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Moving from a Legally Adequate Consent to a Morally Valid Consent: Using Rhetoric and Scientific and Technical Communication to Investigate Latino Understanding of an Informed Consent Conference

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ABSTRACT: While there has been much research on informed consent generally, little has been done to explore the process with non-English-speaking immigrants. This project explores the informed consent conference for non-English-speaking Latinos. Rhetoric and scientific and technical communication will ground the analysis of the results.

KEYWORDS: bioethics, cross-cultural communication, human subject research, immigrant, informed consent, Latino, rhetoric, scientific and technical communication

1. INTRODUCTION

Enrollment of members of minority communities in clinical trials is important for a number of reasons. Research that includes minorities works towards the elimination of health disparities and increases the generalizability of research results. This study looks specifically at Latinos, who, as reported by the Pew Hispanic Center, represent the largest, fastest-growing ethnic group in the United States, numbering 50.5 million, or 16.3% of the total population in the United States (Cohn, Passel, & Lopez, 2011). Hispanics, it has been reported, have a high prevalence of diabetes and obesity (Cohn, Livingston, & Minushin, 2008; Vivo, Krim, Cevik, & Witteles, 2009), dyslipidemia (having too high or too low lipid levels in the bloodstream), metabolic syndrome, and hypertension (Vivo et al., 2009). Having Hispanics take part in research involving these and other health issues is essential since limited participation leads to limited data specific for this population. Finally, for some patients, inclusion in clinical trials represents an opportunity to receive new therapies not otherwise available.

The researcher has a legal obligation to obtain informed consent from the research participants. The basis of informed consent is the Belmont Report. Introduced in 1979, the Belmont Report is a result of hearings of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.1 The report outlines three basic principles that direct the conduct of biomedical and behavioral research that utilizes human subjects: respect for persons, beneficence, and justice. It also provides concepts that serve to guide researchers as to how to adhere to these principles.

1 For a history of federal research policy see McCarthy (1998).

The first ethical principle articulated in the Belmont Report is “Respect for Persons.” This principle contains two ethical tenants, the first being: “that individuals should be treated as autonomous agents” (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [NCPHS], 1979, Part B, para. 2). The second tenant states “that persons with diminished autonomy are entitled to protection” (NCPHS, 1979, Part B, para. 2). In fact, some groups or individuals may be prohibited from participating in experimentation. Determining the extent of protection should depend on the level of risk and the likelihood of benefit (NCPHS, 1979, Part B, para. 5).

This project will be limited to persons assumed to be capable of self-determination. However, being capable of self-determination does not necessarily negate the need for some degree of protection, or at minimum, extended considerations. Recruiting members of immigrant communities may be considered in the category of, what the Belmont report names, “hard cases” (NCPHS, 1979, Part B, para. 6).

The Belmont report lays out specific applications of the three general principles. To operationalize the principle of Respect for Persons, the participant is to “be given the opportunity to choose what shall or shall not happen to them” (NCPHS, 1979, Part C, para. 2). This is done through the process of informed consent. The process of informed consent contains three elements:

1. Information: This element describes what sort of information should be provided. The items generally included are descriptions of the procedure, purposes, risks and benefits, and alternative procedures. Additionally, subjects are given the opportunity to ask questions and the opportunity to withdraw from the research.
2. Comprehension: This element includes issues of the adaptation of the information and allows special provisions for those who may have limited comprehension.
3. Voluntariness: This element includes issues of coercion.

With this disclosure the patient is considered informed and may now make an informed choice as to whether or not they will participate in the trial. The Belmont report states that the “Investigators are responsible for ascertaining that the subject has comprehended the information” (NCPHS, 1979, Part C, para. 8).

Felt, Bister, Strassnig, and Wagner (2009) challenge the current understanding of autonomy. They suggest that the “bioethical ideal” of providing comprehensive information to aid an individual in decision making is incomplete. They speculate that individuals may make decisions on clinical interventions or on participation in clinical trials based on information from sources other than the information presented to them. They write:

The framing of autonomy as informed choice that presents a narrow set of ready-made options for patients is seen as insufficient for describing and taking into account the complexities of social and historical context that contribute to patients’ ways of dealing with medical encounters. (Felt et al., 2009, p. 4).

Their research was done within a single culture and concentrated on tissue donation, which is not directly applicable to this discussion. However, some of the notions introduced are intriguing and worth considering. They feel that there is a discrepancy between the “bioethical ideal” and the practice of informed consent. They found that patients may not attend to information presented in the informed consent process and instead rely on personal
experiences, perceptions, and “imaginations” to make their decisions (Felt et al., 2009). This study opens a space to consider the process individuals use to understand autonomy.

Overall, there are several challenges immigrant populations may face that could affect the process of fully grasping disclosed information. Comprehension can be difficult for recently immigrated persons who have limited English language skills and may have limited formal education. They may be unfamiliar with the medical system in the United States, may be unfamiliar with Western medicine, and may be unfamiliar with the concept of research. Additionally, they may have limited knowledge of the etiology and the nature of their disease and be unfamiliar with medical and physiological vocabulary. Cultural factors may create a terministic screen, to use a Burkean term, through which Latinos receive the informed consent information. For example, the notion of autonomy may pose difficulty for a variety of reasons. Mexico and Latin America rank high in power distance, meaning that there exists a clear social hierarchy (Hofstede, n.d.). Implications of this power distance dimension may be that information presented by a person of respected status, such as a health care provider, be accepted without question.

All of these factors add complications to the execution of the elements of informed consent. The Belmont Report does grant that, “a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided” (NCPHS, 1979, Part C, para. 5). The conventional topics presented in a conventional manner may be incomprehensible to these individuals. What may be needed is background information, explanations, definitions, and time. J. Katz (1993), while discussing potential problems experienced by a physician investigator, makes points valid to this discussion. He observes that “current informed consent forms often provide IRBs rather than the subjects with a better understanding of investigators’ intentions” (J. Katz, 1993, p. 36). In other words they are overly technical and written at higher reading level than is appropriate. Additionally, from the standpoint of the immigrant population, these forms may not contain all of the information that may be needed. J. Katz (1993) notes that to follow his recommendations on how best to secure a morally valid consent (as compared to a legally adequate consent) takes time and “may have to extend over hours, perhaps even days, and must be continued until one is reasonably certain that the patient-subjects understand” (p. 36). This investment in time would certainly improve the consent process of immigrant populations by demonstrating a concern for the individual and the willingness to have a conversation, a more equal sharing in power. This would provide an environment where questions could be asked and concerns aired. Sherwin (1998) also makes the point that obtaining informed consent that truly protects patient autonomy is time consuming. She also identifies a lack of communication skills as a potential difficulty: “This problem [lack of communication skills] is compounded within our increasingly diverse urban communities where differences in language and culture . . . may create enormous practical barriers to informed choice” (Sherwin, 1998, p. 24). Simply translating the information into the native languages does not necessarily make the information more understandable. The Belmont Report recognizes that “[t]he manner and context in which information is conveyed is as important as the information itself” (NCPHS, 1979, Part C, para. 7). How best to adapt the information for an immigrant audience is a complex question.

Another difficult and complicated task is determining comprehension. The Belmont Report also stipulates, “Investigators are responsible for ascertaining that the subject has comprehended the information” (NCPHS, 1979, Part C, para. 8). However, the Belmont Report does not give much guidance on how to do this. The Report does mention cases where the
presentation of the information should be adapted. Such cases include “conditions of immaturity or mental disability” (NCPHS, 1979, Part C, para. 9). There is not a mention, however, of any instance resembling that of enrolling members of immigrant populations. Situations involving individuals who are non-native speakers and are from a different culture are not addressed, most likely because it was not a consideration at the time the Belmont Report was authored. While there has been much research done on this question of comprehension (e.g., Jefford & Moore, 2008; Stunkel et al., 2010; Sudore et al., 2006), very little has been done that focuses on members of immigrant communities. Though the clinical trial researcher is charged with ensuring that the trial participant understands the information presented, the extent of understanding is poorly understood, especially in the immigrant population who are non-native speakers.

The third element, voluntariness, requires that the conditions for consent must be free of coercion. The Belmont Report defines coercion as an “overt threat of harm” or an offer that is “excessive, unwarranted, inappropriate, or improper” (NCPHS, 1979, Part C, para. 11). The predominant issue for the immigrant population is not coercion as defined here, but rather something more subtle. It is an issue of power imbalance. Feminist theory offers a perspective to think about issues involving power, dominance, and privilege. Sherwin (1998) has produced an alternative interpretation of autonomy by applying feminist theory. Though her focus is clinical ethics rather than the research ethics examined here, the issues she identifies are applicable.

It is important to recognize that the status of the researcher and the status of a potential research subject from the immigrant community is often unequal. Members of the immigrant communities are often poor, with little education. Sherwin (1998) points to the strength of the principle of autonomy: “A principle insisting on protection of patient autonomy can be an important corrective to such overwhelming power imbalances” (p. 22). However, she also acknowledges that determining how a power imbalance interferes with autonomy is not well understood (Sherwin, 1998).

Warren (1989) also looks at ethics from a feminist perspective. She makes the important point that “Which questions moral philosophers choose to study—and choose not to study—is itself a moral issue, yet one that is hardly ever raised” (Warren, 1989, p. 76). This could include the issues raised in this paper. She provides an interesting distinction between what she terms as “housekeeping issues” (these are personal issues) and “crises issues” (these are issues such as the withdrawal of life-support). What if, she asks, informed consent is viewed as a “housekeeping issue”? She illustrates this by asking the question, “How should we foster the conditions which make informed consent more likely?” (Warren, 1989, p. 79). This question urges reevaluating the relationship between researcher and potential subject. Warren (1989) then poses a potential solution to help overcome issues of power. She suggests that physicians (in our case we are thinking about researchers) consider themselves educators rather than authorities: “Teachers need to repeat, to connect with this student’s experience, and to get feedback from students so that inaccuracies can be corrected” (Warren, 1989, p. 82).

This approach could potentially address all three elements of the informed consent process. By attending to, and more importantly, connecting with, the audience, the researcher can better understand what information is needed and work toward a comprehensible presentation of that information. Feedback would also help the researcher determine if indeed

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2 Warren refers predominately to woman in her article. I am choosing to follow Sherwin in including minorities and other disenfranchised populations within the focus of feminist study.
there was comprehension of the necessary material. This is a much more relationship-centered approach.

Contemporary rhetorical theory is useful in interpreting and clarifying the problems that arise when a researcher is not connecting with the potential subject, not achieving the “bioethical ideal” of informed consent that Felt et al. describe. Chaim Perelman and Lucie Olbrecths-Tyteca (1991), in their book The New Rhetoric, rethink the Aristotelian notion of persuasion. They introduce a Theory of Argumentation: “the object of the theory of argumentation is the study of the discursive techniques allowing us to induce or to increase the mind’s adherence to the theses presented for its assent” [italics in original] (Perelman & Olbrecths-Tyteca, 1991, p. 4). What is being argued here is that informed consent is a form of persuasion, a form of argumentation, and that for ethical persuasion to take place, the researcher needs to fully understand the needs and values of the potential subject. What needs to be achieved is what Perelman and Olbrecths-Tyteca (1991) term a “contact of minds,” which they describe by saying, “The indispensable minimum for argumentation appears to be the existence of a common language, of a technique allowing communication to take place” (p. 15).

Segal (2005) makes the observation that ties this notion of a “contact of minds” to the process of informed consent:

Chaim Perelman and Lucie Olbrecths-Tyteca say the conditions for rhetoric include conditions for “a contact of minds,” and if these conditions are not met, then the people addressed do not properly constitute a rhetorical audience, and what is going on is not really rhetoric at all but something else: coercion, perhaps. (p. 91)

Rhetorical analysis can assist in examining the rhetorical situation of an informed consent conference.

