groups participation.
3. *Women who are still creating and overseeing a family may feel obligated to spend more time on this.*
   -A Barrier, such as time, is a simple explanation of the gender disparity in research and can be remedied.

RESULTS

Participant Information	Responses
Age Range	18-76
Pregnant	56.48%
Not Pregnant	43.52%
Fertile*	85.71%
Not Fertile*	14.29%
Participated in a Clinical Trial Previously	5.8%

** Fertility is defined as less than 40 years of age for the purpose of this data analysis*

Table 1: summary of the 400 women who completed the surveys used in this analysis

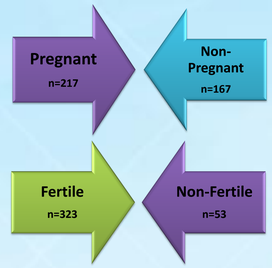


Chart 1: shows the different groups compared during data analysis

Table 2: shows statistically significant results when comparing the groups opinions of factors. The group that favored the factor is listed.

SIGNIFICANT RESPONSES				
FACTORS	RESPONSE	GROUP	AVERAGE RATING	P-VALUE
Motivating	"Knowledge learned from my participation will benefit someone in the future"	Non-fertile	3.18	0.0225
Barrier	"Risk to the fetus/future fertility"	Pregnant Fertile	2.9 2.8	0.0004 0.0133
Resource	"Written material explaining study" "Having all material provided in my own language"	Non-fertile	3.0625 3.24	0.0410 0.0459

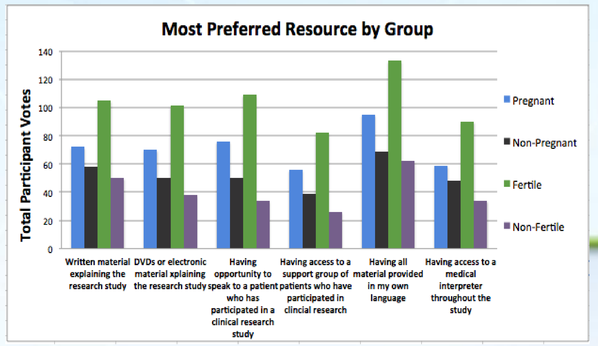


Figure 1: shows the total of "4" votes each resources received, separated by the 4 separate groups of women

CONCLUSIONS

Table 1 shows the general statistics of the 400 female participants whose data was used for this analysis. The age range was from 18 to 76 years old, over half the women surveyed were pregnant at the time, and about 86% of the women were still of fertile age (defined as less than 40 years old.) Less than 6% of women surveyed had participated in clinical research before.

I. The top motivating factor for all factions of women was "How well the research is explained". The top barrier was "Risk of unknown side effects for fertile, non-fertile, and non-pregnant women. Pregnant women feel "Risk to fetus/future fertility" is the greatest barrier. The top resource for all factions was "Having material provided in my own language.
II. Non- fertile women feel that knowledge gained from their participation is more important than fertile women (p=0.0225). *See table 2*
III. Both pregnant/non-pregnant women and fertile/non-fertile women, disagreed about the importance of "Risk to fetus/future fertility" as a barrier (p=0.0004, p=0.0133). *See table 2* *Note some non-fertile women still voted this barrier as "4", pointing out a potential stigma in their minds about clinical research.
IV. Fertile and non-fertile women have statistically significant opinions about the helpfulness of "Written material explaining the research study" and "Having material provided in my own language" (p=0.0459). *See table 2*

The outcomes indicate women are open to clinical research and potential resources, but different approaches may be helpful when recruiting women. A stigma may still exist and must be confronted.

STARTING THE CHANGE

After the data analysis of all of the sites, even clearer influences about female participation will be recognized

Until the time when participation between men and women is equal, or appropriate participation in gender based diseases is acceptable, change needs to be worked for. This can be done by:

1. Making sure women are aware of the disparity. Education is key.
2. Use this study's final findings to influence women in a positive way to participate.
3. Encourage guidelines to be passed by the government or FDA in order to define what is a "reasonable" number of women participating in clinical studies, This can be used to guide organizations that fund research.[2]

REFERENCES

1. Kurt, A. (2014). Protocol, Factors influencing participation in clinical research.
2. Bush, J. The industry perspective on the inclusion of women in clinical trials. *Academic Medicine,* 708-15.