Information Visualization To Improve Pain Communication Between Providers, Interpreters, and Patients with Limited English Proficiency

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Purpose: The overall goal of the proposed study is to modify and pilot test the pain assessment InfoViz tool among limited English proficiency (LEP) Hmong patients in a primary care setting.

Specific Aims:

- To pilot the pain assessment InfoViz tool among LEP Hmong patients in primary care.
    - a. To examine the feasibility of implementing the InfoViz tool.
    - b. To explore congruency of patient–interpreter–provider MU of pain severity, location, and quality.
    - c. To evaluate outcome measures selected to capture satisfaction with communication, quality of communication, pain relief, and pain interference and explore variables identified in the InfoViz tool conceptual framework (MU of pain information, satisfaction with communication, pain diagnosis, and treatment).

Background:

Approximately 25 million individuals in the U.S. have limited English proficiency (LEP), defined as the inability to read, write, and speak English.8 Communication differences between LEP patients, interpreters, and providers contribute to significant health disparities. To achieve mutual understanding (MU) of diagnoses and treatments, LEP patients and providers must each effectively communicate their perceptions of the patient's illness. Interpreters can assist in overcoming language and culture barriers between providers and LEP patients. Yet, an interpreter's ability to accomplish such tasks may be hindered by nuances in the patient's language and culture, including familiarity with medical terminology. One clear example of communication challenges negatively affecting patient outcomes is in pain management disparities among LEP patients. Pain is the most commonly reported symptom in primary care. However, pain in LEP patients is more likely to be underdiagnosed or undertreated than in English-speaking patients due to a lack of MU in patient–interpreter–provider communication and the culturally and linguistically appropriate pain tools that facilitate this communication. Ineffective pain communication results in inadequate pain relief, decreased satisfaction with care, and a poor quality of life.

Information visualization (InfoViz) tools (i.e., visual representations of information) offer a potential solution to pain-communication challenges. These tools help patients and providers understand, communicate, and decide on treatment. Currently, visual pain scales with faces, thermometers, or colors rely on the assumption that all patients perceive the visuals as (1) having the same meanings and expressions and (2) being culturally appropriate. We know that outcomes are more successful when vulnerable groups participate in creating and testing communication interventions and tools. No studies have yet developed or tested culturally and linguistically appropriate InfoViz tools with the triad of LEP patients, interpreters, and providers to facilitate pain communication and the MU of pain information.

My research focuses on pain communication in LEP Hmong (a Southeast Asian

population). The Hmong can benefit substantially from an appropriate InfoViz communication tool; 90% of older Hmong have LEP. Pain is particularly problematic for this group because the Hmong describe pain using visual metaphors often inconsistent with providers' knowledge, and interpreters struggle to translate metaphors accurately between patients and providers. Moreover, the Hmong language lacks discrete descriptors for pain severity, location, and quality – the three components of a comprehensive pain assessment, which provide critical information necessary for diagnosis and management. This study will modify and conduct a pilot test of a pain InfoViz tool to facilitate the patient–interpreter–provider communication of pain severity, location, and quality and increase MU during pain assessment. This study will be the first step to improving pain diagnosis and management in LEP Hmong.

Inclusion Criteria:

Data will be collected from Hmong patients 18 years or older with self-reported pain at the time of recruitment. The LEP Hmong patients will be included if they indicate that they do not speak English well in response to the screening question, "how well do you speak English?" This question is a standard measure used by the U.S. Census in the American Community Survey and a proxy for LEP. English-proficient Hmong patients will be included if they are bilingual.

Interpreters are eligible if they are 13 years old or greater and self-identify as interpreting for a Hmong individual in the health care setting. Consistent with the Affordable Care Act, Section 1557, children of any age can act as medical interpreters for their family members as long as the adult patients consent. We will include children who are 13 years old and older because their cognitive and language skills are complete at this age. Because patients rely on both family (lay) and professional interpreters, both types of interpreters will be included in the study. The inclusion criteria are: self-identified as a professional interpreter or someone who interprets for family member in a healthcare setting.

Data will also be collected from health care providers, including primary care nurse practitioners, medical or osteopathic physicians, or physician assistants who have at least one LEP Hmong patient who has visited the clinic with pain during the study period.

Exclusion Criteria:

Telephone interpreters will be excluded due to being removed from the clinical setting and thus unable to view and use the pain assessment InfoViz tool with patients.

Recruitment Plan:

To pilot the pain assessment InfoViz tool among LEP Hmong patients in primary care. The LEP Hmong patients, interpreters, and providers will be recruited differently. To recruit LEP Hmong patients, we will work with the Clinical Research Data Service (CRDS) at the UW–Madison Institute for Clinical and Translational Research to obtain a daily report containing the contact information of any Hmong patients who identify as LEP and have upcoming appointments at the UW Family Medicine clinics. We will conduct telephone screening to recruit eligible participants and discuss the study's purpose. If an LEP Hmong patient agrees to participate in the study, we will obtain oral consent.

To recruit providers, we will attend a monthly staff meeting to inform providers about the study, invite their participation, and discuss the study's procedures. After the meeting, we will also give providers a chance to decide whether they want to become involved in the study by sending them a follow-up "opt-out" email. Providers who do not "opt-out" by email within a two-week timeframe will be contacted by the research team to confirm their willingness to participate, obtain written consent, and discuss the study's procedures. To recruit interpreters, we will use two different strategies for each interpreter type (i.e., family versus professional interpreters).

To recruit family interpreters, after we speak with LEP Hmong patients who are willing to participate in the study, we will ask the LEP Hmong patient to provide the name and contact information of their family interpreter. We will then call the family interpreter to discuss the study's purpose and procedures, determine their willingness to participate in the study, and obtain consent. This approach was deemed to be appropriate and successful in previous research. After the completion of the study, we will send an email invite the interpreters to participate in a debriefing interview to better understand their experience and how we can better implement the tool in future studies.

To recruit a professional interpreter, we will work with the UW Health interpreter services to identify and recruit professional interpreters, and we will send a recruitment flyer through email to all Hmong interpreters and ask them to contact interpreter services if they will participate. Interpreter services will then prioritize interpreters willing to participate in the study with consenting patients (see letter of support).

Study Procedures and Interventions:

We will follow IRB guidelines on how to obtain consent remotely.

To pilot the pain assessment InfoViz tool among LEP Hmong patients in primary care.

The goal is to obtain information about the feasibility of the study protocol and identify modifications (e.g., study procedures, outcome variables) needed for the design of a larger efficacy study, consistent with the goals of a pilot study. Data will be collected from LEP Hmong patients, interpreters, and providers. We will use the same inclusion criteria for LEP Hmong patients, interpreters, and providers as previously stated. Based on a preliminary survey of patient populations served at the UW Northeast Clinic, we identified 482 LEP Hmong patients who had been seen within the past 5 years. The total number of subjects will be 50 triads of patients, interpreters, and providers. We have selected a sample size of N = 50 triads, which is described in the literature as sufficient for pilot evaluations.

The following are the surveys and interviews we will use.

1) The MUS will be used to assess MU between the patient, interpreter, and provider about pain location and quality. Specifically, we will use the main symptom item of the MUS subscale. The MUS is validated by a multiethnic and multidisciplinary expert panel using a nominal group technique. Because the MUS was developed to assess communication in general, we will adapt it to assess pain communication specifically. Also, the MUS was not developed for interpreters, so we will adapt it to include all members of the triad. We will consult with Dr. Schaeffer, a survey expert, on all the adaptations of existing measures.

2) Pain relief will be measured using a 5-point Verbal Rating Scale (i.e., none, slight, moderate, lots, complete) to rate pain reduction since the clinic visit. Self-reporting is appropriate as pain is a subjective experience. The Verbal Rating Scale is a gold standard for reporting pain and is documented as preferred by less-educated individuals.

3) Pain interference will be measured using a one-item question derived from the 12-Item Short-Form Health Survey (SF-12): “During the past 4 weeks, how much did pain interfere with your normal work including both work outside the home and housework?” This will have five Likert response categories: “not at all,” “a little bit,” “moderately,” “quite a bit,” or “extremely.” We translated and tested this item in Hmong in our previous research.

4) Satisfaction with communication will be measured using one item--"Overall, how satisfied are you with your doctor’s communication with you about pain?" with response categories of very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, or very dissatisfied.

5) Quality of communication will be measured using one item--"Overall, how would you rate this doctor’s communication about pain with you? " with response items of excellent, very good, good, fair, or poor. This question was modeled after the Quality of Communication Questionnaire (Engelberg, Downey, & Curtis, 2006)

6) Debriefing interviews will assess additional information not captured by the outcome measures including exploring the ability of the outcome measures to capture participant

experiences (conceptualization mechanism) related to MU, satisfaction with communication, pain diagnosis and treatments, and pain relief and interference. As part of the pilot test, we will also conduct a debriefing interview with the interpreters to better understand their experience and how we can better implement the tool in future studies.

The time it takes to complete the survey and interviews will vary from 10 to 30 minutes for patients, interpreters, and providers. All survey and interview completion will be conducted in a private area.

Face-to-face research activities will be conducted according to institutional policy at the time in-person visits begin.

Research Procedures:

To pilot the pain assessment InfoViz tool among LEP Hmong patients in primary care, the following are our study procedures. The LEP Hmong patients, interpreters, and providers will be recruited differently. To recruit LEP Hmong patients, we will work with the Clinical Research Data Service (CRDS) at the UW–Madison Institute for Clinical and Translational Research to obtain a weekly report containing the contact information of any Hmong patients who identify as LEP and have upcoming appointments at the UW Family Medicine clinics. We will conduct telephone screening to recruit eligible participants and discuss the study's purpose. If an LEP Hmong patient agrees to participate in the study, we will obtain oral consent via phone. We will audio record the telephone screening process.

1. Prior to the visit, we will email the provider to notify him/ her about the upcoming appointment that our study team will observe. We will also email or text the interpreter based on his/her preference of communication.

2. Arrival at Clinic. Upon a patient and interpreter's arrival at the clinic, the receptionist at the front desk will direct them to the study team prior to the medical consultation with their health care providers. For the usual care phase, the patient and interpreter will continue as normal in the waiting room. For the intervention phase, we will ask the interpreter and

patient to complete the pain assessment InfoViz tool together in the waiting area, a common practice in primary care. Acknowledging potential privacy issues related to this approach, we will encourage participants to sit in areas with fewer people. The RA will observe patient-interpreter-provider interactions in both usual and intervention conditions.

3. During Clinic Visit. For the "usual care" phase, interpreters will continue to interpret as they normally would, with verbal interpretation for patients and providers. For the "intervention" phase, the interpreter will use the pain assessment InfoViz tool with verbal descriptions of pain information. Specifically, during pain assessments, the health care providers will ask questions related to pain, including pain severity, location, and quality. When the providers ask such questions, the interpreter will use the pain assessment InfoViz tool to facilitate the communication of the Hmong patients' pain location and quality responses. For example, when the provider asks the patient, "Tell me where your pain is located," the interpreter will interpret the patient's response with verbal descriptions and show the patient's marked pain location to providers during communication between patients and providers. When the provider asks the patient, "How would you describe your pain?" and if the patient says "It hurts like a chicken pecking" in the Hmong language, the interpreter will look at the tool to identify the corresponding meaning represented in the English medical terminology and translate the patient's pain description using this terminology to the provider. When the provider asks the patient "How would you rate your pain?", if the patient points to the very pale face on the far right, the interpreter will state "10." The RA will repeat the fidelity checklist to assess the interpreters' use of the pain assessment InfoViz tool. We will audio record the conversation of the patient, interpreter, and providers during the clinical visit for both the usual care and intervention phases.