The case study described by Martin and Lantos (2005) illustrates an occasion that lacks a contact of minds. Martin and Lantos conducted community-based research in a Latino community in Chicago where they were attempting to evaluate a community health worker asthma intervention program. While space does not allow a discussion of the merits of participatory research of this type, is should be noted that this critical methodology can be effective in eliminating power issues. In this case study, the researchers created a consent form using plain language translated into Spanish, to be administered orally to account for low literacy. However, their IRB insisted that they directly translate the four page consent form containing complex legal terminology and complex English. The two Latino agencies that were working with the researchers assured the researcher’s that most potential subjects would not be able to understand the form, but they would sign it anyway. This illustrates the ethical dilemma: arriving at a morally valid consent rather than a legally adequate consent.

2. THE FRAMEWORK: COMPLEX AND INTERDISCIPLINARY

This project is complex and interdisciplinary. Literature from the fields of rhetoric and scientific and technical communication will be used to examine the informed consent conference, as well as literature from bioethics and intercultural communication. The field of rhetoric, with a focus on persuasion and audience, and with grounding (in classical theory) within the realms of politics and ethics, can provide direction in identifying and describing
issues in the consent process. Scientific and Technical Communication (STC), a sub-field of rhetoric, can contribute practical ways to present the information.

This project places the informed consent conference as the location of rhetorical study. Rhetorical criticism will be used to identify and analyze the persuasive features of the conference. Pertinent literature comes from classical rhetoric, contemporary rhetoric (e.g., Burke, 1966, 1969; Leff, 1997; Miller, 1997; Perelman & Olbrechts-Tyteca, 1991), rhetoric of science (e.g., Fahnestock, 1998; Harris, 1997) and rhetoric of medicine (e.g., Segal, 2005).

From technical communication, literature on risk communication (e.g., Evia & Patriarca, 2012; Sauer, 1996, 2003) is important as well as literature that examines health communication needs and preferences of U.S Latinos (St. Germaine-Madison, 2009, 2010), ethical technical communication (e.g., Clark, 1987; Dombrowski, 2000; S. Katz, 1992), technical communication methodologies (e.g., Johnson, 2004; MacNealy, 1999) and critical approaches used in technical communication (e.g., Lay, 2002; Slack, Miller, & Doak, 2003; Thralls & Blyer, 2002).

Applicable bioethics literature comes from various areas of the field. This includes work from the area of human subject research (e.g., J. Katz, 1993; Mastroianni & Kahn, 2001), of rule-based ethics (e.g., Beauchamp & Walters, 1994), of feminist ethics (e.g., Sherwin, 1998; Warren, 1989), and of critiques of bioethics (e.g., Fox & Swazey, 2008; Hedgecoe, 2004).

Intercultural communication can also provide important insights (e.g., Albert, 1996; Triandis, Lisansky, Marín, & Betancourt, 1984). Finally, some general medical literature is relevant, especially the literature examining health disparities or cultural competency (e.g., Flores, 2000).

3. EXPLORATORY STUDY (IRB#I210P22682)

This exploratory study will examine the efficacy of a current informed consent process at conveying proscribed information to Latino adults. As Edgar & Rothman (1995) observe:

Despite the amount of time that IRB’s devote to examining the language of the consent form, they are not required to investigate whether the consent language they hammer out either is actually used on the floor or serves to educate the patient about the nature of the research he or she has consented to. (p. 493)

This research, the first phase of a larger project, will consider the informed consent conference on a broad level, including verbal and textual components. Specifically, the research questions are:

(1) What do Latino immigrants understand from the informed consent conference?
(2) After the conference is completed, what do Latino immigrants still want to know?
(3) How adequate is the structure of the conference?

The results of this study will inform future research looking to adapt and improve the informed consent process, especially for non-English-speaking immigrant populations.
3.1 Research Design and Methods for Data Collection

Terminology note: A distinction needs to be made between the term “researcher” referring to myself and “researcher” when referring to the researcher conducting the referenced clinical trial. That individual will be referred to as the clinical trial researcher (CTR). The participants in this study will be referred to as “analogue patients.”

