EXAMINING THE FACTORS AFFECTING THE INCLUSION OF NON-ENGLISH SPEAKING INDIVIDUALS IN CLINICAL RESEARCH

by

Ann Rebecca Johnson

A dissertation submitted to the faculty of
The University of Utah
in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

in

Public Health

Department of Family and Preventive Medicine

The University of Utah

August 2014

The University of Utah Graduate School

STATEMENT OF DISSERTATION APPROVAL

The dissertation of Ann Rebecca Johnson

been approved by the following supervisory committee members:

Stephen C. Alder	, Chair	4/18/2014 Date Approved
Jeffrey R. Botkin	, Member	4/18/2014 Date Approved
Lynne Durrant	, Member	4/18/2014 Date Approved
Joseph Stanford	, Member	4/18/2014 Date Approved
James VanDerslice	, Member	4/18/2014 Date Approved

and by Stephen C. Alder , Chief of

the Division of Public Health

and by David B. Kieda, Dean of The Graduate School.

ABSTRACT

The purpose of this project was to examine the factors that pertain to the inclusion of non-English speaking (NES) individuals in clinical research and recommend strategies for improving their inclusion. Factors were considered from the perspective of academic medical centers as well as clinical researchers and research staff. Strategies were recommended based upon the assessment of these factors.

A case study was used to evaluate the comprehensive policies and procedures of 12 academic medical centers in order to describe their current translation and interpretation policies. Case institutions were selected based upon (a) their level of federal funding, (b) their geographic location in a state with higher proportions of the population that do not speak English, and (c) the comprehensive nature of their policies. After collecting all of the relevant written policies and procedures for each institution, qualitative analysis was performed in order to identify common themes. Five major themes were identified, including translation process, use of the short form consent process, representation of the Belmont Report principles, representation in the Institutional Review Board (IRB) application, and use of interpreters. Four minor themes were also identified.

A study was also conducted to evaluate the perceptions of researchers and research staff toward the inclusion of non-English speaking patients in research. A behavioral framework was used to identify relevant constructs and subsequently design an online survey and conduct in-depth interviews. Most survey respondents (97.7%)

indicate that they have some knowledge of the issues concerning inclusion of non-English speaking patients and 62.6% indicated that they probably or definitely intend to use language services in a future research project to facilitate inclusion of non-English speaking patients. Three primary themes were identified based on the in-depth interviews: (a) researchers had a developed awareness of the NES patient and research cultures, acknowledging that research validity, research participant justice, and the institutional expectations for conducting research must be taken into account; (b) researchers engaged in the process of weighing the costs and benefits of including NES patients in research; (c) researcher's connected the availability of resources and their own preparation to their feelings of self-efficacy.

Recommended strategies for improving the inclusion of non-English speaking individuals in research were presented in detail. These strategies focus on increasing researcher preparation and reducing barriers perceived by the researchers. Strategies for increasing preparation include bringing up the topic of including NES individuals during the planning stages of a study, knowing the local population and those served by the institution, and establishing clear expectations and guidelines for how to appropriately enroll NES individuals. Strategies for reducing barriers include increasing availability of language translation and interpretation services, as well as improvements and flexibility for informed consent documentation and processes.

For ERiK

TABLE OF CONTENTS

LIST OF TABLES

ACKNOWLEDGMENTS

I am grateful for the academic support and guidance from Steve Alder, Jeff Botkin, Jim VanDerslice, Lynne Durrant, and Joe Stanford. I am appreciative for the help of Peter de Schweinitz and Caren Frost during the initial and final stages, respectively, of this project. I also wish to give a special thanks to John Stillman and the IRB staff and members at the University of Utah, who have given of their time and expertise to help further my education and this project.

CHAPTER 1

INTRODUCTION

The health of racial and ethnic minority populations in the United States has become a key focus of public health officials and agencies. The Department of Health and Human Services Office of Minority Health (2013) states that "[t]hese populations experience higher rates of illness and death from health conditions such as heart disease, stroke, specific cancers, diabetes, HIV/AIDS, asthmas, hepatitis B, and overweight and obesity" (Why We Were Established section). These populations also experience limited English proficiency (LEP), which has been shown to be associated with poor health status (DuBard & Gizlice, 2008), fewer physician visits (Derose & Baker, 2000) and possible medical errors due to the physician's diminished ability to communicate with the patient (Flores et al., 2003; Karliner, Perez-Stable, & Gildengorin, 2004). This provides evidence that the inability to speak English is also relevant to the experienced health disparities.

It is well stated by Dawson and Verweij (2007) that "public health is a contested concept" (p. 11). After reviewing various definitions of public health from the literature, they conclude that the practice of public health is a "collective intervention that [aims] to promote and protect the health of the public" (Dawson & Verweij, 2007, p. 21). As part of this definition, these authors posited that three qualifications lead to the meaning of public health: (a) individual health is relevant only as it contributes to the health of the population and is seen in aggregate; (b) there is a distributive dimension to health within a population; and (c) there are societal and environmental determinants that influence the

health of the public (Dawson & Verweij, 2007).

With these three qualifications of public health in mind, a recent public health initiative in the United States called Healthy People can be reviewed. This initiative is based on a 1979 Surgeon General's Report and has provided national goals and objectives for improving public health since 1990. Healthy People 2000 proposed that the United States must attain three primary goals in order to achieve health for all Americans. These goals are as follows: (a) increase the span of healthy life for all Americans, (b) reduce health disparities among Americans, and (c) achieve access to preventive services for all Americans. Subsequently, Healthy People 2010 and 2020 were released, with the stated focus for Healthy People 2020 being to "identif[y], measure[e], trac[k], and reduc[e] health disparities through a determinants of health approach" (Healthy People, 2010).

Comparing Dawson and Verweij's qualifications of public health to the goals and foci stated in Healthy People, we can see that they account for an aggregative (population) dimension, addressing the health needs of the public in aggregate; a distributive dimension, acknowledging that there are health disparities within the population if health needs are not addressed equally; and the prioritization of societal and environmental determinants and their effect on health and health disparities.

The term *health disparity* has become a public health buzzword, as well as an integral component in the discipline of public health, as noted previously. Developing *Healthy People 2020* (Healthy People, 2008) defines *health disparity* as

> a particular type of health difference that is closely linked with social or economic disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater social or economic obstacles to health based on their racial or ethnic group, religion, socioeconomic status, gender, mental

> health, cognitive, sensory, or physical disability, sexual orientation, geographic location, or other characteristics historically linked to discrimination or exclusion. (p. 46).

Health disparity has obvious ties to the principle of justice, where disparity espouses ideas of injustice and inequality. Rawls (1971) considered the ideas of justice presented by various philosophers and refers to justice as "fairness." He elaborated further with two main principles of justice as follows (Rawls, 1971):

1. Each person is to have an equal right to the most extensive basic liberty compatible with a similar liberty for others.
2. Social and economic inequalities are to be arranged so that they are both (a) reasonably expected to be to everyone's advantage, and (b) attached to positions and offices open to all.

In this discussion, Rawls (1971) posited a simple definition of injustice as "inequalities that are not to the benefit of all" (p. 62). Considering these statements, it could be concluded simplistically that justice is fairness as well as the absence of inequalities that are harming others and that justice is increased as health disparities are reduced, thus improving access to health care to the benefit of the whole population.

The Belmont Report (U.S. Department of Health, Education, and Welfare, 1979) echoes this discussion of justice, emphasizing the importance of this principle when selecting research participants for study. Federal regulations in United States have thus required that equitable selection of research participants be directly considered by an institutional review board (IRB) when reviewing research. Consider the following statement from the Belmont Report:

> Injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects

> fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. (U.S. Department of Health, Education, and Welfare, 1979)

The equitable selection of non-English speaking (NES) research participants is a growing concern as the ethnic and racial minority population in the United States increases, especially when being a member of this population is tied to increased health disparities. Justice requires facilitation and inclusion of all eligible persons from the population in research, so that the benefits of research are distributed as fairly as possible. Though these benefits may occur directly to the NES individual who participates, the benefits are also applicable to this community as a whole, providing generalizable knowledge for the prevention, treatment, and care for diseases experienced by NES and associated minority populations. Without their inclusion, the value of current public health and health care interventions and practices may be questionable when applied to this population, reducing the ability to improve access and eliminate disparities.

The purpose of this project was to establish a foundational understanding for how research institutions are currently approaching the inclusion of NES participants in clinical research. The first objective incorporated an analysis of institutional policies and procedures used when assessing and providing language services for clinical research. By gathering and analyzing published information about enrolling NES participants in research, identification of trends and themes is possible, allowing for the assessment of the strengths and weaknesses in current policies and practices.

The second objective was to identify the perceptions that exist among researchers and research staff when considering the inclusion of NES participants in clinical research. Understanding these perceptions creates the opportunity for institutions to address

barriers as well as negative or erroneous perceptions when implementing processes to improve access to research for NES individuals.

The third objective was to provide clear recommendations for increasing the inclusion of NES individuals in clinical research, based upon the current literature and the results of the first and second objectives.

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CHAPTER 2

DESCRIPTIVE CASE STUDY OF INSTITUTIONAL POLICIES FOR INCLUDING NON-ENGLISH SPEAKING INDIVIDUALS IN CLINICAL RESEARCH

Abstract

The purpose of this case study is to describe current policies for including non-English speaking individuals in clinical research as well as language translation and interpretation policies at academic medical centers in areas of the United States with higher proportions of the population that do not speak English. This study explores the policies in order to present what these policies require and how to meet the requirements. Policies were obtained through online searches for information posted on institutional websites, as well as email requests for policies from the human research protection program. Five major themes were identified, including translation process, use of the short form consent process, representation of the Belmont Report principles, representation in institutional review board (IRB) applications, and use of interpreters. Four minor themes were also identified.

Introduction

The equitable selection of non-English speaking (NES) participants is a growing concern as the ethical and racial minority population in the United States increases, especially when being a member of this population is tied to increased health disparities

(Derose & Baker, 2000; DuBard & Gizlice, 2008; Flores et al., 2003; Karliner, Perez-Stable, Gildengorin, 2004). Consider the following statement from the Belmont Report:

> Injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. (U.S. Department of Health, Education, and Welfare, 1979)

There is very little centralized information regarding the policies and procedures followed by academic medical centers in terms of inclusion of NES individuals in research and the necessary language translation and interpretation services for inclusion. While the federal laws and regulations governing both clinical health care and clinical research specify the standards that academic medical centers must follow, the regulations are silent regarding the procedures that should be used to accomplish compliance with the requirements. Institutional review boards (IRBs) are charged with the task of enforcing the equitable selection as well as translation and interpretation requirements for clinical research and institutional policies and procedures have also been created to address the issue; however, a national standard does not exist for the content of the policies and procedures, or for the decision-making process of IRBs. Thus, the quality and complexity of these policies and procedures may vary between institutions.

Regulatory Background

In 1964, the federal government passed the Civil Rights Act, which prohibits any institution that receives federal funds from discriminating based on gender, age, race, and national origin, including those who cannot speak English. In response to this prohibition, Title VI of the Civil Rights Act recommended that institutions provide interpreters to

those who cannot understand or speak English. An Executive Order was signed in 2000, requiring federal agencies to identify the needs for persons with limited English proficiency and to develop and implement systems to provide services to allow meaningful access for those persons (Executive Order No. 13166, Improving Access to Services for Persons With Limited English Proficiency).

Title VI guidance defines a "Limited English Proficient Individual" as one "who [does] not speak English as [his/her] primary language and who [has] limited ability to read, write, speak, or understand English" ("Guidance," 2003). The language services provided for limited English proficient individuals can vary widely, depending on the frequency that these individuals are in contact with a particular program, service, or facility. Increasing language services in the health care field is typically accomplished by providing interpreters for limited English proficient (LEP) individuals; however, translation of written materials is also of interest to institutions and agencies wishing to expand access for limited English proficient individuals ("Guidance," 2003). For the purposes of this paper, the term non-English speaking (NES) participant is used instead of limited English proficient participant, as NES participant is the term more commonly used in reference materials and institutional policies for human subject research. However, it is acknowledged that the term is partially inaccurate, as it implies a person does not speak English, when in fact the person may have limited English proficiency.

The United States Department of Health and Human Services (USDHHS) Office of Human Research Protections (OHRP) and the U.S. Food and Drug Administration (USFDA) oversee the primary federal regulations that govern clinical trials and other human subject research. In regard to NES research participants, the federal regulations

provide requirements specific to informed consent (Public Welfare, 2009, §§ 46.116–117; for ease in referencing, only DHHS regulations are cited in the background descriptions; full reference to DHHS and FDA regulations are provided in Table 1). Additionally, the DHHS and FDA regulations and guidance also discuss the concepts of equitable selection of subjects as well as investigator resources. While the regulation and guidance currently available does not directly interpret equitable selection of subjects and investigator resources in the context of NES research participants, these concepts are used in this manner for the purposes of this study.

A discussion of the regulatory background and the Association for the Accreditation of Human Research Protection Programs (AAHRPP) elements for consent process, documentation of consent, equitable selection of subjects, and investigator resources is presented subsequently. The AAHRPP elements are included as another common standard for human research protection programs (HRPPs), as AAHRPP is currently the largest HRPP accrediting agency in the country, with 192 accredited institutions as of January 2014 (AAHRPP, n.d.). These regulatory components provided the basis for the development of initial codes for the analysis conducted in this study.

Consent Process

As a general requirement for the informed consent process, Public Welfare (2009, § 46.116) states, "The information that is given to the subject or the representative shall be in language understandable to the subject or the representative" (Public Welfare, 2009). The methods for providing this information to NES participants may be in two formats: a written translation of the consent as well as a verbal interpretation of the information discussed during the consent process. AAHRPP elements also directly

Table 1. Initial Codes and Criterion References

	Codes	Federal regulations and guidance	AAHRPP elements[a]
Consent process	Translation of written consent Interpretation of verbal consent process	45 CFR 46.111 (a) (4) 45 CFR 46.116 21 CFR 56.111 (a) (4) 21 CFR 50.20 A Guide to Informed Consent - Information Sheet. FDA, 2011 (USFDA, 2011) Institutional Review Boards Frequently Asked Questions - Information Sheet. FDA, 2011 (USFDA, 2013)	II.3.F III.1.F
Documentation of consent	Option for full consent document translation Option for short form consent document translation Using the full consent document versus the short form consent document	45 CFR 46.111 (a) (5) 45 CFR 46.117 (b) 21 CFR 56.111 (a) (5) 21 CFR 50.27 (b) Obtaining and Documenting Informed Consent of Subjects Who do not Speak English. OHRP, 1995 (Lin, 1995) Informed Consent FAQs. OHRP (USDHHS, n.d.) A Guide to Informed Consent - Information Sheet. FDA, 2011 (USFDA, 2011)	II.3.F III.1.F
Equitable selection of NES participants		45 CFR 46.111 (a) (3)[b] 21 CFR 56.111 (a) (3)[b]	II.3.C* III.1.E*

Table 1. Continued

	Codes	Federal regulations and guidance	AAHRPP elements[a]
Investigator resources	Availability of translation and interpretation services Financial resource planning for costs incurred for translation and interpretation services Training of research personnel for enrolling and interacting with NES participants Training of translators and interpreters specifically for research interactions Translation of other study materials beyond informed consent Interpretation of other verbal discussions beyond informed consent	45 CFR 46.107 (a)[b] 21 CFR 56.107 (a)[b]	II.3.A

[a] AAHRPP (2014)

[b] Not specific to NES inclusion

reference this statement and consent process methods (AAHRPP, 2014).