4. Post-Visit. Immediately after the clinic visit, all the participants (usual care and intervention conditions) will complete the mutual understanding scale (MUS), and answer questions about communication quality, communication satisfaction, and the demographic survey. Patients in both the usual care and intervention conditions will also orally report their pain interference to the RA. Patients and interpreters will complete the acculturation scale. Interpreters and providers will complete all the surveys in writing. All

the participants will also answer three open-ended debriefing questions to further understand the impact of the tool on their MU, satisfaction, and acceptability of the tool. Providers will also be asked to answer two additional questions about their ability to make a pain diagnosis and prescribe appropriate pain treatment in the survey. Patients will complete the surveys orally with the RA and will be audio-recorded. The RA will collect the surveys and complete patient pain assessment InfoViz tools in person at the clinic. Within 4 weeks of the clinic visit (the recommended follow-up period for pain by clinic providers), the RA will contact patients by telephone to orally rate their pain relief, pain interference, and share whether they used the recommended pain treatments (adherence to medication). This conversation will be audio-recorded. After each data collection point, the RA will document the challenges related to attending clinic appointments (i.e., schedule changes, participants changing their minds about study staff observing the patient-provider interaction). The debriefing interviews will provide insight into the mechanisms of intervention effects and ways to enhance the implementation of the intervention and select appropriate outcomes in planning for the larger trial. After the completion of the study, we will also conduct a debriefing interview with the interpreters to better understand their experience and how we can better implement the tool in future studies.

We will also review patients' records to determine if providers are documented patients' pain information more effectively in the absence and during the use of the pain InfoViz assessment tool.

Outcome Measures:

Type	Name	Time Frame	Brief Description
Primary	Feasibility 1. Recruitment and retention 2. Completeness of InfoViz tool 3. Fidelity of InfoViz tool use	1. Throughout the study conduct 2. Immediately post-intervention 3. Immediately post-intervention	1. Proportion of eligible participants enrolled; proportion of enrolled participants who complete the study

			2. Proportion of InfoViz tools with pain severity marked, at least one pain location marked, and at least one pain quality marked on the InfoViz tool. 3. Proportion of items correctly performed on the investigator designed fidelity checklist.
Primary	Mutual Understanding Scale – Main Symptom Item	Immediately post usual care / intervention	One question item from the 6-item MUS asks patients about their main symptom (i.e., "What was the most important health compliant for which the physician was visited?") and providers to report patients' main symptom (e.g., "What was the most important health complaint for which the patient consulted with you?").
Secondary	Visit-Specific Satisfaction Questionnaire (VSQ)-Satisfaction *with communication item*	Immediately post usual care/intervention	*Four items of satisfaction of the VSQ subscale related to explanations of health management (i.e.,* "In terms of your satisfaction, how would you rate the explanation of what was done for you"*, information about the outcome (i.e.,* "In terms of your satisfaction, how would you rate the information about the outcome [diagnosis, treatment options,

			activity participation]; *interpersonal care (i.e.,* In terms of your satisfaction, how would you rate the personal manner [courtesy, respect, sensitivity, friendliness] of the provider)*, and general satisfaction (In terms of satisfaction, how would you rate the visit overall?).*
Secondary	Pain relief	*Four* weeks post usual care / intervention	Patients will be asked to rate the amount of their pain relief experienced since the clinic visit using a 5-point Verbal Rating Scale: none, slight, moderate, lots, complete.
Secondary	*Pain interference*	*Immediately and 4* weeks post usual care/intervention	*One question item derived from the 12-Item Short-Form Health Survey: "During the past 4 weeks, how much did pain interfere with your normal work including both work outside the home and housework?" with response options: "not at all," "a little bit," "moderately," "quite a bit," or "extremely."*

Data Protection Plan:

To address the risk of loss of confidentiality and privacy, there will be no identifiers in the transcripts, surveys, and datasheets. Specifically, each study participant will receive a code number to which all study data will be linked. The code will be known only by the PI

and study team members. All study data will be reported in a tabular/group format, and no individual data including protected health information (PHI) will be released in presentation or publication. Only aggregate statistical output representing groups of subjects will be released. Records will be made available only to research staff and the Federal, State, and Institutional regulatory personnel who may review records as part of routine audits. The design sessions, surveys, and debriefing interviews will be conducted in a private space. Hmong patients and interpreters will be reminded to not share private information disclosed during the design sessions to anyone. All data – including the audio recordings, scanned hand-written notes, and surveys– will be stored in a password-protected computer server at UW–Madison SON. The levels of security for the SON Server are threefold and include: 1) Physical Security: the server is located in a secure server room of the SON building that contains emergency backup power, an uninterruptible power supply, and an automated fire suppression system; the server rack has locks on the cabinet doors; 2) Firewall: located behind the UW–Madison campus firewall; 3) virtual server security, including a) the configuration of permissions at the folder level can be done only by the "administrator," and b) password protection is used at the network levels for all transactions that allow entry and editing of data, provide access to subject data, or administrative privileges. Once the audio recordings have been loaded onto the server, they will be deleted from the audiotape recorder. The audio recordings and transcripts will be maintained for 7 years and then destroyed, consistent with the requirements at the UW–Madison. Paper-copy documents, such as the transcripts including the COVID-19 qualitative item will be secured in a locked file cabinet in a locked storage room within the PI office space. We will collect some information about the impact of COVID-19 on patients as this has turned out to be an important issue for Hmong patients. This data will be collected for future study. We will follow the data protection stated above.

We will restrict access to identifiable data to key personnel who need to know it. We are collecting only the data necessary to address our study aims. The identifiers we will obtain in the dataset are the medical record number (MRN) and the date of service. However, we do not plan to use such data in our analysis. Specifically, we will create a sub-set dataset

without the MRN and the date of service in the analysis. Medical chart extraction will be done on the PI's office or research space in the School of Nursing using password-protected computers. We will store and use data in a manner that substantially reduces the risk of loss of confidentiality. Specifically, we will create a pseudo-ID, a unique three-digit number that allows us to differentiate one individual record. When printed documents are required, such as recording of data from medical record abstractions, the paper copies will be secured in a locked file cabinet within a locked storage room within the PI office at the School of Nursing. Access to the paper records will be restricted to the PI and project personnel. All study data will be maintained in password-protected files on secure servers or in locked cabinets within locked storage rooms. Access to computer-stored information will be strictly controlled. Access to data is restricted to the PI and her designees, the project personnel directly involved in variable and dataset creation. The dataset is stored on a secure SON Data server.

For the audio recordings during the clinic visit, the study team will scrub all PHI identifiers (e.g., age, name) before transcribing or analyzing the data.

Plan to Protect PHI:

All study data will be maintained in password-protected files on secure servers or in locked cabinets within locked storage rooms. Access to computer-stored information will be strictly controlled and stored on the School of Nursing's secure server. It has multiple layers of security and follows best practices for securing PHI data.

After the data has been organized and variables created, we will create a limited dataset (direct identifiers removed, i.e., the date of service) that we will use day-to-day for analysis. The dataset will be stored on a secure School of Nursing Data server. When printed documents are required that include PHI or non-PHI with identifiers, the paper copies will be secured in a locked file cabinet within a locked storage room within the PI's research space. Access to the paper records will be restricted to the PI and project personnel.

Identifiers: The direct identifiers we will obtain in the dataset are the medical record number (MRN) and the date of service. However, we do not plan to use such data in our analysis. Specifically, we will create a sub-set dataset without the MRN and the date of service in the analysis. Therefore, we will not maintain a link to such data. Access will be limited to investigators, data programmers, and the statistician who perform data linkage and subsequently remove direct identifiers, creating the analysis datasets. To further explain our data identification system: Shortly after patient data is obtained from the UW Health back-end database, we will assign a pseudo-ID to each patient record. The pseudo-ID is a unique random number that allows us to differentiate one individual record from another in the dataset. Next, the programmers remove all direct identifiers (name, MR number). In addition, the programmers remove UW Health's back-end database ID number which is a direct identifier but is only useful in the UW Health backend database (and does not appear in Health Link). No sensitive information will be included in the analysis dataset. No individual PHI will be released in presentation or publication. Only aggregated statistical output representing groups of subjects will be released.

For the audio recordings of the conversations during the in-person clinic visits, we will delete all PHI information using a program called Audacity prior to transcribing or listening to the conversation.