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CRC IRB Proposal

November 2011

Lost in Translation: The use of in-person interpretation vs. telephone interpretation services in the clinic setting with Spanish speaking patients

A) Study Purpose and Rationale:

The patient population at the Columbia University Medical Center's AIM Clinic reflects the diversity of New York City. AIM patients largely live in the Washington Heights and Inwood neighborhoods of Manhattan where the Hispanic population reaches greater than 71%. Fifty-one percent of the residents in this neighborhood are foreign born [1]. This provides unique challenges for health care providers. Cultural, financial, and language barriers are among the challenges when caring for a diverse patient population. Multiple studies have shown that language differences between the health care providers and the patient lead to below average health outcomes. Nationwide, 58% of Spanish-speaking Hispanics lacked a primary medical doctor compared to 29% of English-speaking Hispanics [2]. Further, in a study of Medicaid patients examining timeliness of care, provider communication, and staff helpfulness, Spanish-speakers self reported lower scores than English-speakers [3]. Clearly, people with limited English proficiency (LEP) are marginalized in terms of access to quality health care.

The provision of access to services for people with limited English proficiency was addressed in the Civil Rights Act of 1964. It mandates that all organizations receiving federal support ensure that individuals with limited English proficiency receive meaningful access to services [2]. Similar laws have been described by the Department of Health and Human Services and Department of Justice. However, this provision has been most difficult to implement in the field of healthcare. Physician knowledge of how to best provide language services to those with limited English proficiency is lacking and so is research. Further, many clinics do not have the financial resources to provide sufficient translation services. It has been shown that use of a trained health care interpreter does improve communication, satisfaction, outcomes and utilization of services in the clinic setting. There have been no studies to look at the different modalities of interpretation in the primary care setting. Within the AIM clinic, besides physicians that speak Spanish themselves, there are two ways to provide interpretation. On-site, in-person interpretation is available and so is a telephone interpretation service, Pacific Interpreters.

The rate of colorectal cancer screening is a common measure in the literature to objectively examine language barriers as a contribution to health care disparities. Estimations provide that 50-60% of colorectal cancer deaths may be prevented if every adult over the age of 50 were routinely screened [4]. Nationwide, 30% of Hispanics are screened for colorectal cancer compared to 44% of non-Hispanic whites [4]. Accordingly, Hispanics are diagnosed with colorectal cancer at later stages and have lower survival rates [4]. When these statistics are stratified based upon English language proficiency it becomes clear that language is a major barrier to receiving routine screening for colorectal cancer. One study using the 2003-2005 Behavioral Risk Factor Surveillance System (BRFSS) survey data from found that 65% of Spanish speaking Hispanics and 61% of English-speaking Hispanics over the age of 50 report never having had a screening procedure done for the prevention of colorectal cancer [2]. However, another study did a cross sectional analysis of the 2006 BRFSS survey data when the survey was administered in different languages and found that 33% of Hispanics who responded to the survey in Spanish had received a colorectal screening test but 51% of Hispanics who responded in English had been screened [5]. Further, another study looked at English vs. non-English speaking Mexican Americans and adjusted for variables such as socioeconomic status, health care system factors, health status, and health

behaviors. The study found that Mexican Americans with limited English proficiency were far less likely (55% vs. 33%) to have never had any CRC screening test when compared to English language proficient Mexican Americans [6]. Similar findings have been published with regard to routine mammography although the use of colorectal cancer screening rates is most prevalent the literature.

This study will also examine other indicators that likely contribute to health care disparities among limited English proficient individuals. Rates of routine preventive PAP and mammography screening will be evaluated. Additionally attendance to the next follow up visit will be studied as well as completion of ordered lab draws. The AIM clinic has already instituted an evidence based method to improving screening for colorectal cancer: the patient navigator program. The patient navigator program includes one dedicated Spanish speaking individual who schedules patients using a direct referral system [7]. After the institution of the patient navigator program at Lincoln Hospital in the Bronx the rate of colorectal screening increased by 300% and had saw a 10% increase in screening within the service area of the hospital [8]. Using this data in can be inferred that the patient navigator system at AIM has had a similar positive effect on colorectal cancer screening rates.

Further examination of the most efficient, practical, and effective methods of interpreter services in the primary care setting remains paramount to providing quality care to all individuals. This is particularly important among the Spanish speaking population at the AIM clinic as this group is the majority of patients. Improving interpretation will have both outcomes oriented and cost related effects that will improve care for marginalized populations.

B) Study Design and Statistical Analysis:

This will be a prospective, randomized, single-blinded trial to evaluate the most effective method of Spanish language interpretation in the primary care setting. The trial will involve Columbia University Medical Center's AIM Clinic as the study site. The trial will be limited to Spanish speaking patients who are being seen by their PMD for the first time at the AIM practice. The patient must also have a PMD that is an intern or resident who does not conduct their visit encounters in Spanish. Attending physicians will not be included in the trial to minimize the chance that differing levels of provider experience affect the results. New and established patients will be enrolled in the trial, as long as the visit is the first with a new PMD. Due to residents leaving every three years, patients are often established at the AIM practice but get a new PMD every three years. There will be two study arms in which participants will be assigned. The first arm will be participants whose visit is interpreted by one of the hired interpreters who work within the AIM practice and are physically present during the encounter. The second arm of the trial will be participants whose visit is interpreted via Pacific Interpreters, the telephone based service in which the interpreter is communicating via the telephone. The PMD conducting the visit will be aware of the trial's two arms and general purpose of the study although the specific objectives of the study will remain unknown to the PMD. The patient will not be aware that they have been assigned one of two interpretation modalities. The patient will sign a consent form that details the study without compromising the value of blinding the study participant to one of two interpretation modalities. The consent will include permission to use protected health information (PHI) for the purpose of research.

