

Examining the gap between a morally valid consent and a legally adequate consent ¿Entiende?

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PhD Rhetoric and Scientific and Technical Communication (graduated July, 2015)

Project Summary

This grant funded the third study in a three study dissertation research project that examined the adequacy of the informed consent process when members of the immigrant Latino community are recruited into clinical trials. This bioethics question was explored using a multi-disciplinary lens, situating it at the intersection of rhetoric, scientific and technical communication, and intercultural communication.

Data was gathered in three studies using the methodology of analogue participants. The analogue participants were recruited from urban Catholic parishes that serve a large immigrant Latino population. A simulation of a healthy patient consent conference was used in Study 1 and Study 2, while a simulation of a multi-arm diabetes trial was used in Study 3. This change in trial topic was important to more deeply examine the informed consent process by looking at a consent conference for a medical trial, in this case a diabetes trial. Moreover, the Chair in Diabetes Research at the University of Minnesota's medical school granted permission to use the consent materials from a recent diabetes trial, Action to Control Cardiovascular Risk in Diabetes (ACCORD).

Two focus groups were held Nov 9, 2014 with a total of 30 participants. Grounded theory methodology was used to examine this data and the data from the first two studies. Though the trial topic was very different from the previous studies, the previously identified categories held with some adjustments. The results from Study 3 reinforced and enriched those categories. A subcategory of COMMUNITY HEALTH emerged: Navigating Care. This subcategory discusses the difficulties and fears of community members surrounding managing diabetes. There was also evidence of contextualizing to form meaning. Additionally, the data hinted at issues of justice, which was depicted by the category TRIAL DESIGN.

The grounded theory resulting from the data gathered in Study 1, Study 2, and Study 3 suggests a culturally specific way to present trial information to members of this community, describes how that information might be understood, and illustrates the community's social context. Understanding the social context is necessary to understand how to present trial information and to understand the autonomy of community members. I have attached the final conceptual framework as the last page of this report.

Financial Summary

The budget I submitted contained the following:

Stipend	\$4350.00
Supplies & Services	\$2500.00
(Translation & Interpreting)	
Equipment	\$ 150.00
(GC for participants)	
Total	\$7000.00

Translation (check #2513 to Elizabeth Nelson)	\$2500.00
Participants gift (\$15)	\$ 150.00
Stipend*	
Participants gifts	\$ 300.00
Transcription/Translation/Interpreting	\$1446.00
Groceries and Supplies for meal for participants	\$ 172.00
Fliers	\$ 35.00

*I chose to use a portion of my stipend to cover additional costs associated with this research. I have listed those items above.

Publication Plans and Conference Presentations

I intend to propose this entire project as a book and have identified Routledge as the publisher I will approach. The specific book series is titled "ATTW Book Series in Technical and Professional Communication".

I presented the community based research methodology at the Discourses in Health and Medicine Symposium, Sept. 2015. That paper, "Participatory Research: Giving a Voice", will become a book chapter in an upcoming book on research methodologies in the rhetoric of health and medicine, Lisa Meloncon and J. Blake Scott (Eds.)

I will present at the annual Rhetoric Society of America conference, RSA2016 Rhetoric & Change, May, 2016. The title of the presentation is "Changing from a rule-based approach to a rhetorical approach: ethically enrolling immigrant communities into clinical trials"

I am currently preparing an abstract for the American Teachers of Technical Writing (ATTW) annual conference tentatively titled "You gave me the information but you didn't explain it to me", a direct quote from a Study 3 participant. I plan on using this to write an article which I will submit to Technical Communication Quarterly.

I plan on several other article submissions using data from Study 3 and from the entire project.

Future Projects

As mentioned, this funded study was the final part of my entire dissertation research. I successfully defended June 2, 2015.

As an interdisciplinary project, there are a number of directions future research might take. It would be logical to return to these community populations to complete the investigation of the diabetes consent materials and conduct theoretical sampling if necessary. The resulting complete theory should then be brought back to the community for comment.

Creating a consent conference or adapting an existing consent process that incorporates all that has been learned in this study and testing it for efficacy would add credibility to the grounded theory.

To further enrich this theory I also suggest conducting studies with immigrant Latinos living in rural areas. I hypothesize that the urban populations that participated in this study may have the advantage of receiving community-based health education, which might not be available to those in rural areas, affecting both understanding and autonomy.

Using principles learned in this study, I would also like to create a computer-based instruction program to test the use of that mode of disclosing trial information. A computer-based instruction program would also provide a vehicle to include short, culturally tailored quizzes after sections of information to explore comprehension. This could be done using videos and visuals to attend to issues with illiteracy.

Finally, ancillary topics outside of trial enrollment involving this community suggest inquiry into the evolution of the immigrant nuclear family, which might include the effects of children's acculturation on their behavior towards their parents. Also of interest is the lack of English language ability in the immigrants, even those who had been in the U.S. for several decades.

Social Context