For this study, policies were evaluated to determine if the institution describes the requirements for a consent process specific to the NES population, which includes translation of written consent and interpretation of the verbal consent process. Policies were also assessed to determine if the institution specified how the translations should be obtained and the interpretations accomplished in a manner acceptable to the institution.

Documentation of Consent

The regulations (Public Welfare, 2009, § 46.117) describe the allowable methods of documenting informed consent: either a full written consent document, which is the traditional method; or a short form written consent document. A short form document is defined as, "[a] document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative" (Public Welfare, 2009). Both DHHS and FDA regulations allow for use of either a full written consent document or a short form written consent document, and AAHRPP elements reflect these regulations (AAHRPP, 2014). Investigators may use either method to obtain consent from NES participants, at the discretion of an IRB, by translating either the full written consent form or the written short form. When using the short form method, it is also required that a written summary of the elements be created and used in the oral presentation of informed consent and then given to the participant with a copy of the written short form. Often, the full consent form in English is used as the written summary to accompany the short form document.

Guidance from OHRP that specifically addresses enrolling NES participants states:

> §46.117 (b) (2) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary. (Lin, 1995)

The guidance further describes the details of the short form consent process when used with non-English speaking participants, including how the process should be documented by the reviewing IRB and the investigator. OHRP provides additional guidance about informed consent, stating,

> Subjects who do not speak English should be presented with a consent or permission document written in a language understandable to them. OHRP strongly encourages the use of such a document whenever possible. (U.S. Department of Health and Human Services, n.d.)
>
> It is the responsibility of the IRB to determine which of the procedures at §46.117 (b) is appropriate for documenting informed consent in protocols that it reviews. (Lin, 1995)

The FDA also provides similar guidance, which states,

> If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation. (FDA, 2011)
>
> While a translator may be used to facilitate conversation with the subject, routine ad hoc translation of the consent document may not be substituted for a written translation. (FDA, 2013)

This guidance from both OHRP and the FDA has been interpreted to mean that a full consent document is preferable over use of the short form document, and thus, translation of the full consent document is preferred.

For this study, policies were evaluated to determine if the institution describes the methods for documenting informed consent using either a full translation or a short form

translation. Policies were assessed to determine if all elements required by federal regulation for how to use the short form method were addressed. Additionally, policies were evaluated to determine if the institution directly describes when the use of a full translation versus a short form translation is acceptable to the institution.

Equitable Selection of NES Participants

Both DHHS and FDA regulations require that equitable selection of research subjects be directly considered by the IRB when reviewing research (Institutional Review Boards, 1981; Public Welfare, 2009). AAHRPP elements reference these regulations directly (AAHRPP, 2014). Although the regulations and guidance do not provide direct interpretation regarding the inclusion of NES participants, exclusion from research based upon language alone is generally viewed as unacceptable within the research community, as reflected in the previously quoted statement from the Belmont Report.

For this study, policies were evaluated to determine if the institution describes the requirement or need for equitable selection specifically with the NES population, as well as whether there are methods or plans in place to ensure that individuals from the NES population can be included in research conducted by the institution.

Investigator Resources

The codes for investigator resources are indirectly derived from federal regulation and AAHRPP elements. DHHS and FDA regulations indicate "the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice (Institutional Review Boards, 1981; Public Welfare, 2009). This does not include a direct

interpretation within the context of having resources for enrolling NES participants. However, AAHRPP (2014) elements directly indicate that an IRB should evaluate whether research has the necessary "resources for participant communication, such as language translation services" (p. 82).

Specific interpretation of these references was required for the purposes of this study, in order to derive codes applicable to enrolling NES participants. Polices were thus evaluated to determine if the institution describes the requirements and methods for the following items:

- Availability of translation and interpretation services
- Financial resource planning for costs incurred for translation and interpretation services
- Training of research personnel for enrolling and interacting with NES participants
- Training of translators and interpreters specifically for research interactions
- Translation of other study materials beyond informed consent
- Interpretation of other verbal discussions beyond informed consent

Study Design

To improve the level of access to and the quality of language services provided to clinical patients in a research setting, it is important to first understand how institutions are currently addressing this problem. The purpose of this study is to explore the policies of institutions conducting clinical research in order to present *what* these policies include (requirements) and *how* the institutions accomplish their policies (criteria and methods). Understanding the diversity of policies and the options currently being used to fulfill

federal requirements can be valuable to institutions that desire to design and implement solutions for their own patients. A descriptive, multiple case study is well suited to answer these questions (Aday, 2006; Creswell, 2007), highlighting thorough policies from institutions across the country.

Methods

Cases were selected according to the following four criteria.

Criterion 1: An institution that is in the top 100 NIH-funded research institutions in 2012 (USDHHS, 2012). This criterion was utilized for two primary reasons. First, federally funded institutions are the focus of Title VI of the Civil Rights Act requiring that an appropriate level of language services be provided to persons with limited English proficiency. Second, institutions with higher levels of federal funding for research are most likely to be conducting a greater amount of human subject research. As such, it is presumed that these institutions have robust human research protection programs to accommodate such research, which is likely to include written policies and procedures that can be reviewed.

Criterion 2: An institution that is or includes an academic medical center. As this case study focuses on clinical research, the presence of a medical center is an indicator for the conduct of clinical research.

Criterion 3: An institution that is within a state in the 3rd or 4th quartile for percentage of the state population that reports speaking English "less than very well" according to the American Community Survey (U.S. Census Bureau, 2009). We assumed that institutions in states with a higher percentage of NES individuals are more likely to encounter NES patients who are eligible for clinical research. Thus, it is more likely that

these institutions have written policies and procedures for providing language services to these individuals. Those who report speaking English "less than very well" are being categorized as NES for the purposes of this study.

Criterion 4: An institution that has policies and procedures for enrolling NES participants, including provisions for language services. This is a required criterion to fulfill the purpose of the study. Documents that were considered to demonstrate policy or procedure include the following:

- Standard Operating Procedures (SOPs) or other formal policy/procedure document
- Guidance documents or investigator handbooks
- IRB (or other review committee) applications with relevant questions/instructions
- IRB (or other review committee) review checklists with relevant questions/instructions
- Templates (consent forms, letters, etc.) for use in research with relevant questions/instructions
- Online information pages or instruction pages
- Training materials

Of the top 100 NIH-funded research institutions, 85% represented an institution that is or includes an academic medical center. Seventy percent were located in states within the 3rd or 4th quartile for percentage of the state population that reports speaking English "less than very well." Fifty-nine institutions were eligible for inclusion based on the four criteria for a case (Table 2).

Table 2. Number of Institutions Meeting Case Criteria

Criteria	Institutions meeting criteria
Criterion 1: An institution that is in the top 100 NIH-funded research institutions in 2012.	100
Criterion 2: An institution that is or include an academic medical center.	85
Criterion 3: An institution that is within a state in the 3rd or 4th quartile for percentage of the state population that reports speaking English "less than very well" according to the American Community Survey.	70
Criterion 4: An institution that has policies and procedures for enrolling NES participants, including provisions for language services.	93
All 4 criteria met	59

A review of the policies available online was conducted for the 59 eligible institutions in order to select cases. The decisions for case selection were influenced by the primary researcher's IRB and regulatory background and understanding of this issue while performing the preliminary review of policies for the 59 eligible institutions. A purposive sampling approach (Babbie, 2013) was used and cases were selected based on two factors: (a) the comprehensive nature of the policies and procedures available via the internet and (b) the inclusion of original policies or practices for providing language services to NES participants. Because of this sampling method, the cases selected are not to be considered a representative sample of all institutions. While other eligible institutions had similar policies or practices compared to the 12 cases, the cases selected represented the most comprehensive policies. Policy and procedure documents were obtained through an online search of information posted on institutional websites, as well as telephone and email requests for written policies and procedures from institutional representatives from the HRPP.

Initial codes were developed prior to document review, representing information that was anticipated based upon federal regulations and AAHRPP accreditation standards (Table 1). Additional codes were then developed as new information was observed in the documents, to allow for flexibility in analysis and to capture new observations. Observations, codes, and themes were labeled by document source and by institution to enable combination and comparison. Thematic memos were written throughout the process to document preliminary patterns in the codes and explore possible themes. To ensure credibility of the codes and themes, an expert familiar with the federal regulations regarding human subject research and HRPP policies and procedures reviewed coded

observations.

Case Descriptions

The 12 cases selected are displayed in Table 3 and discussed subsequently. The cases represent 10 states, with a percentage range for individuals reporting their ability to speak English "less than very well" from 4.9-19.7% of the total state population (U.S. Census Bureau, 2009). Of the 12 cases, 10 have accredited human research protection programs. State laws governing informed consent in the research setting influence institutions in California and Illinois. Policies and practices for these institutions reflected this influence. This is discussed in subsequent sections of the paper. The majority of the documents reviewed originated from the institution's IRB, research compliance office, human research protection office, or equivalent. An overview of the HRPP accreditation status and documents reviewed for each case is presented in Table 4.

Cross-Case Comparison

Analysis revealed five major themes and four minor themes among the policies (Table 5). These themes represented the main policy components that were included in the institutional policies and are discussed in detail in this section.

Translation Process

The most prominent theme for each institution was the set of requirements for the written translation process. The federal regulations and guidance do not delineate preferred or required translation techniques or methods, but only state that documents should be translated into "a language understandable to the subject" (Institutional Review Boards, 1981; Public Welfare, 2009). Thus, each institution included a thorough

Table 3. Case Geography and Population Demographics

Institution	State	Total population[a]	% less than "very well"[a]	Quartile for less than "very well"
University of California Irvine University of California San Francisco Stanford University	CA	34,423,976	19.7	4th
University of Texas Health Science Center at San Antonio	TX	22,850,447	14.5	4th
Columbia University	NY	18,144,411	13.3	4th
University of Illinois at Chicago	IL	11,950,566	9.6	4th
Tufts University	MA	6,144,975	8.8	4th
Fred Hutchinson Cancer Research Center	WA	6,219,654	7.9	3rd
University of Colorado Denver	CO	4,624,055	6.9	3rd
Oregon Health and Science University	OR	3,566,512	6.4	3rd
Virginia Commonwealth University	VA	7,419,283	5.6	3rd
Duke University	NC	8,791,977	4.9	3rd

[a] (U.S. Census Bureau, 2009)

Table 4. Accreditation Status and Documents Reviewed by Case

Institution	AAHRPP accreditation[a]	No. of documents reviewed	Primary types of documents reviewed
University of California Irvine	AAHRPP: 9/16/2005	21	SOPs and policy descriptions Flowchart diagrams for consent documentation methods Short form consent templates Protocol templates and instructions IRB applications and instructions
University of California San Francisco	AAHRPP: 12/16/2005	18	SOPs and policy descriptions Templates for the experimental subject's bill of rights, which acts as the short form consent document IRB applications IRB reviewer guides HRPP training presentations
Stanford University	AAHRPP: 3/17/2006	34	SOPs and policy descriptions Consent and short form consent templates IRB applications IRB reviewer checklist
University of Texas Health Science Center at San Antonio	AAHRPP: 6/11/2009	17	SOPs and policy descriptions Consent templates IRB applications and instructions
Columbia University	AAHRPP: 3/12/2010	20	SOPs and policy descriptions Short form consent templates Protocol templates IRB application templates
University of Illinois at Chicago	AAHRPP: 3/12/2010	14	SOPs and policy descriptions Consent and short form consent templates IRB applications IRB review guides
Tufts University	N/A	16	SOPs and policy descriptions Short form consent templates Protocol templates IRB applications
Fred Hutchinson Cancer Research Center	AAHRPP: 3/14/2008	16	SOPs and policy descriptions Short form consent templates and instructions Interpreter and translator certification forms and instructions IRB application templates and instructions

Table 4. Continued

Institution	AAHRPP accreditation[a]	No. of documents reviewed	Primary types of documents reviewed
University of Colorado Denver	AAHRPP: 6/11/2009	13	SOPs and policy descriptions Short form consent templates IRB applications and instructions IRB reviewer checklists
Oregon Health and Science University	N/A	9	SOPs and policy descriptions Short form consent templates and instructions IRB applications and instructions
Virginia Commonwealth University	AAHRPP: 6/15/2007	17	SOPs and policy descriptions Protocol templates and instructions IRB applications and instructions IRB reviewer forms
Duke University	AAHRPP: 3/27/2009	18	SOPs and policy descriptions Consent templates and samples IRB applications IRB reviewer checklists

[a] AAHRPP (n.d.)

Table 5. Major and Minor Themes

Major themes	Minor themes
Translation Process	Cost for Translation Services
Use of the Short Form Consent Process	Evaluating Informed Consent
Representation of the Belmont Report Principles	Comprehension
Representation in the IRB Application	Language Services Outside of Informed Consent
Use of Interpreters	Materials to Support the Investigator

description of their own preferred or required translation processes, starting with how to obtain a written translation of a study document—mainly consent documents—and following through to the process for how to receive IRB approval for the translated documents. The basic process for obtaining a written translation was fairly consistent across all institutions, commonly including a requirement for the qualifications of the translator and a method for ensuring translation accuracy. However, specific institutional requirements for fulfilling this translation process varied to a greater degree.

Translator Qualification

All institutions made a statement in policy about the need for a qualified translator, although different terminology was used across sites. Seven institutions presented the concept of a *certified translator*, although only one institution provided a formal definition. While the definition of *certified* was generally vague within the policies of the other six institutions, three institutions mentioned a notarized statement from the translator as a way to determine that he or she was certified.

Certification was distinguished from a *qualified translator*, which was generally defined as someone who has characteristics such as speaking a language natively, has evidence of fluency in a language, has education in the language (e.g., a bachelors degree in Spanish), and has knowledge of medical, scientific, and/or legal terminology. All 12 institutions used the term *qualified* or a term similar, such as *professional* or *acceptable*, but the degree to which this was defined varied greatly. Ultimately, all institutions found either a certified translator or a qualified translator to be acceptable options.

Three institutions mentioned the concept of cultural sensitivity in regard to the written translation, stating that a translation is accurate only when the words and cultural

meaning are translated. One institution formally requires the certified or qualified translator to document his or her bicultural qualifications in order ensure cultural sensitivity in the translation. Additional discussion on this idea is presented in the next section.

IRBs at three institutions specifically endorsed a translation service that was either internal to the institution or a contracted translation company. Two other IRBs provided the names of translation companies, but specifically did not endorse the translations from any of the companies referenced.

Methods for Ensuring Translation Accuracy

All 12 institutions have policies that recommend or require certain methods for ensuring the accuracy of a written translation. The concept of back-translation is required or recommended at nine of the institutions. Back-translation is a three-step process that involves first translating the document from English into the desired language, then translating the non-English version back into English, and finally reconciling the differences found between the two English versions such that a perfected non-English translation can be created. Two institutions also accept a double-forward translation, where the English document is translated into the desired language twice and then the two non-English versions are reconciled into a perfected translation. With both of these methods, the institutions describing these options also state that two translators working together to compare the different versions should perform the processes.

While the full variety of translation options allowable at each institution cannot be fully detailed in this paper, one factor that influenced the method of translation was the risk level of the study. Two institutions require the back-translation method for studies

that are determined to be greater than minimal risk, but require only a single translation by a qualified translator for minimal risk studies. Another institution uses the risk level to delineate when a certified translator must be used, indicating that a certified translator is required for greater than minimal risk studies, while a translator who can demonstrate fluency is required for minimal risk studies.

As mentioned previously, three institutions include requirements for cultural sensitivity of the translation as a part of ensuring accuracy for the population to which the translation is presented. Two of these institutions' IRBs require that documentation be made to indicate that cultural sensitivity is addressed. As explained before, one institution requires that cultural sensitivity be a documented qualification for a certified or qualified translator before the IRB will approve the translated document. The second institution requires that a cultural consultant specific to the non-English speaking population be included as an ad hoc reviewer to the IRB, who can verify that the translation is appropriate for the intended population.

IRB Review Process for Translations

All of the institutions' IRB policies specify that translated documents may be submitted via an amendment or change application after initial approval of the English version, as a way limit retranslation and to ensure the translation will be made from the final English version. Ten institutions have policies stating that documentation of the translator's certification or qualifications must be provided to the IRB with the translated document. For the other two institutions, one explicitly states that this documentation is not required, while the other institution's policy is silent, presumably because the institution recommends use of their medical center's translation services office, which is

stated to be endorsed by the IRB. Two IRBs keep the credentials of translators on file, such that investigators do not have to submit this documentation each time the translator is used.

Use of the Short Form Consent Process

Another primary theme described in the policies of all institutions was the use of a short form for obtaining consent from NES participants. All 12 institutions had policies that described the details of the short form consent process that are required by the OHRP guidance (Lin, 1995), including the following:

1. The short form must be translated into the language understood by the participant;
2. The approved English consent document may serve as the informed consent summary sheet to be presented with the short form;
3. The witness must be fluent in both English and the language understood by the participant, which may be an interpreter assisting with the oral presentation;
4. The short form document should be signed by the participant and the witness; and
5. The English consent document should be signed by the person obtaining consent and the witness.

Each of the 12 institutions also has written policy regarding when the short form process may be used instead of a process using a fully translated consent document. Many institutions echo or reference the OHRP guidance (Lin, 1995), stating that use of a fully translated consent form is *preferred* or *encouraged*. The IRB criteria for

determining when the short form process is appropriate vary in detail and method across the 12 institutions; however, the criteria reviewed can be generally categorized as follows:

- Likelihood of NES encounter
- Numeric threshold
- Risk level of the study
- Ability to obtain full translation
- Short form process not allowed (Table 6).

Likelihood of NES Encounter

The level of likelihood for encountering an eligible NES individual was the most common criterion described in policy to determine if the short form consent process was appropriate for an individual study. This criterion is likely the result of current federal guidance. As stated earlier, FDA guidance indicates that routine use of an oral presentation using the short form is not acceptable, as the short form should be used for unexpected encounters.

The concept of *low likelihood* was most often described as an *unexpected* or *occasional* NES encounter, which is consistent with the FDA's terminology. *High likelihood* was thus the opposite of this, describing the NES encounters as *anticipated* or a *significant number or proportion*. Three of the nine institutions who used this criterion went on further to define low or high likelihood in numerical terms, thus providing a numeric threshold (discussed as the next criterion) for determining the use of either a fully translated document or a short form. Some policies also indicated that using the

Table 6. Criteria for Determining Use of Short Form Consent Process

Case no.	Likelihood of NES encounter	Numeric threshold	Risk level of study	Ability to obtain full translation	Not allowed
1	X	X			
2	X		X		X
3	X	X			
4	X			X	
5				X	
6	X	X	X		
7		X			
8					X
9	X				
10	X				X
11	X				
12	X				

NES population as a target population for the study was an example of high or certain likelihood.

Numeric Threshold

Again, as a likely result of OHRP and FDA guidance, four institutions have set numeric thresholds on the number of times a short form may be used for the consent process, preventing *routine* use. Three of these institutions utilize a fixed value, regardless of a study's overall enrollment goal, as follows: (a) one use per study; (b) three uses in the same language per study; (c) five uses in the same language within a 12-month period per study. The fourth institution uses a percentage of the overall enrollment goal as the threshold. In this case, 5% is used and defined as the threshold for *a significant number* of subjects.

Risk Level of the Study

Two institutions indicate that studies with greater than minimal risk may not be allowed to use the short form, as determined by the IRB. These institutions give examples of studies that may result in greater risk to participants, such as research on gene transfer, phase I clinical trials, research with a true placebo control, or research with the federally-defined vulnerable populations that are at greater risk for possible undue influence. Although not directly stated by either institution, some of these example scenarios may also have the possibility of a decreased benefit to participants, specifically phase I and true placebo-controlled studies.

From the opposite standpoint, increased benefit may be seen as a reason to allow the use of the short form in situations where other criteria described earlier are also met.

One institution implies this by indicating that a short form may be acceptable for a therapeutic study, so long as the NES encounter is also unexpected and the need for treatment is urgent.

Ability to Obtain a Full Translation

When describing the likelihood of NES encounter criterion for using the short form, a few institutions also add the caveat that a full translation of the consent document must not be available. One institution takes this a step further and implies that a full translation must not be available and cannot be obtained in an appropriate timeframe for enrollment of the NES participant. This institution presents this concept by describing the enrollment situation as either urgent or nonurgent, in combination with the likelihood of NES encounter criterion. Thus, an NES participant may be enrolled with the short form if the NES participant was encountered unexpectedly and the situation is urgent. In contrast, an NES participant must be enrolled with a fully translated consent document if the situation is not urgent and there is an acceptable time period for obtaining a full translation.

Short Form Process Not Allowed

Three institutions have policies that prohibit or strongly discourage the use of the short form in certain situations, although none of these institutions outright prohibits its use. The strongest policy against use of the short form is applied by one institution, which indicates that use of the short form is considered by the IRB to be a deviation, such that the short form should only be used in exceptional cases. In this case, when a short form must be used, a full translation must be obtained after enrollment and provided to the

participant at a later time.

One institution prohibits use of the short form at particular locations, based upon state law that requires use of a fully translated consent at these locations. The third institution strongly discourages the use of a short form with Spanish-speaking participants, given the high likelihood of an NES encounter in Spanish. However, the policy does not fully prohibit short form use in this case if strong justification is given by the investigator and accepted by the IRB.

Representation of the Belmont Report Principles

The Belmont Report (U.S. Department of Health, Education, and Welfare, 1979) highlights three core principles that guide the current federal regulations for research: respect for persons, beneficence, and justice. Each of these principles can be related to the issue of including NES participants in research and all 12 institutions did this directly in policy for at least one of the core principles.

Respect for Persons

This principle is associated with a participant's right to informed consent, which was easily tied into the policies of all 12 institutions, as informed consent is a prominent hurdle to overcome due to the language barrier between NES participants and investigators. It is also easily addressed in policy regarding NES participants because it is the only area where the federal regulations give direct requirements for this population specifically. Eleven institutions had policies that directly quoted or similarly expressed the regulatory statement that informed consent information should "be in language understandable to the subject" (Institutional Review Boards, 1981; Public Welfare,

2009). In all institutional policies, informed consent is by far the most addressed aspect of including NES participants in research and becomes a main focus of this paper. Thus, all remaining discussion on informed consent will be made in the other relevant sections.

Justice

Justice is discussed next, as it was the second most common principle addressed in policies specific to the inclusion of NES participants. This principle is associated with the equitable selection of participants for research. Of the 12 institutions reviewed, 11 include a statement in policy indicating that NES individuals should not be excluded from research participation based solely on their language if they are otherwise eligible to participate.

Three of the 11 institutions further tied this statement to the concept of direct benefit, indicating that inclusion is most important when a direct benefit to the participant is possible. One institution elaborates on this point and states that exclusion of NES individuals is a sensitive issue that must be considered, especially when the study offers the potential for benefit and no other standard of care treatment options are available or acceptable. Additionally, another three institutions also go on to reference local demographics, some including direct reference to the latest U.S. Census information for the state or local area, indicating that exclusion based upon language is not appropriate because of the large number of NES individuals that are served by the institution.

Four institutions propose direct methods for preventing exclusion of NES participants. Of these, three institutions indicate that the short form process may be used to prevent exclusion. The other institution asserts that translation of recruitment materials may be required in order to prevent exclusion.

Seven institutions require the inclusion of NES participants to be addressed in their initial IRB applications. All seven institutions require that justification be provided if NES individuals are excluded from the research, with one application asking for the justification to be *scientific* or *ethical*. Another application specifically indicates that *lack of resources* is not an acceptable justification. Additionally, two institutions ask a question about exclusion via the IRB continuing review application, requiring an explanation if any NES individuals were excluded because of their inability to speak English during the last approval period.

Beneficence

The final principle of beneficence embodies the concepts of risk and benefit, asserting that there should be as little risk as possible and as much benefit as possible, with the risk-benefit ratio being acceptable overall. When considering the inclusion of NES participants, beneficence is often linked to the principle of justice, as access to benefits should be equitable for NES and English-speaking individuals. However, beneficence is more directly related to the risks and benefits NES participants may specifically experience as individuals and as a group.

As mentioned previously, three institutions state that it is particularly important to include an NES person if there is the possibility for direct benefit at the individual level, though none indicate that this benefit be related to their status as an NES participant; in fact, this is more applicable to the principle of equal access to benefits, such that the NES status should not be relevant. The idea of benefit explicitly for NES individuals as a group can be implied when policies discuss this population being specifically targeted for a study, as it can be assumed the aims of the project are meant to benefit this population

as whole. Beyond this idea, there is little discussion in the institutional policies of risks and benefits specifically for NES individuals in research. One institution notably addresses the concept of risk, indicating that if language barriers cause the possibility of individual harm to become too great, it may be appropriate to consider exclusion of the NES individual. This institution encourages investigators to consider these possible added risks for NES individuals to ensure they remain balanced with the possible benefits. One other institution also approaches the concept of risk when discussing the informed consent process, stating that such a process for NES individuals should have procedures in place to ensure adequate communication and comprehension so that possible risks are minimized.

Representation in the IRB Application

Another major theme that emerged was the representation of this issue—inclusion of NES participants in research—in the IRB applications. There is great variation in the format and content of each institution's IRB applications. First, some institutions utilize application forms only, while others use a combination of application forms with research protocol documents. For the purposes of this project, an IRB application is defined as the full set of information required for a complete submission to the IRB, such that both of these format contingencies are taken into account.

Another difference is that some institutions utilize one version of the initial, new study application for all types of studies, while other institutions have separate versions of the application for different study types, such as exempt versus nonexempt studies; interventional versus observational studies; biomedical studies versus social/behavioral studies; and so on. Comparison across all types of applications becomes challenging and

for the sake of simplicity, comparisons in this section are described according to three categories of applications: initial (new study) applications, continuing review (renewal) applications, and amendment (modification) applications. However, it must be recognized that if an institution utilizes different applications for different study types, inclusion of specific questions in one application does not guarantee inclusion in the other applications.

Lastly, in considering how the IRB application represents policy specific to the inclusion of NES participants, it was necessary to separate the information that the policy says is required for IRB submission versus the information that the IRB application actually asks for directly. For example, some policies clearly indicate that a description of the informed consent process specific to NES participant must be described in the IRB application, yet the IRB application only asks for a description of the informed consent process overall without clear direction for addressing NES participants. Many IRB applications also had the capacity for NES considerations to be addressed under broadly written questions about the inclusion/exclusion criteria and resources used by the investigator. For this analysis, the IRB application was considered to be representative of NES policies if the application directly asked questions about NES participants or if the application included guidance for how to answer questions directly in terms of NES participants. Further investigation into how the IRB and investigators utilize broad topic questions to address NES considerations, when no direct guidance was included in the application, was not completed as part of this project.

Initial Applications

Questions about NES participants were most commonly seen in the initial applications with 11 institutions including NES-specific questions in the initial application (the initial application for the 12th institution was not accessible for analysis). Eight institutions directly ask if NES participants will be enrolled in or excluded from the study. Two of these identify NES individuals in a list of vulnerable populations that can be selected and, as mentioned earlier, seven institutions require justification if NES individuals are excluded.

In regards to the informed consent process and consent documentation, nine institutions asked questions about the overall consent process for NES participants, with six institutions directly asking if either a full consent translation or a short form consent process will be used. As part of the question(s) about the informed consent process, many applications direct the investigator to address plans for written translations, oral interpretation of the consent conversation, and the details of the step-by-step process for this interaction. One institution directly asked for an explanation for how the investigator will have the continued ability to communicate with NES participants throughout the study past initial enrollment.

Continuing Review Applications

Four institutions include NES-specific questions in their continuing review applications. All four institutions ask for the number of NES participants enrolled in the study during the last approval period, although each asks for this number differently. Two of these institutions ask for the number of NES participants enrolled to be separated from the total number enrolled, with one institution asking for this number to be further

separated into those enrolled using a fully translated consent document or the short form consent. Another institution combines the NES participant enrollment number with the number of vulnerable populations enrolled overall. The final institution asks only for the number of NES participants enrolled using the short form consent process, as a way to assess if the study has reached the numeric threshold for short form use set by policy (as described earlier). One institution directly asks if NES individuals were excluded because they did not speak English; however, another asks for more general reasons as to why NES individuals were not enrolled, such as the study being closed to enrollment or no NES individuals met the study inclusion criteria.

Amendment Applications

Amendment applications tended to be simple in their structure and did not include much substantial information or questioning about NES considerations. Broad topical questions were asked regarding the proposed amendment, which could easily include changes concerning NES participants, though not directly specified for NES considerations. Three institutions give instruction in the amendment application to include written translations of approved documents when applicable, with two of these applications including specific sections for updating translations.

Use of Interpreters

All 12 institutions had policies that discussed the use of interpreters when including NES participants in research; however, the details about interpreters were much fewer than for obtaining written translations. Two institutions' policies included a definition of interpretation as separate and distinct from translation. The themes that

emerged regarding the use of interpreters include interpreter qualifications, access to interpretation services, and additional resources for the interpretation process.

Interpreter Qualifications

Seven institutions described the need for an interpreter with appropriate qualifications. As with the concept of a qualified translator, different terminology was used across the sites, such as *qualified*, *professional*, or *certified*. Most institutions do not have a formal definition for a qualified interpreter; however, all give some indication as to how an interpreter can meet the institution's standard. According to most policies, an interpreter is considered to be qualified if he/she is fluent in both English and the desired language, has an understanding of medical terminology, and has enough experience to exhibit cultural sensitivity during the interpretation. At two institutions, documentation of the interpreters' qualifications must be provided to the IRB or other administrative research office.

Five institutions also addressed whether patient family members or study team members could act as interpreters in the research setting. Three institutions discourage the use of patient family members as interpreters due to the medical terminology that must be discussed and two of these institutions require that the patient formally waive the use of a qualified interpreter available through the institutions' medical centers. Only one institution has policy that indicates a family member is allowed to act as the interpreter. Four of these institutions also have policies that state study team members may act as the interpreter if fluent in the language spoken by the participant, but the institutions also remind that if a study team member acts as the interpreter and the person obtaining consent, he/she may not also act as a witness to the consent process.

Access to Interpretation Services and Additional Resources

Interpretation services available within the normal patient setting were easy to identify through the medical centers at each institution. Four institutions made reference to using the medical centers' interpretation services for research purposes, while the other institutions did not provide recommendation for the interpretation services that could be used. Furthermore, three institutions also provide additional information and resources for working with medical interpreters. Two institutions provide questions to consider that may be discussed between the study team and the interpreter in preparation for the consent process. The other institution provides links to online information about medical interpreters via professional interpreter organizations.

Minor Themes

The analysis also presented minor themes that are of interest. These are themes that were addressed by fewer of the institutions' policies or were not discussed in a great amount of detail in the policies. Though minor, these themes are relevant to the overall context of enrolling NES participants in research and are discussed further in this section.

Cost of Translation Services

This could be considered a subtheme to the translation process; however, it is being discussed separately as a minor theme because it was primarily coded under *investigator resources* as opposed to the codes for *consent process*. Eight institutions' IRBs made statements about the cost of translation services. These statements primarily indicate that the cost of translation services for study materials is the responsibility of the investigator. A few policies also state that costs may be high based upon the number of

languages needed as well as the complexity of the documents to be translated. Additionally, some policies indicate that investigators should prepare for the costs during the development of the study budget such that a study sponsor may pay for costs. Two institutions that have internal or contracted translation services available to researchers provided additional instruction about how to request a cost estimate on translation services for the study. Two institutions state that an investigator has the responsibility to ensure there are adequate resources for translation, though they do not specifically use the term *cost*.

Language Services Needed Outside of the Consent Process

Nine institutions have policies that discuss the need for language services outside of the consent process. Some address this for both translation and interpretation services, while others only address one of these components. General statements about the need for ongoing language services were made by seven of the institutions. Four institutions made specific reference to the methods of recruitment used specifically for NES participants and three institutions mention the translation or verbal interpretation of survey instruments and questionnaires.

Evaluating Comprehension during the Consent Process

Three institutions go beyond the basic statements that a translated consent document and an interpreter be used for the consent process and further indicate that an investigator should evaluate the NES participant's comprehension of the study. Two institutions specifically state that this is the responsibility of the investigator and that an NES participant should not be enrolled if understanding is questionable. One institution

provides a non-NES-specific evaluation tool and references its use by the investigator and the interpreter to determine the participant's level of comprehension.

Materials to Support the Investigator

It is worth noting the abundance of ancillary materials provided by IRBs to support investigators in enrolling NES participants. Many of these materials support institutional policy statements and were analyzed as such; however, the types of ancillary materials available are the focus of this section. This paper has previously mentioned that there are institutions with internal or contracted translation services as well those that provide information materials for working with an interpreter. Additionally, 11 institutions provide translated short form documents, a few with more than 20 different translations posted online for use. Four institutions provide translated consent document or HIPAA templates in Spanish, which reduces the amount of unique text translation for each study. All California institutions also provided translated versions of the Experimental Subject Bill of Rights, which state law requires be provided to all research participants. Lastly, five institutions provide checklists, quick guides, flowcharts, or summary instructions for the consent process with NES participants, which can be used by investigators to ensure compliance with institutional policy.

Discussion

The policies reviewed used a fairly consistent model that has three components: (a) the requirement, or what is required; (b) how to adhere to the requirement using specific criteria; and (c) how to adhere to the requirement using specific methods. Typically, both the specific criteria and the methods for adhering to the requirement are

necessary to perform the action appropriately. This is shown in Figure 1 with an example for the consent process for NES participants. In this example, federal regulation indicates that consent must be in a language understandable to the participant, and thus this is reflected as the requirement in policy. The criteria used by an investigator to adhere to this requirement are that a translator who is qualified according to certain criteria must be used to secure a linguistically and culturally accurate translation and an interpreter who is qualified according to certain criteria must be used to perform the verbal consent discussion. The methods used to adhere to this requirement for translation are securing a qualified translator though a specified resource, such as the institution's translation office or a contracted translation company, and using a specified method, such as back translation or double forward translation. The methods used to adhere to this requirement for interpretation are securing a qualified interpreter through a specified resource, such as the institution's interpretation office, and using a specified method, such as the steps outlined for obtaining consent and signatures using the short form method.

The primary pattern that can be seen from this analysis is that institutions focus their policies on the direct requirements in federal regulation and guidance, as the major themes strongly correspond to the federal information. Though most institutions had similar policies for the requirements component, interesting differences between institutions appear when considering how to adhere to the requirements, because while regulations and guidance often directly describe the requirement component, the criteria and methods are described infrequently. Fewer institutions had clearly defined criteria for adhering to the requirements, with fewer providing or suggesting clear methods for adherence.

What: Requirement	
The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. (45 CFR 46.116)	
↓	
How: Criteria used to adhere to requirement	
Translate written documents using a qualified translator. A qualified translator is defined with criteria.	Facilitate the verbal consent discussion using a qualified interpreter. A qualified interpreter is defined with criteria.
↓	
How: Methods used to adhere to requirements	
A qualified translator may be secured through a specified resource. A written translation is made using a specified method.	A qualified interpreter may be secured through a specified resource. The consent process is conducted and documented using a specified method.

Figure 1. Components of a Policy for Obtaining Consent From NES Participants

The effect of the federal regulations and guidance is obvious when considering the theme for use of the short form consent process, which is well described federally. All 12 institutions described the requirement for obtaining consent in the language of the participant and that a short form process is an option for this. All institutions had criteria for when a short form process is allowable, as well as a method for how to get access to a translated short form and then obtain consent using the short form process. Compare this to the theme for use of interpreters, which is addressed much less in federal regulation and guidance. Although all institutions describe the need for interpreters, only seven institutions provide any criteria to determine if the interpreter is qualified, and only four indicate a specified resource for securing an interpreter. The correlation with federal regulation and guidance is also obvious when looking at the codes for Investigator Resources and the associated themes, such as cost for translation services and language services outside of informed consent. Because federal regulation and guidance do not directly address the idea of investigator resources for NES participants, other than informed consent, few institutions addressed this in their policies.

Because of the lack of federal regulation and guidance in certain areas, these institutions have developed differing criteria and methods for adhering to requirements. The theme for translation process is a good example of this. All 12 institutions address the concept of translator qualifications, but each has a slightly different set of criteria for determining a translator to be qualified. Additionally, all had methods for ensuring translation accuracy, but the methods varied across institutions, including back translation, double forward translation, and single forward translation as acceptable methods. Though it may be tempting to assume that the lack of federal regulation and

guidance has a negative impact on the comprehensiveness of institutional policies, consideration must also be given to the flexibility this allows for the institution. Based on institutional experience and resources, an institution is able to set its own standards in a way that is well suited for the institution and its research participants. This latitude is valuable as it provides for site-specific customization, considering institutions and patient populations can vary greatly across the country.

Even as differences in criteria and methods are seen from each institution, it is interesting to see the similarities that still exist when comparing the policies. These similarities reflect an emerging, grassroots standard that may help to shape the policies of other institutions and ultimately influence any new standards that may be developed on a national level. For institutions that are in the process of developing policies for their site, consideration of the major and minor themes as well as the consistently observed policies components described here may help to determine criteria and methods that are appropriate and executable at the institution, as well as ensure a comprehensive representation of the theme surrounding enrollment of NES participants.

Resnik and Jones (2006) also conducted a small study of online IRB policies and procedures from thirty top-ranked medical schools and research institutions in the United States, which was published in 2006. The results reported by Resnik and Jones identify the lack of published guidance about the IRB's interpretation of federal regulation as well as the lack of published guidance about the IRB's requirements for translation of informed consent documents and other study-related documents. Resnik and Jones provide a basic, categorical overview of IRB policy contents; however, their study does not provide any in-depth analysis or comparison of the policy components that are

deemed important for the IRB decision-making process or the researcher-patient consent process. The present analysis of these 12 cases expands on the outcomes of Resnik and Jones's, providing an in-depth comparison of policies and presenting common themes.

New questions also emerge based on the results of this study. First, it would be helpful to understand how the policies of each institution evolved over time and the institutional experiences that influenced the policies. This understanding would provide greater insight for institutions developing their own policies, as well as show whether policies are founded on anecdotal experience alone or were influenced by systematic inquiry on the topic. Second, though these policies provide us with institutional paradigms for enrolling NES individuals, further investigation would be needed to determine an institution's compliance with policy as well as the practical feasibility of the policy criteria and methods. The level of success experienced at each institution when implementing the policy would also provide valuable information toward developing a standard or securing resources. Finally, while this study only represents the point of view from the institution level, the perspectives of the researchers and participants would also be beneficial, especially when trying to understand feasibility from the researcher's point of view as well as satisfaction and comprehension from the participant's point of view.

The results of this study are not intended to represent a complete sample of policies and procedures for all clinical research institutions in the United States. The cases do not represent all states or cultural and geographic regions. However, this study was designed to focus on particular regions of the United States, specifically those with a higher proportion of NES individuals and this was reflected in the case definition. Findings may still be considered relevant to all institutions that adhere to the same

regulatory requirements. Also, because of the case definition and selection methods, it is possible that other institutions with comprehensive policies were not included. Additionally, while efforts were made to assess the full set of existing policies at each institution, it is possible that some policies were not included in the analysis, either because they were unavailable online or they were unable to be obtained via direct contact with institutional representatives.

As this topic is newly investigated, this case study serves as a reference for themes and policy components that exist when considering the inclusion of NES participants in clinical research. This case study provides a detailed, semigeneralizable resource for institutions that are assessing their own policies and procedures. It also serves as a baseline for future qualitative and quantitative research to assess specific components of policy and procedure that are identified in this analysis.

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CHAPTER 3

PERCEPTIONS OF RESEARCHERS AND RESEARCH STAFF TOWARD THE INCLUSION OF NON-ENGLISH SPEAKING PATIENTS IN CLINICAL RESEARCH

Abstract

The purpose of this study is to understand the perceptions of researchers and research staff toward the inclusion of non-English speaking (NES) patients in research, such that these perspectives may be accounted for when improving access for NES patients. This study uses a behavioral framework to understand perceptions of researchers and research staff via an online survey (*n*=175) as well as in-depth interviews (*n*=17). Survey and interview data were coded based upon the initial behavioral framework as well as upon the emerging themes. Three primary themes were identified that reflect the researcher's attitudes toward this issue. First, researcher's had developed an awareness of the NES patient and research cultures, acknowledging that research validity, research participant justice, and the institutional expectations for conducting research must be taken into account. Second, researchers engaged in the process of weighing the costs and benefits of including NES patients in research. Third, researcher's connected the availability of resources and their own preparation to their feelings of self-efficacy.

Background and Introduction

In the United States, an increasing number of individuals are not able to speak English sufficiently, creating the inability to facilitate communication on complex and technical levels. According to the American Community Survey 5-year estimates for 2007-2011, approximately 8.7% individuals living in the United States report their ability to speak English as "less than very well" (U.S. Census Bureau, 2009). While there are many difficulties for individuals who wish to obtain health care services in the current system, the barrier of language remains a prominent concern. Research has shown an association between limited English proficiency and poor health status (DuBard & Gizlice, 2008), fewer physician visits (Derose & Baker, 2000), and possible medical errors due to the physician's diminished ability to communicate with the patient (Flores et al., 2003; Karliner, Perez-Stable, Gildengorin, 2004). This provides evidence that the inability to speak English is relevant to the health disparities experienced in the United States. This association may be attributed to a number of socioeconomic factors related to an individual's inability to communicate effectively in English, including lack of health insurance, insufficient income to cover health related costs, and low educational level; however, the inherent flaws in communication when using an unfamiliar language are also significant, regardless of socioeconomic factors. Providing language translation and interpretation services for non-English speaking (NES) individuals is necessary in order for the nation to reduce health disparities and achieve the goal of improving access to comprehensive, quality health care services, as outlined in the public health initiative, Healthy People 2020 (Healthy People, 2010).

Justice is an important principle in the human research setting, being cited as one

of the three fundamental principles for conducting ethical human research in the Belmont Report of 1979 (U.S. Department of Health, Education, and Welfare). As a result, federal regulation states that individuals participating in research must not be unequally or unfairly put at risk and should equally receive the benefits of the research outcome (Public Welfare, 2009). In practice, this involves appropriately recruiting and screening individuals without scientifically unsound biases based on race, gender, income, social standing, or language. Additionally, informed consent is a highly valued principle within the research setting and the elements associated with informed consent make up a large portion of the federal regulations governing human subject research. The extra language interpretation and translation services needed to facilitate informed consent can be difficult and cumbersome if the right resources and infrastructure are not in place to accommodate these needs. If language services are unavailable or underutilized, NES patients may be denied the opportunity to access health care via clinical research.

While most major health care facilities have professional interpretation services available, research has shown that providers in the nonresearch setting do not always use these services, citing inconvenience, interpreter unavailability, and personal confidence in the provider's own fluency as reasons for underuse (Diamond, Schenker, Curry, Bradley, & Fernandez, 2009; Karliner et al., 2004). Other research and reports also describe the likely barriers to inclusion of NES patients in different types of research, such as the financial costs of recruitment and translation of study materials as well as measurement errors due to inaccurate language translation (Casado, Negi, & Hong, 2012; Li, McCardle, Clark, Kinsella, & Berch, 2001). However, current research does not address the full perceptions of clinical researchers and research staff toward the use of both

language translation and interpretation services, hereafter referred to as language services, in the research setting. It is important to understand these perceptions in order to increase the use of language services and the inclusion of non-English speaking individuals in clinical research.

For the purposes of this paper, the term non-English speaking individual (NES individual) is used instead of limited English proficient individual, as NES individual is the term more commonly used in federal guidance and institutional policies for human subject research. However, it is acknowledged that the term is partially inaccurate, as it implies a person does not speak English, when in fact the person may have limited English proficiency.

Theoretical Framework

Several behavioral theory models currently exist that can be related to a researcher's perceptions and decision to include NES individuals in his or her studies. Because of the overlap in constructs in the prominent theories, a behavioral framework (Figure 2) was created to build a full picture of the potential constructs that may be related to researchers' perceptions and decision-making. The Integrated Model approach was used, as integrating or extending existing models has been expressed in the literature as a way to further investigate the determinants of behavior (Glanz, Rimer, & Viswanath, 2008; Noar & Zimmerman, 2005; Prochaska, Redding, & Evers, 2008). Though this behavioral framework itself is not being tested or validated, it provides a paradigm for understanding and measuring the behaviors of clinical researchers and staff and was used for designing appropriate and comprehensive questions toward this aim.

The behavioral framework combines the constructs of the Health Belief Model (

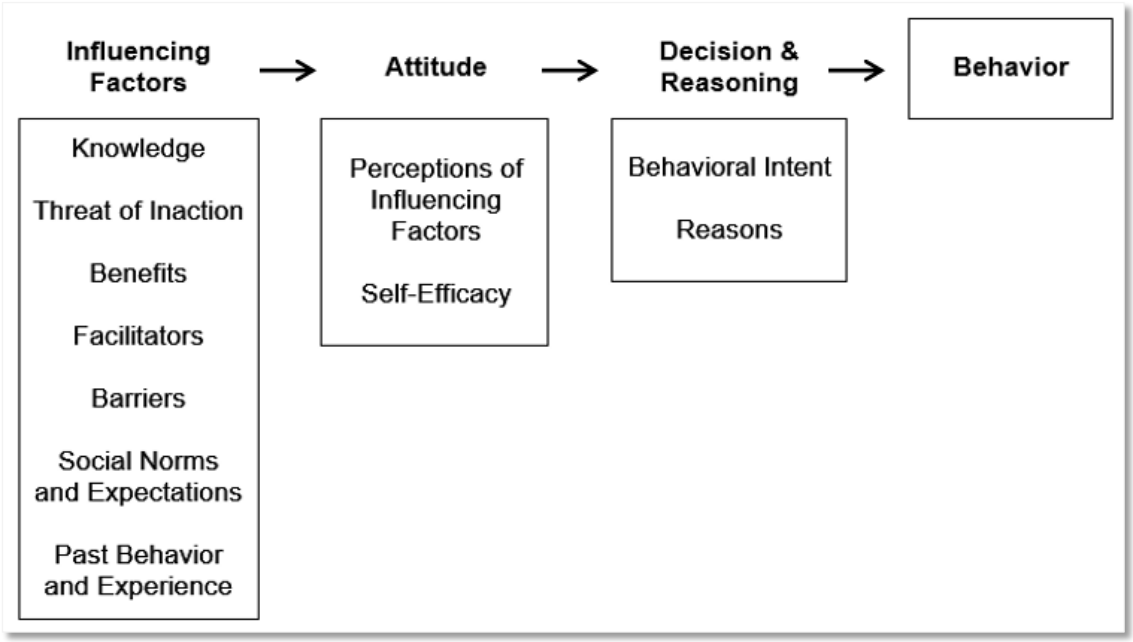

Figure 2. The Behavioral Framework

HBM), the Theories of Reasoned Action and Planned Behavior (TRA/TPB), the Transtheoretical Model (TTM), the Social Cognitive Theory (SCT), and the Behavioral Reasoning Theory (BRT). The behavioral framework centers on the constructs of attitude, decision, and reasoning as the main factors that determine the behavior of using language services. Attitude can be broken into two components: (a) the researcher's perceptions about influencing factors, and (b) the researcher's self-efficacy toward performing the behavior. The influencing factors include knowledge concerning the behavior, threats if the behavior is not performed, benefits of the behavior, barriers to the behavior, facilitating factors supporting the behavior, social norms and expectations regarding the behavior, and past behavior and experience.

Decision and reasoning encompass the researcher's behavioral intent as well as the reasons behind the intent. Reasons are the product when an individual distills all of his or her perceptions represented by the preceding constructs into a primary justification for positive or negative behavioral intention and behavior. The framework as a whole includes all of the possible factors that influence an individual, such that the behavior may be understood fully; however, when making a decision, the individual prioritizes these factors by relevance and importance, depending on his or her own circumstance as well as the value and meaning he or she ascribes to each factor. Table 7 outlines the constructs included in the framework and provides reference for the existing theories and models that address each construct.

Methods

An online survey and in-depth interviews were used to ascertain the perceptions of researchers and research staff toward including NES individuals in clinical research.

Table 7. Behavioral Framework Construct Descriptions and References

Construct	Description	Reference
Influencing factors	Factors that influence attitude and motivation to perform a behavior.	See references for subcomponents of influencing factors
Knowledge	The information possessed by an individual that is relevant to understanding the behavior and associated factors.	HBM: knowledge (modifying factor) (Champion & Skinner, 2008) TRA/TBP: posits that individuals must have knowledge about an action in order to reasonable consider the action (Ajzen, 1985) TTM: lack of knowledge as a component of the pre-contemplation stage, consciousness raising (Prochaska et al., 2008) SCT: behavioral capability (McAlister, Perry, & Parcel, 2008)
Threat of inaction	The negative consequences of not performing the behavior.	HBM: perceived susceptibility and severity (Rosenstock, 1974; Rosenstock, Strecher, & Becker, 1988) SCT: outcome expectations (McAlister et al., 2008) TRA/TPB: behavioral outcomes (Ajzen, 1991)
Benefits	The positive consequences of the behavior.	HBM: perceived benefits (Rosenstock, 1974; Rosenstock et al., 1988) SCT: outcome expectations (McAlister et al., 2008) TRA/TPB: behavioral outcomes (Ajzen, 1991)
Facilitators	The factors that facilitate the successful performance of the behavior.	HBM: cues to action (Champion & Skinner, 2008) SCT: facilitation/behavioral capability (McAlister et al., 2008) TTM: stimulus control (Prochaska et al., 2008)
Barriers	The obstacles that prevent or limit successful performance of the behavior.	HBM: perceived barriers (Rosenstock, 1974; Rosenstock et al., 1988)
Social norms and expectations	The social practices and expectations regarding the behavior.	TRA/TPB: subjective norm (Ajzen, 1991) SCT: social outcome expectations, observational learning (McAlister et al., 2008) TTM: helping relationships (Prochaska et al., 2008)
Past behavior and experience	The individual's past experience with the behavior and associated factors.	SCT: observational learning, self-evaluative outcome expectations (McAlister et al., 2008)

Table 7. Continued

Construct	Description	Reference
Attitude	"Appraisal of the positive and negative aspects of the behavior and expected outcome of the behavior." (Noar & Zimmerman, 2005)	See references for subcomponents of attitude
Perceptions of influencing factors	The beliefs an individual has toward the influencing factors.	TRA/TPB: behavioral beliefs, attitudes (Ajzen, 1991) TTM: decisional balance (Prochaska et al., 2008) See references for individual influencing factors
Self-efficacy	The beliefs an individual has toward his or her ability to perform the behavior.	HBM: self-efficacy (Rosenstock et al., 1988) SCT: self-efficacy and behavioral capability (McAlister et al., 2008) TRA/TPB: perceived control (Ajzen, 1991) TTM: self-efficacy (Prochaska et al., 2008)
Decision and reasoning	Motivation to perform a behavior.	See references for subcomponents of decision and reasoning
Behavioral intent	An individual's decision toward intention to perform the behavior.	TRA/TPB: behavioral intention (Ajzen, 1991) TTM: stages of change (Prochaska et al., 2008)
Reasons	The primary justification for behavioral intention.	HBM: salient beliefs (Rosenstock et al., 1988) TRA/TPB: salient beliefs (Ajzen, 1991) TTM: decisional balance (Prochaska et al., 2008) BRT: reasons (Westaby, 2005)

Survey and interview questions were designed using the behavioral framework. The survey was piloted with six individuals who had responsibilities as a researcher or research staff in order to improve the survey's reliability and validity. The pilot participants completed a version of the survey online and then completed a cognitive interview regarding the survey synopsis and each survey question. Final changes to the survey were made based upon the pilot data.

Researchers and research staff were sampled from various institutions and specialties across the country using email and in-person invitations made through various clinical research networks, professional organizations for researchers and research staff, and institutional listserv resources. Individuals who completed the survey were given the opportunity to volunteer for participation in an in-depth interview and interview participants were selected from these volunteers.

There were 175 respondents (Table 8) who completed the survey. Twenty-nine percent of survey respondents identified as either a principal or subinvestigator for their primary research role, with 61% identifying themselves as a study coordinator or research nurse. Pediatrics was the one individual specialty that was most reported by respondents. Eleven percent of respondents indicated that they were not native English speakers.

Of the 175 surveyed, 87% reported the name of the primary institution where they conduct research, which was then recoded into a location variable for region of the United States based upon the proportion of the population that reports speaking English "less than very well" according to the 2007–2011 American Community Survey (U.S. Census Bureau, 2009). Each region represents a quartile based upon the proportion data from the American Community Survey, with the fourth quartile representing states with

Table 8. Characteristics of Survey and Interview Respondents

Characteristic	Survey % (*N* = 175)	Interview result (*N* = 17)
Primary research role		
Principal investigator	24.9	4
Sub-investigator	4.1	0
Study coordinator	53.3	9
Research nurse	7.7	1
Student researcher	1.2	0
Research compliance/auditor	1.8	0
Other	7.1	3
Education level[a]		
MD	20.6	3
PhD	9.7	1
Physician assistant or nurse practitioner	0.6	0
RN	13.7	4
Master's degree	24.0	3
Bachelor's degree	41.7	8
Other	4.6	1
Years of research experience[b]		
< 1 year	4.1	1
1–2 years	11.6	2
3–5 years	24.3	3
6–10 years	22.0	3
> 10 years	38.2	7
Primary specialty		
Pediatrics	32.4	8
Cardiology	8.2	3
Oncology	7.1	0
Emergency medicine	6.5	1
Obstetrics and gynecology	5.9	1
Other[c]	39.8	4
Native English speaker		
Yes	89.0	15
No	11.0	2

Table 8. Continued

Characteristic	Survey % ($N = 175$)	Interview result ($N = 17$)
Regional quartile for NES[d]		
1st	4.6	1
2nd	9.2	5
3rd	64.1	5
4th	22.2	6

[a] Education level is not a mutually exclusive category

[b] $N = 16$ for the interview result

[c] Other category combines all individual specialties that were indicated that were not in the five most frequent specialties

[d] Regional quartile represents the quartile for percentage of the state population that reports speaking English "less than very well" according to the American Community Survey

the highest proportions of NES individuals. States in the third and fourth quartiles were most represented by the respondents, with 64.1% and 22.2%, respectively.

Survey respondents were presented with a short synopsis that described the topic of providing language services for enrolling NES participants in clinical research. The subsequent survey questions elicited the respondents' demographics as well as initial information about their overall knowledge and past experience regarding the use of language services in the research with which they are affiliated. Additionally, the survey collected information about the respondents' primary perceptions and intent toward the decision to use language services in a future, up-coming project. Most questions provided categorical answers for selection; however, some questions were open-ended, allowing for a free text response.

In-depth interviews were conducted with 17 researchers and research staff members who had previously been invited to participate in the online survey. Interview participants were from 11 institutions in 11 states across the United States and represented the following specialties: pediatrics, cardiology, critical care, emergency medicine, nursing, and obstetrics and gynecology. Table 8 shows the key characteristics of the interview participants.

Interviews were conducted by telephone and email using an interview guide. Interview participants were provided with the interview guide prior to the actual interview as a way to prepare and become familiar with the topics to be discussed. After the initial interview, additional follow-up questions were sent to the participants via email and their responses were then included with the interview data. Interviews were audio recorded and transcribed. The transcripts were verified by the researcher and then sent to

the interview participant for review. Corrections and comments provided by participants were incorporated into the final interview transcripts and accompanying data prior to analysis.

Categorical data were cleaned and coded according to the responses selected. Open-ended survey and interview responses were coded based on the constructs of the behavioral framework, as well as for themes within and between each construct. Initial codes were derived from the survey responses and used during analysis of the interview transcripts and associated data.

Survey Results

Questions 1-3 (Table 9) of the survey asked about the respondents' knowledge of the topic as well as their past behavior and experience with research and the use of language services. The vast majority of respondents (97.7%) indicated that they have heard about or considered the issue of providing language translation and interpretation prior to reading the topic synopsis at the beginning of the survey. Additionally, most respondents (77.5%) indicated that they have used language translation and interpretation services in their research prior to completing the survey, with 85.5% indicating that they have conducted projects in the past for which language services would have been useful or relevant.

Question 4 asked about the respondents' behavioral intent for the use of language services in future, prospective research projects. A majority indicated that they definitely (34.5%) or probably (28.1%) would use such services in their next prospective research project, with 18.7% unsure about their decision. Question 5 asked respondents to expound on their answer to question 4 by stating the top three reasons affecting the

Table 9. Survey Questions and Responses

Question	Response	%
Q1: Have you heard about or considered the issue of providing language translation and interpretation before reading the synopsis? *(n*=173)	Yes	97.7
	No	1.7
	Unsure	0.6
Q2: Have you used language translation and interpretation services in your research prior to today? (*n*=173)	Yes	77.5
	No	22.0
	Unsure	0.6
Q2A: Approximately how many studies have you conducted or worked on prior to today? (*n*=134)	≤ 5	27.6
	6–10	20.2
	11–20	20.9
	≥ 21	31.3
Q2B: Approximately what percentage of your studies have you used language translation and interpretation services? (*n*=134)	< 25	46.3
	26–50	23.1
	51–75	11.2
	76–100	19.4
Q3: Have you conducted research projects for which language translation and interpretation services would have been useful or relevant? (*n*=172)	Yes	85.5
	No	10.5
	Unsure	4.1
Q4: On your next prospective research project where consent will be obtained from participants, will you use language translation and interpretation services? (*n*=171)	Definitely yes	34.5
	Probably yes	28.1
	Undecided	18.7
	Probably not	17.0
	Definitely not	1.8

Note. Q2A and Q2B were only asked if Q2 was answered "yes."

decision to provide language services in an up-coming project, ranking these reasons in order of most important to least important. One hundred and fifty-five respondents provided at least one primary reason, with fewer providing additional reasons in the second (n=109) and third (n=63) positions of importance.

A total of 44 codes were assigned to the reasons provided, although the 10 most common reasons are detailed in Table 10. Financial cost of language services stands out as a perceived barrier to providing language services, being the most common reason stated overall and was also the most common reason placed in the second and third positions of importance by participants. However, the most common reason placed in the first position of importance was the perception that the likelihood of contact with an NES individual is high, meaning respondents felt that they were likely to encounter an NES individual during the course of the study.

The desire to treat all potentially eligible patients equally was coded as research participant justice, and it was observed that respondents not only expressed justice positively as a benefit, but also as a threat of inaction if an otherwise eligible individual were excluded from research participation based upon his or her inability to speak English. Additionally, concern for study enrollment and concern for study validity were also both expressed as either a benefit or a threat of inaction.

Interview Results

By using the constructs of the behavioral framework to guide the questions of the interviews, distinct themes emerged, which encapsulated and connected the constructs in ways that were meaningful to the participants' experiences. A pattern for participant attitude (Figure 3) appeared with distinct themes as follows. First, the participants'

Table 10. Most Common Responses to Survey Question 5: List the Top 3 Reasons That Are Affecting Your Decision in Question 4, in Order of Most Important to Least Important

Coded response	Constructs	Overall % (n = 155)	Reason 1 % (n = 155)	Reason 2 % (n = 109)	Reason 3 % (n = 63)
Financial cost	Barriers	25.81	9.68	20.18	11.11
Concern for research participant justice	Threat of inaction Benefits	17.42	10.97	8.26	3.17
Perception that likelihood of NES contact is low	Knowledge Past behavior and experience	16.77	10.97	5.50	7.94
Perception that likelihood of NES contact is high	Knowledge Past behavior and experience	16.77	14.84	2.75	0.0
Concern for study enrollment	Threat of inaction Benefits	16.77	9.68	7.34	7.94
Concern for study validity	Threat of inaction Benefits	13.55	6.45	6.42	9.52
Time and effort cost	Barriers	13.55	7.10	9.17	7.94
A requirement from an oversight group (i.e., sponsor, IRB, institution, etc.)	Social norms and expectations	11.61	5.16	5.50	6.35
Interpreter unavailability	Barriers	10.97	5.16	4.59	7.94
Unknown likelihood of an NES encounter	Knowledge Past behavior and experience	10.97	6.45	5.50	3.17

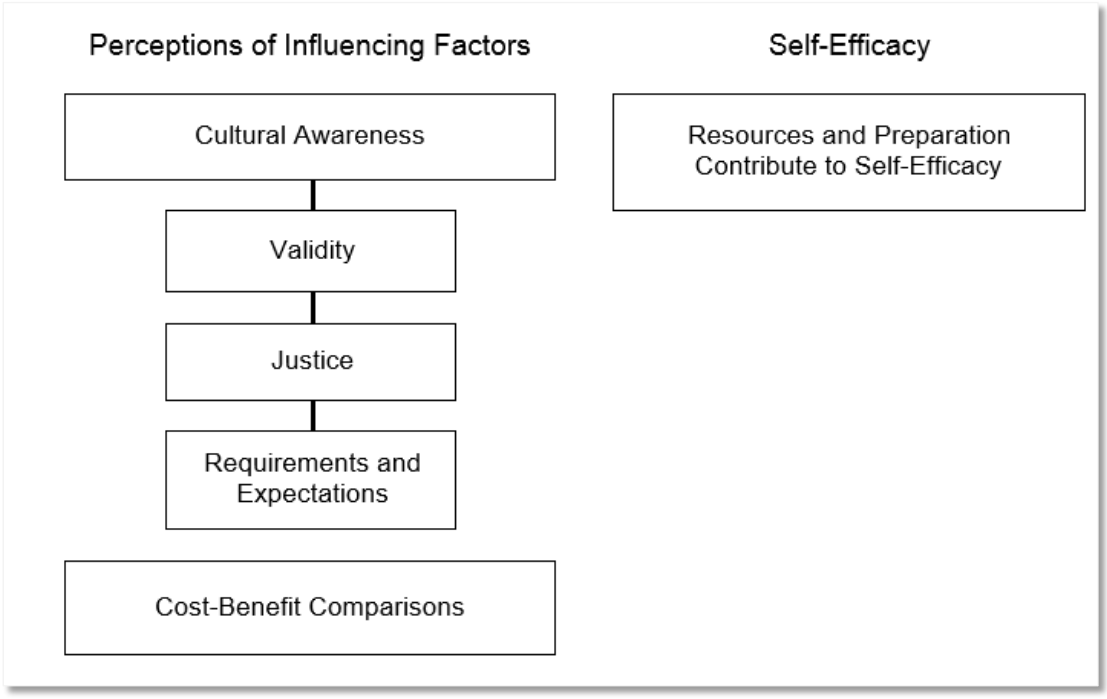

Figure 3. Themes Related to the Attitudes of Researchers and Research Staff

expressed cultural awareness of the ethnic and social culture connected to NES individuals and the local geographic areas, as well as awareness of the research culture nationally and at their institutions. This cultural awareness is connected to three sub-themes: (a) the validity of research is affected by the inclusion or exclusion of NES individuals; (b) justice, both socially and individually, is affected by the inclusion or exclusion or NES individuals; and (c) there are requirements and expectations that exist regarding the inclusion or exclusion or NES individuals. Second, weighing the costs against the benefits of including NES individuals in research is an important process when evaluating the influencing factors. Third, having available resources and making preparations for the inclusion of NES individuals in research leads to self-efficacy.

Cultural Awareness

Participants described their various perceptions regarding the ethnic and social cultures relevant to their local geographic areas, which were then connected to their perceptions about including NES individuals in their research. Additionally, participants described their perceptions regarding the research culture that exists in the United States, at their institutions, and across the various research organizations and agencies with which they are affiliated. Together this has been categorized as the possession of cultural awareness and though none professed a perfect knowledge or understanding of the issues surrounding inclusion of NES individuals, each participant demonstrated that he or she was conscious of a variety of relevant issues.

Many participants voiced their own understanding of ethnic and social cultures related to the NES populations in their local areas. Some connected NES-status to minority status and the potential for NES individuals to come from lower socio-economic

populations in the United States. The concept of building rapport with NES individuals in the research setting emerged as one of importance to the participants, indicating the need for careful communication and understanding between the researchers and NES patients, as well as acknowledging the possibility of mistrust that NES individuals may feel because of either mistreatment of certain populations or misunderstanding of their cultural norms. Though the language and cultural differences were acknowledged as a possible barrier to including NES individuals in research, many participants expressed that trust and rapport are necessary to overcome this barrier. One participant explained this in terms of benefit to the NES individuals:

> The other benefit I see is to the patients/families. I think it is important for non-English speaking patients to see that they are just as important to our institution. I think it is important for them to benefit from my studies, even if it isn't directly but from participating in research in general.

Another connected the benefits of trust to both the social and research cultures:

> [W]e have to build a trust with the populations around us to actually do the research. So doing it the right way is just going to facilitate further research.

A few participants also expressed that there is value in diversity and understanding the differences between cultures. As 1 participant stated:

> And you realize that, you know, maybe I'm a little holistic about this, but my life is certainly better or more enriched because I've been both at the bedside and in research to appreciate cultural differences and realize that it can make a difference…, maybe not on the data, but in how research is perceived in their culture.

Participants frequently described the demographics of their geographic location and many went on to compare this to other locations in the United States with which they are collaborating on research. Most perceived the local NES population as either high or low based on their location in the United States or personal encounters with NES

individuals, with those who perceived the NES population as high generally attributing more importance to the inclusion of NES individuals because of the need for enrollment.

Additionally, many participants acknowledged that there are languages that are commonly spoken in the local area versus others that are rare, with nearly all participants indicating Spanish as the most commonly encountered language other than English. Some participants stated that NES individuals who speak an uncommon language have a greater barrier for inclusion in research, because of the difficulty in providing language services for uncommon languages. A few participants spoke of experiences when an NES individual was excluded because he or she spoke an uncommon language for which language services were not readily available. One participant described this personal experience:

> Yes, we had one experience with the language called Tagalog, [which] Filipino people speak. We explained everything in the consent form, the co-investigator and myself. Then they were ready to sign the consent form but at the end, [the patient] felt like the medical knowledge, what we [were explaining], [was] a little difficult. They said that if we had an interpreter that speaks Tagalog, [they would like to use the interpreter], but at the time we didn't have anyone who speaks Tagalog and we couldn't enroll the patient.

Participants also noted the general communication barriers to the informed consent process that are experienced in the research culture. Some participants described experiences where both English-speaking and NES individuals had difficulty understanding the terminology in consent documents and the previous quote about the Filipino patient gives an example of the difficulty in understanding medical terminology. Recognizing the need to improve communication in the research consent process, many participants emphasized the importance of effective communication and recommended strategies to mitigate the difficulty in understanding, including simplification of consent

document language, having discussions about the study in lay-language, and having trained people, such as medical interpreters and proficiently bilingual study staff, to provide interpretation during the consent process.

The perceptions toward the availability of resources for including NES individuals in research varied across participants, particularly in the types of resources that are available at their location and via their sponsors and research networks, as well as the level of satisfaction with the available resources. For example, some participants had access to translation services within their own institution, while others had to seek translation services outside of the institution. Additionally, some participants voiced satisfaction with the interpreter services available through their medical center while others were dissatisfied. Though this variability exists and is expected, all acknowledged that they were aware of at least some resources available for securing language services for potentially eligible NES individuals. The participants' perceptions of the resources are discussed further in this paper in the sections addressing the cost:benefit ratio and self-efficacy, although it is important to mention it here as it shows the participants' understanding of the research culture.

Though participants noted a variety of barriers to including NES individuals in research, some participants expressed how the research culture is changing to better meet the needs of researchers and NES patients. This included bilingual staff on the IRB to verify written consent translations, improved IRB-approval times for written consent translations, additional language services available within the institution, and pre-translated short form consent documents available for use. As described by one participant:

> It's a changing environment so that's improving. People don't look at me like I'm crazy to say that we need to have all languages, so that part has made it easier… It's becoming normative and compared to when it was an exception, now it is the expectation.

As participants voiced their understanding and knowledge of the research culture, they also focused on issues concerning research validity, justice, the requirements and expectations they must abide by at their institution or in response to a financial sponsor or research network. These were prominent themes relevant to cultural awareness and are discussed subsequently.

Validity

Validity is the overall term used to represent the many expressions that were made regarding research generalizability, bias, and representativeness. Participants expressed a concern for a study's validity and ability to generalize if NES individuals were not included, indicating this in a variety of ways and often linking the concept of validity to others such as justice, cultural awareness, and the ability to identify new knowledge and understand research results:

> I think you can get a selection bias if you systematically don't enroll people who don't speak English. I think your study is in question for generalizability. It doesn't always happen, but sometimes language barriers run along socio-economic lines and you can't not include people from all walks of life if you are going to generalize.

> Yes, I think it's very important [to include non-English speakers in the research that I do]. For generalizability's sake and because that's what our country has, many different people. I think research needs to address as many different populations as possible. I'm biased because I'm a pediatrician, so the fact that so many studies in the past have been able to exclude kids is…a big part of my bias, so I feel it should be the same with non-English speaking participants, that the research should be as inclusive as possible.

> [E]ven when we think we are looking at a physiologic illness like pertussis, so much of what happens in health care is affected by what happens outside of the

> health care setting. So many times there are cultural influences on our health practices, there are neighborhood influences, there are economic influences. You can't get at any of that if you exclude groups.

Justice

Justice is the overall term used to represent the participants' expressions that inclusion of NES individuals should be considered fair with an equal opportunity to receive the direct and indirect benefits of research. As mentioned previously, participants also tied the concept of justice with that of validity, viewing generalizable research results as a benefit that is applicable to the NES population as a whole if NES individuals are included in the research.

> I feel that ethically anyone eligible for enrollment should be given the choice to do so. If non-English speaking participants are not enrolled into studies specifically for that reason, a bias is created and the scientific value of that study decreases. I have a study that looks retrospectively at patients with ventricular shunts who have had multiple x-rays and therefore, high levels of radiation exposure. The study enrolls patients who are interested in receiving a thyroid ultrasound to see if nodules have developed, possibly as a result of the radiation exposure. I feel this is a very beneficial study for these patients because this is a screening they otherwise would not have. This study is investigator initiated and because of the small budget, I cannot enroll non-English speaking patients. I feel that the data from this study will be hurt because of that, and that many patients are losing out on an important health screening.

Some participants felt that the inclusion of NES individuals was an ethical decision and that exclusion on the basis of language alone creates discrimination, as expressed by these participants:

> [Y]ou don't want to have somebody go to the hospital and be eligible for a study and then not have the opportunity to participate, because they might have some benefits, too. You can't, it's basically discrimination, I think, if you don't enroll them if you can.

> I think that some of the studies where, for instance, we would perhaps pay for treatment or pay for some type of appointment for the study through the study, I think it would almost be seen as discrimination not to enroll somebody just

because they don't speak English if they have that opportunity.

However, some participants expressed that given the barriers of providing language services to NES individuals, it was not as upsetting to exclude someone based on language alone, especially for a study that does not provide direct benefit to the patient:

> It seemed like a negative for the study that there was this patient who could have given us great data, but the study would not have provided direct benefit to the patient, so I didn't feel badly that they didn't have the opportunity to be involved.

Requirements and Expectations

Participants conveyed knowledge of the federal and local requirements to which their research was subject. Though this knowledge was not always ingrained to the point of memorization, participants indicated that they knew how to obtain full instruction on the requirements, primarily stating that they would contact their IRBs for more information. Many participants indicated their trust for the IRB as a source of complete and accurate knowledge of the federal regulations and local requirements, with a few participants directly referencing their IRBs' guidance materials online during the interviews.

Participants also expressed their understanding of the expectations set forth by their study sponsors, research collaborators, and research networks. This included two primary expectations: (a) the local site will adhere to the federal regulations and requirements set forth by the institution and IRB; and (b) the local site is responsible for securing and providing the necessary language services for enrolling NES individuals into research. Some participants indicated that when specifically sought, their study sponsors and research networks helped to contribute toward translation services for the

local site.

Cost-Benefit Comparisons

Participants compared the costs and the benefits of including NES individuals in research, weighing the levels of each. Participants used terms and phrases such as “trade off,” “balance,” “outweigh,” “it depends,” and “worth it” when making cost-benefit comparisons. The potential costs described in the interviews were consistent with those in the survey responses and most notably included the financial cost of written translations, time and effort costs to secure language services, difficulty using interpreters, and the lack of validated study instruments (such as questionnaires). The potential benefits described in the interviews were also consistent with the survey responses and most notably included improved patient justice, patient trust, study validity, and enrollment numbers.

Participants attributed varying levels of value to each cost and benefit based upon the situation. For example, some participants expressed that the financial cost of translation services was acceptable given the large number of potentially eligible NES individuals they expected to encounter during the study; however, others were not as accepting of the financial costs if the number of NES individual encounters were expected to be low. In addition to the example of high versus low numbers of expected NES encounters, the level of value attributed to the costs and benefits often varied when participants considered common and uncommon languages, the possibility of financial support, study design, and a study’s target population.

Many of the cost-benefit comparisons made by participants were based upon speculative circumstances, describing situations where the cost-benefit ratio could change

based on circumstantial factors. One participant provided this example:

> I think the biggest reason why [the data coordinating center would decide to have the consent form translated] is…if sites feel they have a large enough population of non-English speakers of a particular language and we feel that we really want to include those subjects to help the enrollment numbers and make the study better. If [the sites] are saying that it would be helpful for them and helpful for their subjects to have a translated consent or study materials, then that's where the decision would come in as what's the benefit to the study overall versus the time and the effort it would be to have that done.

A few participants described personal experiences that demonstrated how the costs and benefits of including NES individuals were weighed, including this example:

> [The] flu survey that I mentioned is one that they really want to get the computer survey translated [into] Spanish because that would include so many more people. I think that's one where [it is] resources that [are] holding [the translation] back.

Some participants also offered advice about making a cost-benefit comparison when considering the inclusion of NES individuals, including the two participants quoted below:

> I would just say, still go through with it, still make it work, just put in a little bit of extra time when you do it. It's usually worth it.

> [Do] not rule it out up front. So many times people will put in that "English speaking only" almost as a default clause because they think that it's hard to do or that it's going to be cost prohibitive, or that it's going to be a problem. And I really think that first, think about what is your scientific question, rather than first saying, "this is too hard."

Resources and Preparation Contribute to Self-Efficacy

Though participants provided many examples of barriers to including NES individuals in research, many expressed confidence to include NES individuals when adequate resources are available and preparation for NES individuals is made prior to initiating study enrollment. Participants discussed the availability of resources and their level of confidence in being able to secure them, mainly financial resources to obtain

written translations of study materials as well as access to interpreters for oral interactions. Participants pursued resources from a variety of places, including study sponsors and collaborating research networks, the IRB, the medical center, and companies outside of the institution. Participants were most positive about the availability, consistency, and quality of resources when they had built relationships with the people that provide the resources.

Many participants placed specific emphasis on the idea of preparation for including NES individuals. Elements of preparation expressed by participants included consideration of the following: the likelihood of NES encounters and the languages that are most likely to be encountered; the added value to the quality of study data if NES individuals are included; financial resources available for written translations of study materials, primarily for informed consent; and time-points at which translation and interpretation services will be required beyond initial enrollment, including follow-up visits and phone calls. Though all of these elements were discussed in the interviews, participants most often connected their level of confidence in preparing for NES individuals to their level of confidence in securing resources for language services; being prepared for NES individuals was most often expressed as knowing that resources are available and how to secure them specifically for a study.

The idea of preparation can be seen in previously cited participant quotations about considering the costs and benefits prior to study initiation. Some participants further indicated the need to "bring it up," to raise the topic of including NES individuals during the preparation and design stages of a study protocol, as participants felt that this element was often overlooked:

> I don't even think anyone has brought that up…As far as I know, it's up to [the individual sites] if they are getting informed consents transcribed into Spanish or whatever language. As far as interpreter use, I don't know, we don't talk about it. So really, I don't know what [the sites] are doing. We don't discuss that, and you know what, we should.

> I think if we have somebody that kind of pioneered including more non-English speakers in our network, as long as we had someone who kind of took the lead to get that done, I don't think it would be a problem. But nobody really seems to take that on, or even bring it up.

Additionally, some participants noted that being prepared before study initiation requires the expenditure of resources, which might never be rewarded with the actual enrollment of an NES individual.

> We don't plan ahead enough for non-English speaking families, so as a result, a lot of the times what we are asking for is a quick turn around time [for consent form translation]…Again you are going to get your grumblers [that] say, "Well we've already got so much to do, how do we do this now, too?" It's a difficult situation because you certainly don't use [a translated consent form] 100% percent of the time, but when you do need it, it is really important. So that's a sticky situation.

> [W]e were prepared. The cost was something on the order of $500 for the translation and we did that and put that expense in with the budget. But we didn't enroll any [non-English speaking] people...[The fact that we didn't enroll anybody did not influence our decisions in the future to be prepared]. That's my personal bias. The investigators I worked for felt the same, especially if they didn't have to bear the cost, but the sponsor was willing. And they said they would support that with sponsor's approval.

Discussion

Results of the survey and interviews show that most researcher and research staff participants have knowledge of the issues regarding the inclusion of NES individuals in research and many are influenced by personal experiences, social norms, and social expectations. Additionally, participants have developed perspectives of the cultural and demographic characteristics of the populations that they serve, showing that they have

gained knowledge of these characteristics. It is important to note that this study did not seek to validate the participants' perceptions with independent data, such as actual demographic characteristics of the participants' institutions or institutional policies detailing requirements and expectations for including NES individuals in research; however, this study reveals that knowledge, past behavior and experience, and perceptions toward social norms and expectations have already been developed. Because perceptions about the demographic characteristics of the local population already exist and are a common reason contributing to the participants' decisions to include NES individuals in future research projects, it is important that an institution consider whether or not these perceptions are based upon factual information. If the perception exists that the NES population in the area is low, there may also be low inclusion of NES individuals in research, despite the actual size of the NES population in the area.

Participants view the inclusion of NES individuals as an important aim in the research culture, fulfilling their desire for research validity as well as social and individual justice for NES individuals. Though the desire for validity and justice is prominent, participants also recognize the barriers that must be overcome in order to achieve the aim, including their own propensity to overlook the issue when preparing for a new research project. This study suggests that preparation during the design phase of a research project as well as access to resources for language services contributes to participants' self-efficacy for inclusion of NES individuals in research. Although the barriers identified by participants were not all resource-based, this study suggests that having means to overcome the resource-based barriers, such as financial costs of translation and availability of interpreters, is more likely to increase self-efficacy.

Where the interview data give an overall understanding of the participants' knowledge, experience, and attitudes regarding inclusion of NES individuals, the survey highlights the primary reasons that are used by researchers when making a decision. The interview data show that participants' see a large number of potential barriers and benefits, while the survey pinpoints those that are most important to the participants' behavioral intent. For institutions wanting to increase the inclusion of NES individuals in clinical research, these primary reasons should be the area of focus when addressing researchers' needs and concerns.

Previous survey results from research by Frayne, Burns, Hardt, Rosen, and Moskowitz (1996) indicated that NES individuals were frequently excluded from studies about provider-patient communication. Though their survey did not include respondents who authored clinical research overall, including research with medical interventions, it highlighted similar issues considered by researchers, including financial costs of translation and interpretation and the perceived likelihood of a recruitment encounter with NES individuals. Among respondents who reported excluding NES individuals, 51% state that they had not considered the issue of exclusion (Frayne et al., 1996). Interestingly, the present survey shows that the high majority, 97.7%, report having considered the issue of providing language translation and interpretation before completing the survey. This increase may be due to various clinical and public health efforts to improve cultural competency, as well as the overall increase in the NES population since 1996.

On a whole, this study was able to gain insight into all of the constructs that lead to behavior, with a thorough look at participants' attitudes toward including NES

individuals in research. The pattern and themes that emerged from the interview portion of this study fit within the behavioral framework under the construct of attitude (Figure 2). The perceptions of the influencing factors are evident in the themes of cultural awareness and cost-benefit comparison. Cultural awareness and its subthemes clearly encompass participants' primary perspectives about their knowledge, past behavior and experiences as well as the social norms and expectations, threats of action, barriers, and benefits. Additionally, participants explored many combinations of costs and benefits, which correlate with the constructs of barriers, threats of inaction, and benefits. The construct of self-efficacy is also addressed by the theme that resources and preparation lead to self-efficacy. The survey goes on to further quantify the participants' knowledge, past behavior and experience, as well as behavioral intent, followed by a more qualitative view of the participants' primary reasons for their behavioral intent.

Though this study has provided important insights into the attitudes of researchers, there are limitations. First, the diversity of the study sample may not be wide enough to accurately represent the perceptions of all researchers. The study sample heavily represented the specialty of pediatrics and did not include participants from all possible medical specialties. Although the study sample does not represent all states, it does represent a wide variety of states and demographic areas; however, the majority of participants are from the same area of the United States. Second, though the study is based on a framework influenced by several established behavioral theories, the framework has not been validated separately. Additionally, the survey has not been validated by previous studies. Third, because the interview guide was designed based upon the behavioral framework, there may have been topics and concerns that were not

discussed and considered in the resulting themes. Finally, because the results about researcher attitudes are primarily qualitative, the study cannot quantify the prevalence of these attitudes. The survey results provide a preliminary quantitative understanding of researchers' knowledge, past experience and behavior, behavioral intent, and reasons contributing to behavioral intent; however, it has limited ability to draw conclusions using correlation and regression models because of the sample size.

While other studies have described various barriers experienced by researchers, this study leads out to directly and more fully assess researcher and research staff perceptions toward the inclusion of NES individual. As the research community moves forward, these insights into the perceptions regarding the inclusion of NES individuals in research can help to shape future decision-making and behavior. These results also raise more questions about how the attitudes of researchers and research staff are linked to behavior, with the potential for future qualitative and quantitative inquiry to establish possible behavioral interventions that effectively increase the number of NES individuals included in clinical research.

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CHAPTER 4

STRATEGIES FOR INCREASING THE INCLUSION OF NON-ENGLISH SPEAKING PATIENTS IN CLINICAL RESEARCH

Abstract

The clinical research community has an interest in including non-English speaking (NES) individuals in human subject research. Because of the additional standards required in the research context, as well as the added difficulty in communication with NES individuals, there are several barriers that must be overcome in order to more easily facilitate including NES individuals in clinical research. The purpose of this article is to discuss possible strategies for increasing researcher preparation and reducing barriers, such that researchers may feel more confident that they can appropriately include NES individuals in their studies. Strategies for increasing preparation include bringing up the topic of including NES individuals during the planning stages of a study, knowing the local population and those served by the institution, and establishing clear expectations and guidelines for how to appropriately enroll NES individuals. Strategies for reducing barriers include increasing availability of language translation and interpretation services, as well as improvements and flexibility for informed consent documentation and processes.

Introduction

The rising number of non-English speaking (NES) individuals in the United States is an important concern for the clinical and population-based research community, as the NES population experiences many health conditions and disparities that are being studied for the development of new treatments, prevention methods, and health services improvements. Unlike the general clinical context where NES patients may be evaluated and treated with limited access to language services, such as written translation of materials and oral interpretation of conversations and discussions, NES patients seen in the research context must be fully informed of study information and requirements prior to research inclusion and must continue to be informed throughout the course of a study. This necessitates greater access to language translation and interpretation services, which can stand as a barrier to the inclusion of NES individuals in research.

In a recent study of researcher and research staff perceptions toward the inclusion of NES individuals in clinical research, three common themes arose: (a) Research teams have an awareness of issues surrounding social and ethnic cultures as well as the research culture; (b) Research teams compare the costs and benefits of including NES individuals in research; and (c) Resources and preparation contribute to self-efficacy for inclusion of NES individuals in research (Johnson, 2014). These results suggest that improving researcher preparation prior to study initiation and reducing barriers may increase the inclusion of NES individuals in research. This goal is supported by the *Diverse Voices* report from the National Institute on Aging and National Institute of Child Health and Human Development (Li, McCardle, Clark, Kinsella, & Berch, 2001), as well as Casado, Negi, and Hong (2012).

The idea of researcher preparation can be summarized as a researcher's consideration of including NES individuals in research prior to initiating a study. Elements of preparation include understanding the characteristics of the NES population, determining the federal and institutional requirements for including NES individuals in a compliant manner, assessing the resources necessary to fulfill the federal and institutional requirements, and evaluating the potential costs and benefits. Preparation is thus tied to the concept of barriers, as researchers must consider how to overcome barriers during the preparation phase. Health care providers, researchers, and research staff in clinical and research settings have identified many barriers to language translation and interpretation. Prominent barriers include financial costs, additional time and effort expenditures, limited access to translation and interpretation services, and the complexity of communication barriers due to language and cultural differences (Casado et al., 2012; Diamond, Schenker, Curry, Bradley, & Fernandez, 2009; Johnson, 2014; Li et al., 2001).

The purpose of this article is to discuss possible strategies for improving researcher preparation and reducing barriers, with a focus on actions that can be taken by institutional administrators, such as institutional review boards (IRBs), research oversight bodies, and translation and interpretation departments, as well as research teams. Additionally, this article includes a discussion of strategies that should be considered by research sponsors and funding agencies to enhance inclusion of NES populations.

Strategies

Create Triggers to "Bring It Up"

Preparing to include NES individuals in research is only as good as the triggers that initiate preparation in the first place. In a previous study (Johnson, 2014), researchers

and research staff have noted their own lack of preparation, using the phrase, “bring it up” when describing their need for more discussion about the elements of preparation early in the planning process. Research teams must create consistent triggers for instigating discussions about the inclusion of NES individuals during the design phase of a study (Johnson, 2014). Additionally, the institution may consider having standardized triggers during regular study initiation processes, such as grant submission, contract negotiation, and IRB submission.

Sponsors and funding agencies may choose to defer discussion and decision-making regarding the inclusion of NES individuals to the institution and the researcher, likely due to differences in policies and requirements across institutions. This may cause sponsors and funding agencies to remain silent on the issue during the preparation phase of a study. However, sponsors and funding agencies should provide more proactive support toward the inclusion of NES speakers by initiating and supporting these discussions (e.g., incorporating explicit items about inclusion in proposals, sponsoring workshops or conferences on the topic, etc.), while also making clear the resources that they have available to support inclusion of NES speakers, which is considered in more detail subsequently.

Know the Population

Having or lacking knowledge about the NES population may impact whether or not a research team attributes value to the inclusion of NES individuals in their research. Lacking an understanding can negatively impact the preparation process of a research team that chooses to include NES individuals. Thus, research teams must gain an understanding of the NES population, particularly in their local community, in order to

appropriately plan for the inclusion of NES individuals. This means understanding the NES population's cultural characteristics as well as the demographics of the local community.