- **Participant Selection:** A total of 20–25 participants will be recruited for this study. The location for recruitment is a Catholic church located in an urban community that serves a large Latino population. The parish priest and the administrator have agreed to allow this research to take place in the parish. Women and men, who are parents, will be recruited to participate. This location was chosen for several reasons. While it provides the investigator access to a convenient sample of participants, more importantly, this location provides the participants a place that is convenient, safe, and familiar. An additional protection will be provided to the participants by not referring to the name or location of the research site in any document other than the IRB application.

  At the suggestion of the parish administrator, the researcher will introduce the parish to the study after a Sunday mass. The congregation will be invited to participate. A table will be set up in the foyer where participants can sign up to participate in the study. Additionally, flyers will be posted around the church.

- **Experimental research design:** At the start of the session, the researcher will explain the intent of the study and will read aloud this study’s informed consent form in Spanish and ask for questions or concerns. Signatures are not required. The researcher will then verbally administer a short demographic questionnaire (attached) and a health literacy questionnaire, the SAHLSA-50 (Lee, Bender, Ruiz, & Cho, 2006). Health literacy refers to the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.

  This research employs the concept of analogue patients. Analogue patients are research participants who are asked to imagine that they are the patient, or in this case a potential clinical trial participant, in a particular medical circumstance. According to Blanch-Hartigan, Hall, Roter, & Frankel (2010), “this methodology has been used in previous studies in an attempt to understand patient perceptions when an actual patient population is not available” (p. 316).

  In this study the analogue patients, recruited from the church, will be asked, individually, to view two videos. The first is a priming video, which features the CTR explaining why they are being asked to enroll in this study. The CTR will provide the background necessary for the analogue patient to understand why the analogue patient’s physician has suggested they consider participating in a clinical trial. The analogue patient will then view a second video in which the CTR conducts a conventional clinical trial recruitment conference with the patient. Both of these videos are conducted in Spanish. The analogue patient will have the referenced informed consent form from this study, translated into Spanish, (attached) to consult while watching the video. The use of videos provides a consistent stimulus for this study.

  The video of the recruitment conference uses the script from an actual ongoing study “NET-Works”: Now Everybody Together for Amazing and Healthy Kids. The CTR is an enroller for Spanish-speaking participants in the NET-Works study.
Permission to use this script was given by the Project Director, Division of Epidemiology & Community Health, at a major university. This study was chosen, in part, because it seeks to enroll healthy patients. Healthy patient enrollment is a situation that is easier for an analogue patient to imagine than being asked to imagine they are suffering from a chronic or serious illness.

An interview, which will be audio recorded, will follow the viewing videos to explore the research questions. An interview format was chosen over a focus group format after considering the advantages and disadvantages of each method as well as the cultural values of the analogue patients. For example, the cultural value of *simpatía* (Triandis et al., 1984) may play a role since Hispanics typically do not like to create conflict or openly disagree with someone. Therefore, a strong opinion verbalized in a focus group may effectively extinguish other opinions.

3.2 Approach for Analysis

A transcript will be made from the audio recordings of each interview. These transcripts will then be translated into English. The responses to the questions and any other conversation will initially be sorted into the following categories, which are based on the research questions:

- Comments related to elements of informed consent: autonomy, nature of the illness, risks and benefits, propose of the treatment or procedure, or the nature of the treatment or procedure.
- Comments that seek information not provided.
- Comments regarding the process, including materials provided

After initial categorization, the sorted data will be re-examined for efficacy of the framework and for additional themes. Further categorization will then be done. A colleague will sort a minimum of 10% of randomly selected raw data. The level of agreement in terms of the percentage of items sorted by myself and my colleague will measure the inter-rater reliability. The data will be analyzed descriptively, using rhetorical analysis to draw conclusions. In addition to examining the transcript for direct answers to the research questions, the transcript will be analyzed against the demographic data and the SAHLSA scores.

This study will be completed in the summer of 2013.

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