PROTOCOL TITLE: Impact of Companion Presence during Placement of Neuraxial Analgesia

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OBJECTIVES:

The purpose of the study is to evaluate the impact of the presence of a companion during epidural catheter placement for labor analgesia. It will be focused on parturients having their first child. Additionally, it will investigate the effect of ethnicity, health literacy (as evaluated by the Newest Vital Sign questionnaire), catastrophizing (as evaluated by the Pain Catastrophizing Scale), and the relationship of the companion to the parturient. We hypothesize that there may be specific subgroups in which the parturients satisfaction is improved by the presence of a companion during labor epidural catheter placement; however, a significant improvement in maternal anxiety, when including all participants, will not be appreciated.

BACKGROUND:

Currently at our institution, the support team for the parturient in labor is asked to exit the room during the placement of the labor epidural catheter. However, there has been a recent movement in many institutions to allow a companion to be present during this perceived stressful procedure, as it may improve maternal satisfaction and anxiety, in a similar fashion as having a support person present during a cesarean delivery under neuraxial anesthesia.

There have only been two randomized controlled trials published that have investigated the presence of a companion during neuraxial procedures in a parturient. The first was published by Orbach-Zinger et al. in Anesthesia and Analgesia (2012), investigating 84 couples in Isreal, randomized between partner in (n=41) and partner out (n=42). They investigated both partners' anxiety utilizing the State Anxiety Inventory questionnaire before and after epidural placement, as well as asking the parturient to rate the pain associated with the epidural placement. They found that there was actually an increase in anxiety when the partner was present in the room, and that the parturient perceived a more painful placement in this situation as well. However, they did not evaluate whether the parturient wanted her partner present. Additionally, this study did not focus on an American population, a population that has been described repeatedly to place high value on individual choice. Iyengar and Lepper published a study in the Journal of Personality and Social Psychology (1999) describing the value that Americans place on individual choice, and showing that this value was present even in early childhood. Therefore, the results of a study in the United States focusing on the choice of the parturient may very well yield different results than those found by Orbach-Zinger et al.

The second study was published earlier by Prabhu et al. in the International Journal of Obstetric Anesthesia (2009), and evaluated the anxiety of parturients both before and after the placement of neuraxial anesthesia prior to cesarean delivery. They compared the anxiety level of the parturient using a VAS, and found a small improvement in anxiety in those parturients whose partners were present during placement. This study was conducted in Ann Arbor, MI, and investigated an American population, but did not specifically address the choice of the parturient. Instead, as with the first study mentioned, the groups were randomized to partner in versus partner out, and never inquired as to the preference of the parturient. Additionally, the neuraxial procedure occurring in an operating suite, as opposed to a labor and delivery suite, and the

pending surgical intervention may have confounded the anxiety experienced by the parturient.

During the month of August, a small, random sampling of parturients in the labor and delivery ward at Prentice Women's Hospital were surveyed as to whether they would want a companion present during the placement of a labor epidural catheter for analgesia. Those that already had a labor epidural catheter in place were asked if they would have liked to have a companion present during the placement, while those who did not yet have one placed were asked if they would choose to have someone present if they were given the choice. An overwhelming number of parturients (29/34) stated that they would choose to have a companion present for the procedure. Additionally, of those who would not have chosen to have someone present (5/34), two stated that they still would have appreciated being given the choice. Our study would add to the two prior studies by specifically demonstrating whether giving the parturient her choice in the presence of a companion improves satisfaction, as well as anxiety, during the placement of a labor epidural catheter for analgesia.

INCLUSION AND EXCLUSION CRITERIA:

Parturients will be screened for eligibility on a basis of reason for admission to the labor and delivery ward. Those that are being induced for labor or arrive in spontaneous labor will be considered. Those admitted for a planned procedure, other than labor, will not be eligible.

Companions will be approached on the labor and delivery unit 8th and 9th floor Prentice Women's Hospital and the study team member will introduce the study as well as the requirements for participation. A verbal consent will be obtained.

Physician Participants

A) Attending Physicians will be approached on the labor and delivery unit on the 8th floor Prentice Women's Hospital to participate in the study before the epidural catheter has been placed. Risks and benefits as well as responsibilities of completing the questionnaire will be discussed.

B) Resident Physicians and Anesthesiology Fellows

The resident physician or fellow will be approached on the labor and delivery unit on the 8th floor Prentice Women's Hospital in the Anesthesiology work room before the epidural catheter has been placed. Risks and benefits as well as responsibilities of completing the questionnaire will be discussed as well as the ability for the resident to opt out of study participation.

Inclusion:

Parturients will be included if they are delivering the first child and are planning to labor with neuraxial analgesia. Additionally, there will need to be sufficient time before delivery to allow the completion of the Pre procedure questionnaire, State-Trait Anxiety

Inventory (STAI) questionnaire both before and after the procedure, as well as the Newest Vital Sign questionnaire and the Pain Catastrophizing Scale questionnaire before the procedure. They will be included if they are ASA 2. Furthermore, they be required to read and comprehend the English language, as the Newest Vital Sign questionnaire requires them to read and interpret a nutrition label.

Physician Inclusion:
Anesthesiology Attending, Fellow or Resident Physicians who participants in the placement of the epidural catheter placement

Companion Inclusion:
Primary companion identified by parturient over the age of 18

Exclusion: Parturients will be excluded if they are receiving neuraxial anesthesia for a cesarean delivery, external cephalic version, or other non-labor procedure. They will also be excluded if they begin to push for delivery before completion of the STAI questionnaire following labor epidural catheter placement. They will be excluded if there is no support person present at the time of the neuraxial procedure. They will be excluded if they are ASA 3 or greater, or if they have a contraindication to receiving any of the medications routinely used in the placement of a labor epidural catheter (lidocaine, bupivacaine, epinephrine, fentanyl). Adults who are unable to consent and minors will be excluded.

STUDY-WIDE NUMBER OF PARTICIPANTS:
The total number of participants has been determined to be 75 per group, for a total of 150.

STUDY-WIDE RECRUITMENT METHODS:
Potential participants will be recruited while they are on the labor and delivery ward at Prentice Women's hospital, prior to the placement of a labor epidural catheter. They will be approached by a member of the research team.

Potential participants will be identified by interview and personal history, as well as by anesthesia and obstetric notes in the electronic medical record.

No advertisements will be used to recruit participants for the study.

MULTI-SITE RESEARCH:
N/A

STUDY TIMELINES:
The duration of an individual's participation extends from initial enrollment while on the labor and delivery ward prior to labor epidural catheter placement until the completion of the STAI questionnaire and survey following this procedure. The duration of the study enrollment is anticipated to be 3-5 months, with the plan to enroll an average of 2-4

parturients daily, and accounting for study drop-outs. The estimated date for study completion is late spring to early summer of 2017.

STUDY ENDPOINTS:

The primary endpoint for the study is:

- Does having a support person present when it is the desire of the parturient has a positive effect on maternal satisfaction during the placement of epidural catheter for labor analgesia?

The secondary endpoints are:

- Does having a support person present when it is the desire of the parturient has a positive effect on maternal anxiety during the placement of epidural catheter for labor analgesia?
- Does having a support person present when it is the desire of the parturient have a positive effect on maternal perception of pain during the placement of epidural catheter for labor analgesia?
- Does the presence of a support person affect the perceived difficulty of the procedure by the provider placing the labor epidural catheter?
- Does the level of health literacy of a parturient affect her level of anxiety?
- Does the degree of Pain Catastrophizing affect the parturients level of anxiety?
- Does the relationship of the parturient to the support person have an effect on the level of anxiety of the parturient?
- Does the ethnicity of the parturient have an effect on the level of anxiety?
- Does induction of labor versus spontaneous labor have an effect on the level of anxiety of the parturient?

PROCEDURES INVOLVED:

Parturients who have been admitted to the Labor and Delivery ward at Prentice Women's Hospital will be approached by a member of the research team prior to the placement of a labor epidural catheter. They will be asked if they are considering neuraxial labor analgesia, and if they are they will be screened using the inclusion and exclusion criteria to determine study eligibility. Once they have been evaluated and found to be appropriate for the study, they will be invited to participate.

Participants will be asked to fill out the STAI questionnaire to assess the level of anxiety prior to placement of the labor epidural catheter, and before knowing their group assignment. They will then complete the pre procedure questionnaire. This questionnaire asks about expectations she has for the labor epidural procedure. They will then be given the page of the Newest Vital Signs questionnaire with the Nutrition Facts, and be asked the 6 questions by the recruiter. Then they will be asked the Pain Catastrophizing Scale questionnaire with 13 statements, and asked to respond as directed by the instructions stated by the researcher. They will then be asked who their primary support person is. A form will be handed to that person to confidentially record if he/she would prefer to be present for the procedure. This form will be collected from the support person, and without the parturient aware of the support person's response, she will be asked for her preference with regard to the presence of a support person in

the room, which will be recorded on this form as well. Finally, she will be asked which ethnicity she most relates to, also to be recorded on this form.

After all these data have been collected, the parturient will be randomized as to whether her companion will be allowed in the room or will be asked to leave. This will not be communicated to the parturient until the time of the labor epidural catheter placement. When she requests the neuraxial labor analgesia, the provider placing the labor epidural catheter will be made aware of which group she has been randomized to, and will either ask the companion to leave for placement, or provide the companion a non-mobile chair to sit on in front of the parturient for placement of the labor epidural. The companion will be asked to remain in the chair. He/she will be asked to focus on the parturient. It will be emphasized that he/she must remain seated and will not be allowed to observe the procedure being performed. This is to prevent loss of consciousness in the companion, which has been documented in the literature (Devore and Asrani, 1978; Crosby and Halpern, 1989). One violation will result in a warning, and after a second the companion will be escorted out of the room and the participant will be removed from the study.

The provider will place the labor epidural catheter in the regular fashion, as is common practice at Prentice Women's Hospital. After preparation and draping of the skin in the sitting position, infiltration with Lidocaine 1% will be conducted at L3-L4 or L4-L5. A 17g Tuohy needle will be advanced into the epidural space, using a loss of resistance with either saline or air, depending on the provider's preference. After the epidural space has been located, a 27g pencil-tip spinal needle will be placed through the Tuohy, into the intrathecal space, and an intrathecal dose of medication will be administered. The exact dose to be injected will be left up to the discretion of the provider, who will determine the appropriate dose based on the patient's situation at that time. After the intrathecal dose is administered, the spinal needle will be removed and a 19g epidural catheter will be placed through the Tuohy into the epidural space. It will be secured at the skin with a sterile dressing and tape, leaving 5cm of the catheter in the epidural space. The patient will then be placed in a lateral position.

After the completion of the neuraxial procedure, the study participant will be asked to record her overall satisfaction with the procedure, as well as her perception of pain during the placement of the labor epidural catheter, using two VAS from 0-100mm. