INVESTIGATOR STUDY PLAN

Urogynecological Office Visits and Patient Satisfaction of Limited English-Proficient patients with phone Interpreter Services compared to In-Person Interpreters: Randomized Controlled trial (SIPI)

NCT03470194

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1. TITLE
Urogynecological Office Visits and Patient Satisfaction of Limited English-Proficient patients with phone Interpreter Services compared to In-Person Interpreters: Randomized Controlled trial (SIPI)

2. EXTERNAL IRB REVIEW HISTORY*
N/A

3. PRIOR APPROVALS:
None
Conflict of Interest (COI): N/A
Clinical Engineering Department: N/A
Biohazardous Agents: N/A
Radiation*: N/A*

4. OBJECTIVES*
Primary Objective: To determine if In-person interpreters increases patient satisfaction of Urogynecological(URGYN) office visits compared to the use of phone interpreter services for Limited English Proficient (LEP) patients

Secondary Objective: To determine if type of provider, years spent in the US, income level, or level of education influences patient satisfaction of UROGYN office visits

5. BACKGROUND*
Cultural and linguistic competence are two vital principles, regardless of specialty, providers and health care systems must understand to offer quality health care to patients. Linguistic competence, initially described in 2004 by Good and Jones refers to an organization and provider's capacity to respond effectively to the health literacy needs of the populations served [1]. The National Center for Cultural Competence (NCCC) for years has emphasized the importance of cultural and linguistic competence as a fundamental aspect of quality health care and mental health care for diverse populations [1]. Moreover, this awareness is key to develop essential strategies for reducing health care disparities by improving access, utilization and quality of care. [1]

Both linguistic and cultural competency are important; however, in recent years there has been published literature investigating strategies to optimize linguistic competence. To improve upon current linguistic competence, the field of Emergency Medicine has studied and researched key ways to improve its linguistic competence, mainly by investigating the optimal way of providing translation services to patients. Barriers are created when the patient and physician do not speak the same language this can have a negative impact on patient satisfaction. It has been reported in the literature one way to limit this barrier is by using in-person interpreter for all limited English proficiency (LEP) patients. Bagachi et al randomized patient presenting to the ED to receive in person interpreter services or the usual interpreter services (Ad Hoc and telephone).[2] They concluded that use of in person interpreters significantly increased patients' and providers' satisfaction. [2] Garcia et al found similar results when they evaluated the influence of hospital

trained, Ad Hoc, and telephone ~~i~~nterpreters on perceived satisfaction of limited English proficient parents presenting to a pediatric Emergency Department [4]. In their study, they found parents of patients were significantly more satisfied (p <0.001) with in person hospital trained interpreters. [4] Patient satisfaction can impact a variety of outcome measures, one being, satisfied patients are more compliant with recommended treatment plans[3] Patient satisfaction in the ED setting has also been associated with improved patient understanding of self-care and follow up plans, reduced errors, and better treatment adherence [2]. It is for these reason providers and organization try to optimize patient satisfaction.

It is logical to assume that patients will have improved patient satisfaction with the use to in person interpreters in other specialty areas as well; however, to our knowledge this has not been evaluated or reported in the Urogynecology literature. In a rapidly evolving field that focuses primarily on quality of life outcomes, it is important we adequately communicate with our patients to offer appropriate treatment plans. In our study, we evaluated LEP patient's satisfaction of UROGYN office visits with phone interpreter services compared to in-person interpreters.

References

1. Goode TD, Dunne MC, Bronheim SM. *The Evidence for Cultural and Linguistic competency in health care*. New York, NY: Commonwealth Fund;2006

2. Bagachi A, Dale S, Verbistsky-Savitz N, et al. Examining Effectiveness of Medical Interpreters in Emergency Department for Spanish-Speaking Patients with Limited English Proficiency: Results A randomized Controlled Trial. *Ann Emerg Med*. 2011; 57:3:248 – 256

3. Boudreaux ED, O'Hea El. Patient Satisfaction in the emergency department: a review of the literature and implications for practice. *J Emerg Med.* 2004;26:13-26.

4. Garcia EA, Roy C, Okada PJ, et al. A comparison of influence of hospital-trained, ad hoc, and telephone interpreters on perceived satisfaction of limited English -Proficient parents presenting to a pediatric emergency department. Pediatr Emerg Care. 2004; 20:373 -378.

5. Gany et al. Patient Satisfaction with Different Interpreting Methods: A randomized Controlled Trial. *J Gen Intern Med 2007*. 22 (suppl 2): 312 -318.

6. INCLUSION AND EXCLUSION CRITERIA*

Inclusion Criteria:

- LEP speaking Spanish and Portuguese female patients presenting to the U Mass UROGYN clinic with or without Ad-hoc interpreters
- Spanish and Portuguese speaking female patients with LEP presenting to the U Mass UROGYN clinic for an office visit of any type

Exclusion Criteria:

- Unable to provide consent
- Under 18 years of age
- Pregnant women
- Prisoners
- LEP subjects who decline interpreter services
- Non -Spanish or Non – Portuguese speaking subjects
- Patients with cognitive impairment
- Visually or hearing impaired patients
- Patients not requiring a follow up appointment

7. STUDY-WIDE NUMBER OF SUBJECTS*

N/A

8. STUDY-WIDE RECRUITMENT METHODS*

N/A

9. STUDY TIMELINES*

Subjects will be enrolled and randomized at their initial visit and participation will occur at the subsequent visit. Participation will be for the duration of the single subsequent office visit, and then participation will be done.

Our Urognecology department has approximately 15 Spanish or Portuguese LEP per month and given this trend we anticipate approximately 14 months for recruitment of patient. Taking into consideration time needed for data entry, statistical analysis, and manuscript writing we anticipate the duration of the study will be 17 months.

10. STUDY ENDPOINTS*

The primary outcome, patient satisfaction will be measured by a fourteen-item questionnaire previously used and internally validated by Garcia et al. The questionnaire has 3 sections that evaluates satisfaction with the interpreter, provider, and nurse. We will be assessing the interpreter satisfaction section scores of each subcategory as well as the overall score. All items are answered on a scale of 1 to 4 and weighted on a 100 - point scale.

Secondary outcomes evaluate patient satisfaction in relation to type of provider, years spent in the US, income level, and level of education.

11. PROCEDURES INVOLVED*

This study is a randomized controlled trial. Patients presenting to our UROGYN clinic will be screened for eligibility using inclusion and exclusion criteria.. LEP patients will be identified as patients that

initiate conversation in a non-English language and are only able to communicate adequately regarding their medical problem in a non-English language. This definition was adapted from a previously used technique to identify LEP patients as described by Gany et al. [5]

After patients, have been seen for their scheduled office visit they will be invited to participate in the study. Once the patient has agreed to participate in the study the participant will be randomized. Participants will be given ample time to read the fact sheet and given the opportunity to take the fact sheet home for further review if they choose. Participants must call to be enrolled prior to their next visit, because randomization will occur before the follow up visits. No randomization will occur at the follow-up visit. Patients cannot request to be enrolled at the time of the follow up visit. Study assignment will be revealed using sequentially numbered sealed opaque envelopes. Randomization will be performed using software and a block randomization scheme to yield a 50% chance of having an in-person interpreter. Portuguese and Spanish LEP participants will be randomized from two separate blocks. Bilingual participants will be identified at that time and be asked the primary language they would like for medical interpreter services for the subsequent office visit. Those assigned to the control group will receive phone translation services and the experimental group will have in person interpreters. Once randomized, research team members will make a note in the computer scheduling system if an in-person interpreter is needed for the next visit.. At the subsequent visit, demographic information will be collected and patients will then receive interpretation services from the phone or an in-person interpreter.

At completion of the follow up visit subjects will complete two forms, in their native language. The first form is a fourteen-item patient satisfaction questionnaire that has been previously used in published studies. The first form also has two question from the Consumer Assessment of Healthcare Providers and System Hospital Survey (*www.cahps.ahrq.gov*). The second form will assess subjects English proficiency, overall health status, and yearly household income.

For eligible patients who decline participation we will be collecting non-identifiable information including; patient age, type of visit, language, provider, and if the patient was alone for the visit. This will provide us non-identifiable data for comparative analysis between the group of eligible patients who agreed to participate and those who declined.

12. DATA AND SPECIMEN BANKING*

N/A

13. Data Analysis and Management*

Power calculations were based off findings from Garcia et al. which showed a mean difference of 12 between telephone and translator nursing satisfaction scores. In their study patients' satisfaction was evaluated looking specifically looking at three main subcategories, nursing, physician, and interpreter satisfaction. Sample size calculations were based off seeing a minimum of 12-point difference between mean scores for nursing satisfaction. Our sample size is of sufficient enough size to detect a meaningful difference between mean scores of the other two subcategories as well. We calculated an initial sample size of 48 with a significance level of 5% and power of 80%. Taking into consideration data analysis with multivariate linear regression analysis we added 10 additional participants per variable (Expected dependent variables include: English fluency, interpreter service experience, language, and age)

48 +(10 x 4) = 88. Based on our patient population and taking into consideration potential conflicts that could arise with patients cancelling follow up appointments we are expecting a 30% drop out rate. This gave us to a final total sample size of 114 (57 each arm)

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

The datasheets will be kept in a locked cabinet in a locked office in the administrative offices of the division on Jaquith 2. The data will be entered into a de-identified, password protected file kept on the departmental computer servers.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

We do not anticipate a situation where a subject would have to be removed from the study. A unique situation that could arise, is that a participant could become incarcerated prior to their follow up visit. Section # 18 details how this situation would be addressed. Moreover, should a situation arise, excluding a randomized subject from the study would not pose any harm to the subject. Subjects who fail to show for their follow-up visits will not be withdrawn from the study

16. RISKS TO SUBJECTS*

This study poses minimal risk to subjects, there is the potential risk of embarrassment that the participant might feel with the question about household income. That is not the intent of the question, and the question is optional. Other items that could cause potential embarrassment are the patient satisfaction questionnaire, and questions regarding English proficiency and education level. These questions have been well thought out and written with care to try to avoid this.

There is no economic risk to the patient, as the medical interpreter service is not an additional fee for the patient. There is a risk of breach of confidentiality since protected health information is being collected The datasheets will be kept in a locked cabinet in a locked office in the administrative offices of the division on Jaquith 2. The data will be entered into a de-identified, password protected file kept on the departmental computer servers.

17. POTENTIAL <u>DIRECT</u> BENEFITS TO SUBJECTS*

N/A

18. VULNERABLE POPULATIONS*

N/A. No known vulnerable populations are routinely offered these procedures. We do not serve a pediatric population or pregnant population. In the last 5 years, the Urogynecology service has not seen a patient that was incarcerated. Should an enrolled participant become incarcerated she would be withdrawn from the study because there would be no way to guarantee a follow up visit.

As this study involves only Non-English speaking patients we are providing participants a fact sheet translated into their native language, as a safeguard to protect their rights and welfare.

19. MULTI-SITE RESEARCH*
N/A

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*
N/A

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*
Subjects will not be notified of the results. Questionnaires will be scored once all data has been collected and entered into the database.

22. SETTING
Subjects will be identified and recruited in the urogynecology clinic located in two locations, UMass Memorial and Northborough UMass Memorial Health Care. The urogynecology division has two full-time designated surgeons (including the PI) and both will participate in the study. In addition, the nurse practitioner and department fellows will work as co-PI and study assistants. This comprises the team who will recruit subjects and obtain intraoperative and postoperative study data.

Data entry and analysis will be performed in the administrative offices of the division on Jaquith 2 in U Mass Memorial.

23. RESOURCES AVAILABLE

Roles of the research team members:

- Principal investigator: The PI's role will include identifying potential subjects for the study, consenting of subjects, participating in data analysis, preparing submissions to the IRB, oversight of the conduct of the study and research personnel. The PI has overseen numerous research studies within the department.
- Co-PI: The role of the Co-PI will include identifying potential subjects for the study, consenting of subjects, participating in data collection, analysis, and , preparing submissions to the IRB. Study assistants: All study assistants will identify potential subjects for the study, collect data, and consent subjects, All study assistants have participated in prior research studies conducted by the UROGYN division.
- Biostatistician: The OB/GYN departmental biostatistician will help with data analysis She has worked with the urogynecology division on several research studies previously. She will not participate in the recruitment of study subjects.

The PI, co-PI, Biostatistician and study assistants are CITI-trained. All of them, except the biostatistician are also clinical members of the urogynecology division at UMass Memorial Medical Center Department of Obstetrics and Gynecology. Before initiation of the research, all research team members will be instructed on the study protocol and

research procedures at the urogynecology department's scheduled bimonthly research meetings.

24. LOCAL RECRUITMENT METHODS

Our power calculations, as detailed previously in question 13, calculated 114 study participants will be needed. Based off our clinic trends we anticipate approximately 17 months to recruit 114 subjects for the study.

All subjects will be identified and recruited through the urogynecology clinic, at the two clinic sites previously mentioned in question 22. Our two full-time attendings (including the PI) will both participate in the study, as well as the department, nurse practitioner and fellows—therefore, this yields access to every urogynecological patient. The study team will screen potential subjects using inclusion and exclusion criteria at office visits. No identifiers will be recorded during screening. Once eligibility has been determined, potential subjects will be offered enrollment in the study by their provider after the clinic office visit has been completed. Clinical staff will not be involved in the recruitment process. The study will be reviewed in detail and ample opportunity for questions will be given. The opportunity to decline participation will also be given, and no information on these patients will be recorded for this study. An un-identified tally will be recorded counting screened patients who were "ineligible" or "declined". For women agreeing to participate, a fact sheet in the participant's native language will be given.. There will be no payment to subjects in the study.

25. LOCAL NUMBER OF SUBJECTS

We seek to enroll 114 subjects in the study.

26. CONFIDENTIALITY

Data on subjects will be stored under a study participant ID number to ensure confidentiality. This data will be stored initially as a hard copy in a locked closet in a locked office until the second office visit has occurred. Study data will be collected only under the study participant ID number, and later transcribed monthly into a de-identified Redcap database by the study assistants. This database is password protected on the secure Redcap server. At that point, completed study charts will be stored in the locked closet. Only the PI and study assistants have access to this key. The document that links the study participant ID number to patient identifiers (medical record number) will be stored in a separate locked filing cabinet in a different departmental locked office. Once the study is published, this document will be destroyed, thus anonymizing data.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS. We will be requesting a HIPPA Wavier of authorization. All patients being recruited will be recruited by research staff members that are already familiar with the patient; however, for data collecting purpose office/clinic note and problem list may be reviewed. This may be reviewed by a research team member who is not that participant's provider. The HIPPA waiver of authorization will be in

participants' native language. An English version of the HIPPA waiver of authorization will be translated by language line services to Spanish or Portuguese. This is a reputable translation company recommended by U Mass Memorial interpretation services.

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28. COMPENSATION FOR RESEARCH-RELATED INJURY

Because there is minimal risk, there will be no compensation for subjects participating in the study. In the highly unlikely event of research-related injury, no funds have been set aside and the study subject will be responsible for the cost of care of any research related injury.

29. ECONOMIC BURDEN TO SUBJECTS

There is no economic burden to the subjects. Both randomized groups will receive our standard of care and all necessary examinations, interventions, and procedures will continue regardless of the subject's participation in the study

30. CONSENT PROCESS

Once participants have agreed to be enrolled, participants will be given a fact sheet that will be reviewed with them. We will be using the Fact Sheet Template form found on the IRB website under forms and templates. The Fact sheet will be translated into participants' native language, by language line translation services. We are requesting a waiver of documents of consent for the following reasons

- The research present no more than minimal risk to subjects
- The research involved no procedures for which written consent is normally required outside of the research context
- We will be proving subjects written information about the study that embodies the elements of the consent

How to review the fact sheet with subjects will be reviewed at our monthly research meeting prior to study recruitment, and all recruiting study staff are CITI trained.. Patients will be given ample time as previously described in section #11 to decide if they wish to partake in the study. Additionally, subjects will be encouraged to ask additional questions regarding the study and they will be informed that they may withdraw from the study at any time despite their initial enrollment. A copy of the fact sheet will be provided to the patient, along with the principal investigator number. Subjects will be encouraged to call with any additional questions.

31. PROCESS TO DOCUMENT CONSENT IN WRITING

N/a

We will be requesting a waiver of documents of consent as previously described in section #30

32. DRUGS OR DEVICES

N/A