Concepts such as cultural competence and cultural awareness focus on respecting and understanding cultural traits and behaviors. Feelings of cultural awareness may help build a researcher's desire to create relationships with NES individuals and ascribe benefit to their inclusion in research (Johnson, 2014), as it has previously been shown that cultural competency affects the attitudes of health care providers (Beach et al., 2005; Paez, Allen, Carson, & Cooper, 2008). Also, research teams should understand how culture and language might affect the outcomes of the research, such as the potential validity concerns if data collection instruments are not culturally and linguistically appropriate. There are many existing methods that can enhance cultural awareness and aid in improving communication. Though this article does not endorse any specific methods, it is recommended that institutions provide quality information and training regarding cultural characteristics and issues that are relevant to their communities. The Department of Health and Human Services (USDHHS) Office of Minority Health (2013) offers guidance and resources on the topic of cultural competency that may be useful to institutions.

Researchers' perceptions about the likelihood of an encounter with NES individuals during recruitment may affect whether or not they make preparations prior to study initiation for the enrollment of NES individuals (Johnson, 2014). Researchers and research staff have indicated that the likelihood of an encounter is one of their top considerations when making the decision to plan for the necessary language services to

enroll NES individuals. Another consideration is the number of languages spoken in the population, with some languages being less common than others (Li et al., 2001; Johnson, 2014). Researchers tend to feel more prepared for enrolling NES individuals who speak one of the more common languages in their local community (Johnson, 2014).

It is recommended that institutions devise quantitative means to determine (a) the number of NES individuals that have received or are currently receiving services through the institution, (b) the number of NES individuals that may potentially come into contact with the institution for services, and (c) the languages spoken by these patients and potential patients. Use of local census information can provide demographic information about the local community at large, while medical records can be used to collect specific data about the number and preferred languages of NES patients. In addition to collecting this information, institutions should find meaningful ways to disseminate this knowledge to research teams. This could include regular reporting to ensure research teams are aware of up-to-date information, as well as stratifying numbers based upon meaningful categories, such as by department or specialty, diagnosis or medical condition, demographic characteristics, and so on.

Sponsors and funding agencies should also consider the collection of data relevant to NES populations. For example, the National Institutes of Health (NIH) requires the reporting of race and ethnicity data for subjects in research that is supported by the NIH (USDHHS, 2001). This information can be used to help guide institutions and research teams in evaluating the relevant populations being enrolled in research at their institution over time. However, sponsors and funding agencies must make these data available to institutions and researchers in an ongoing and meaningful way, such as through annual

reports and accessible datasets.

Establish Clear Expectations and Guidelines

During the preparation process, researcher teams should feel confident in their ability to identify and understand the expectations and guidelines espoused by their institution for the inclusion of NES individuals. While research teams may maintain a cursory understanding of the requirements, they often rely on others to act as a resource for the more specific details, primarily indicating that this expertise should reside with the IRB (Johnson, 2014). Research teams trust the IRB to provide them with compliant methods for including NES individuals in research. Though the IRB is not the only body that can or should design and enforce institutional policy or guidance addressing this issue, it should be recognized that research teams see the IRB as a centralized home for disseminating and interpreting such information. It is recommended that institutions focus attention on providing resources, such as online materials and personnel training, through existing IRB channels as research teams have confidence in receiving complete information through these resources.

In addition to knowing where to receive information about expectations and guidance, research teams should also have access to this information in a manner that is plain and clear. If research teams cannot understand the expectations exactly or are unsure of how to operationalize the expectations, their desire and confidence to include NES individuals in their research may be diminished. It is recommended that institutions establish expectations and guidance that address the requirements that must be met by research teams, as well as the criteria and methods to be followed to meet the requirements. For example, if an institution requires that a certified translator translate the

informed consent document, the institution should specify the criteria that would indicate a translator is certified, as well as the methods the translator should use to document this certification. Clear requirements, criteria, and methods may be presented and organized in a number of different ways. Organizing information into flowcharts, checklists, template forms, and so on, can provide a direct way for research teams to understand and adhere to the requirements, as well as formally documenting their compliance.

Increase Availability of Resources for Translation and Interpretation Services

Resources in this context are typically expressed in two ways: (a) physical resources for translation and interpretation services and (b) the financial resources to pay for the physical resources. Barriers may be present in both situations, where the physical resources are limited or may not exist, or the financial resources are not available to cover the cost of language services. This section focuses on increasing availability by creating connections to physical resources as well as options for financial subsidization of studies in need of language services.

Translation Services

An institution has the option of providing translation services internally or obtaining them externally. While a system for providing translation services internally has financial costs associated with personnel, it also has benefits. First, institutional needs will always inherently be given priority, as the service is designed to serve the institution specifically. Second, internal systems have the option to bill for costs based upon a sliding fee schedule, which can accommodate translations for studies that have little funding. For example, a sliding fee schedule would allow an institution to selectively bill

for translation services based upon a study's overall need for translation services and/or ability to pay based upon predetermined criteria, such as the following: (a) the number or proportion of NES individuals eligible to be served or likely to be encountered by the study, (b) the frequency with which NES individuals come in contact with the study, (c) the nature and importance of the study, and (d) the financial resources available to the study via funds from the institution, grants, and industry.

An internal system for translation services may not be feasible for an institution, at least not wholly, as the overall costs may be prohibitive or the institution needs translation for many languages for which it is not cost effective or even possible to hire translators. Thus, an institution must consider external services. An institution may seek to contract with one or more translation companies in order to accommodate the needs of the institution and secure favorable costs. Whichever options an institution chooses, it is recommended that the institution devise means for increasing accessibility and ensuring that these options are communicated effectively to the research community.

Interpretation Services

Like translation, interpretation services may be provided internally or externally. Because of the guidance from the USDHHS in regards to applying the Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons ("Guidance," 2003), many institutions providing health care services have some level of internal interpretation services in place for general clinical purposes. However, this does not guarantee that interpreters will be available for research needs if their services are of high demand in the regular clinical setting. Additionally, the inclusion of individuals who speak languages that are less common to the geographical area may

make it difficult to identify an appropriate interpreter.

For interpretation services that the institution has established for clinical purposes, the institution should indicate how these services are to provide for research needs, indicating if there are any differences between how to use the services for clinical versus research purposes. The institution should provide clear expectations and guidelines regarding interpreter availability, such as how a research team may schedule a research appointment with an interpreter that is either internal or external to the institution, as well as approximate wait times if an interpreter is needed impromptu. Institutions may consider hiring additional interpreters or contracting with outside interpreters who are specifically designated for research purposes if the need is high.

Bilingual Staff Members and Nonprofessional Translation and Interpretation

Bilingual staff members and other individuals with nonprofessional skills for translation and interpretation may also be a successful avenue for increasing availability of language services. Other nonprofessional individuals may include community volunteers, bilingual university students, and others who are not employed professionally as an interpreter. Though Karliner, Jacobs, Chen, and Mutha (2007) show that research indicates the use of professional interpreters is associated with improved clinical care for NES patients, they have also indicated that the level of training that determines an interpreter to be *professional* varies, as there is no national certification for interpreters in health care (Care, n.d.). As such, bilingual staff members and other individuals with language skills who seek appropriate training and experience may be qualified to act as interpreters and translators in the clinical research setting.

Institutions should consider scenarios in which it would be appropriate for bilingual staff members and others with appropriate qualifications to substitute for or supplement the work of a professional interpreter or translator. Such scenarios may be based upon the overall risk level or complexity of the study, or delineated by particular research activities, such as informed consent, data collection, study visit interactions, and so on. In addition to establishing these standards for their research communities, institutions should also consider offering or publicizing training opportunities that a bilingual individual may pursue in order to become qualified to act as a research interpreter or translator at the institution. The National Council on Interpreting in Health Care provides resources for interpreters, as well as standards for training (CertifiedMedicalInterpreters.org). Published research also exists that suggests areas of competency and focus for interpreters and translators in health care and research (Hornberger et al., 1996; Moreno, Otero-Sabogal & Newman, 2007; Refki, Avery & Dalton, 2013). Institutions may also consider incentives for bilingual individuals to become qualified according to the institution's standard, including additional pay for bilingual staff members who are performing these additional tasks.

Increased Resources from Research Sponsors and Funding Agencies

Funding from research sponsors and funding agencies can play a large role in covering the costs of language services. Because of this prominent role, sponsors and funding agencies must be prepared to have funds available for these services and communicate their availability to research teams. Sponsors and funding agencies may also hire or contract with language services providers to centrally facilitate translation

and interpretation activities, making additional resources available for research teams and streamlining the process. For example, for-profit sponsors or federally-funded research networks can coordinate and pay for the translation services necessary for the multi-centered studies they oversee, allowing for a more streamlined translation process for multiple, similar (perhaps identical) study materials.

Reduce Barriers Associated With Informed Consent

Informed consent is a key principle in human subject research to ensure that the rights and autonomy of individuals are protected. It is also one of the primary barriers to the inclusion of NES individuals in research for two key reasons. First, diminished literacy and comprehension are documented problems for all research participants, regardless of the language spoken; however, this problem is compounded for NES individuals because of the language barrier. Second, language translation and interpretation services are required in order to obtain informed consent from NES individuals. This adds another layer of financial- and time-based costs to the list of requirements for enrolling research participants.

Improving Comprehension and Literacy

The concern over informed consent comprehension and health literacy in the research context is not new. Studies have shown that research participants struggle to understand informed consent documents as well as medical- and research-related terms (Berg, Appelbaum, Lidz, & Parker, 2001). Researchers and research staff have also expressed their particular concern for NES individuals, indicating that lack of comprehension may result in the NES patient or the researcher feeling uncomfortable

about research inclusion, which may keep NES patients from being enrolled (Johnson, 2014). Systematic reviews have described many studies recommending methods for presenting informed consent documents and processes in order to improve research participant comprehension, such as illustrated formats, follow-up discussions, or computerized and video consent presentation (Dunn & Jeste, 2001; Eyler & Jeste, 2006; Flory & Emanuel, 2004). It is recommended that institutions and research teams evaluate and use appropriate methods to improve the informed consent documents and processes, as this will benefit NES and English-speaking individuals alike. Improved comprehension may serve to increase the confidence of research teams and the NES patients that this segment of the population can participate in the research in an informed way, such that NES patient inclusion is increased.

As discussed earlier, many institutions provide interpretation services for the clinical setting, which are often used in the research setting as well. While these interpreters may have training relevant to medical terminology, they are not likely to be trained in research terminology, nor the various methods and purposes of research. As such, it may be more difficult for these interpreters to communicate research concepts effectively. Institutions should also consider ways to train interpreters to understand these concepts. It would also be beneficial for members of the research team to discuss individual research projects with the interpreter prior to interacting with the NES patient. This discussion would allow the interpreter to ask questions about the project and for the research team member(s) obtaining consent to collaborate with the interpreter in a plan to address potential patient comprehension problems.

Reduce Costs by Utilizing All Allowable Consent Documentation Methods

While the idea of gaining access to language translation and interpretation services is discussed in other sections of this article, it is important to also address the informed consent method options that are allowable by federal regulation, such that the full range of options may be used in research and translation costs can be reduced. Both the DHHS and FDA regulations allow for informed consent to be documented using either a full written consent document or a short form written consent document accompanied by a written summary of the study (Family Welfare, 2009; Institutional Review Boards, 1981). When using either of these options with NES individuals, the full consent document and the short form consent document must be translated into a patient's language; however, the written summary may still be provided in English. Typically, a short form consent contains fewer elements, leading to lower financial and time costs for translation. Additionally, the short form consent document may be easily modified for applicability to many studies, which would again result in lower financial and time costs, as one translated short form consent document could be used by multiple studies. When combined with effective consent process methods, the short form consent document can be a cost-reducing method for obtaining informed consent from NES individuals.

Many institutions have policies that support the use of the short form written consent document for NES individuals (Johnson, 2014). However, variation exists regarding the circumstances under which the short form consent document can be used, which is likely the result of federal guidance that indicates preference for translation of the full written consent document (Lin, 1995; U.S. Food and Drug Administration, 2011,

2013). In order to increase inclusion of NES individuals in research, it is recommended that institutions consider the development of policies that will maximize the use of the short form consent document in appropriate situations. Institutions may consider policies that allow for use of the short form written consent document based on the proportion of NES individuals in the local population or the risk level of a study.

In addition to specifying the method of consent documentation described above, the federal regulations also allow for consent documentation to be waived if the study is determined to meet certain conditions (Institutional Review Boards, 1981; Public Welfare, 2009). This means that a researcher would not be required to provide a research participant with a written consent document, but could provide the necessary information about the study in a different manner, such as orally; however, the regulations also stipulate that an IRB may still require the researcher to provide a written statement about the study. Also, the researcher would not necessarily be required to obtain the research participant's signature to document their agreement to participate. Use of this option would further allow for the financial and time costs of translation to be reduced, as minimal written information for obtaining informed consent would require translation. Again it is recommended that institutions consider policies that would maximally allow for use of this option in appropriate situations, in order to increase inclusion of NES individuals in research.

Conclusion

Utilizing these strategies begins to address the barriers for inclusion of NES individuals in research, providing researchers with means for preparing their own studies and accessing the necessary resources. Though other barriers and perceptions exist that

may be preventing researchers from moving toward inclusion, these strategies focus on the primary concerns toward which a resolution may have the greatest impact. As strategies are implemented, systematic assessment should be conducted in order to determine the success of each strategy, such that effective methods may be refined and further developed.

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CHAPTER 5

CONCLUSION

The issue of including non-English speaking (NES) individuals in clinical research has three groups of stakeholders: (a) the research institution as a collective body of policies and influence, (b) the researchers and research staff who have direct interaction with NES participants, and (c) the NES population. The design and results of this project focused on the first two groups, providing an initial understanding into how the research institution, researchers, and research staff view and address inclusion of NES participants.

The analysis of policies and procedures from select academic medical centers provided a foundation for understanding the themes in these policies, revealing a primary focus on the requirements of the federal regulations for the informed consent process and the requisite translation and interpretation services that facilitate this process with NES individuals. With the understanding of researcher and research staff perceptions that was gained through this project, researchers and institutions now have a place to begin focusing improvement efforts for increasing the inclusion of NES individuals in clinical research. Future inquiry into the policies and procedures of research institutions can answer more questions, including the effect policies have on the actual behavior of researchers and research staff, the motivations for implementing certain requirements, and the success particular policies may have in increasing the inclusion of NES individuals over time.

The results of the study provide enough information to begin designing new strategies to influence researcher and research staff attitude and behavior. This includes the strategies discussed in this paper. Any strategies initiated should be evaluated to determine if behavior changes result and the number of NES individuals included increases over time.

Additional research is needed to understand this issue from the perspective of the NES population. Qualitative and quantitative projects should be utilized to understand the interactions that NES individuals have with institutions and researchers. This includes their attitudes toward research participation with particular focus on the barriers they experience.

As the literature on this topic grows, it is hoped that NES individuals will have an equal opportunity to participate in clinical research and that their inclusion increases. New clinical knowledge about the NES population will inform the body of public health such that interventions can be designed to focus on decreasing this population's health disparities and improving their access to health care.