Patient selection will be completed by the patient financial assistants (PFAs) asking one question to all patients 50 years of age and over: Do you prefer the use of Spanish during your visit? If the patient qualifies and has a PMD who does not speak Spanish, one hired person from the study will consent the patient prior to their visit. Randomization will accomplished using a computer program to randomly divide qualifying patients into the two arms of the study mentioned. The patient will only be randomized to a study arm once he or she has consented to be part of the study. This method will make the attrition rate near zero. The hired study employee will also be responsible for making the participating PMD aware of which study arm the patient was randomized. The PMD will verify the interpretation modality used via a mandatory check box in the AIM Primary Provider Note. If the consented patient requests a

specific interpretation modality upon the visit encounter that differs from the group they were randomized, the patient's request will be honored and the patient will continue to be part of the study. Analysis will be intention to treat and these patients will be considered crossovers.

The sample size was determined using the outcome with the smallest anticipated difference between the two arms: colorectal cancer screening. This was based on an approximation that 50% of patients who use the telephone based interpreter service, Pacific Interpreters, attend scheduled screening procedures/test while the attendance rate of those patients who use in-person translation is 55%. Assuming an effect size of 5% (P2-P1), and in order to achieve 80% power with 5% type 1 error, a sample size of 3,210 subjects (1,605 in each arm) was calculated using the Chi-square test:

$n=8\{[(0.5 \times 0.5) + (0.55 \times 0.45)] / 0.05^2\} + (2 / 0.05) + 2$. An 80% power calculation allows for a 20% chance of type 2 error.

C) Study Procedure:

The study intervention should not change the course of physician decision making. The use of both interpretation modalities are currently in place within the AIM practice and both services are widely used by providers. Only the patients who would use the intervention even if they weren't part of the study are being included. No part of the intervention is solely for research purposes. The patient will not experience any undue discomfort, pain, or suffering from this study.

The duration of each patient's participation will be limited to the first study encounter. Compliance with ordered preventive screening (colonoscopies, mammography, and PAP smears), show rate at the next follow up visit, and completion of routine ordered lab tests prior to the next visit will be collected for each patient for orders during their one study visit. Patient enrollment and length of study are likely to be approximately one year.

D) Study Drugs:

- Not applicable. No study drugs will be used.

E) Medical Devices:

The telephone used to access Pacific Interpreters will be used by one arm of the study. The speaker function is most frequently used during interpretation so that the patient and provider are not passing the receiver back and forth. This device, nor the use of Pacific Interpreters, is investigational. Both are established technology used in the medical field.

F) Study Questionnaires:

- No questionnaires will be used during this study.

G) Study Subjects:

Inclusion Criteria:

- Spanish speaking and Spanish as the language of choice for an office visit
- Age > (or equal to) 50
- Patient's PMD must be an intern or resident
- New PMD

Exclusion Criteria:

- Age < 50
- Patients present for a follow up visit with their established provider
- Patient's PMD is an attending

The study is limited to AIM patients. AIM patients are typically Medicaid or Medicare enrolled and may be considered a "vulnerable population" by virtue of socioeconomic status. However, the study is designed to determine how best to serve these patients. Their rights will be protected by ensuring de-identification and honoring their request of interpreter services if they choose the modality that differs to what they were assigned.

This study does include women and minority populations, as well as an exclusively limited English proficiency population.

H) Recruitment of Subjects:

Patients will be recruited from a population of AIM patients who meet inclusion criteria for the study as described under study design and procedures. The patient's assigned PMD will agree that the patient is suitable for the study but there is no need for the PMD to ascertain from the patient that the subject would be willing to discuss the study.

I) Confidentiality of Study Data:

Individual patient information will be de-identified for confidentiality of subject data and to protect the identity of study subjects. Each participant will be given a unique coded number distinct from the assigned medical record number. Data will be stored in a password protected environment accessible to only the investigators.

J) Potential Conflict of Interest:

- There are no potential conflicts of interest.

K) Location of Study:

- Columbia University Medical Center AIM Clinic.

L) Potential Risks:

The study is low risk to patients as new medical therapies are not being studied. One arm of study participants is at risk of attending less screening procedures/tests and follow-up visits if the study is positive.

M) Potential Benefits:

The participant may or may not directly benefit from participation in the study. The greatest chance of benefit is potential benefit to society. As described the study rationale and purpose language barriers remain a prevalent contributor to health care disparities. By determining the best interpretation method we can better serve the needs of individuals with limited English proficiency and reduce health care spending on non-emergent emergency room care.

N) Alternative Therapies:

- Not applicable.

O) Compensation to Subjects:

- No compensation will be provided to study subjects.

P) Cost to Subjects:

- The subject will incur no additional cost as a result of participating in the study.

Q) Minors as Research Subjects:

- Not applicable.

R) Radiation or Radioactive Substances:

- Not applicable.

References

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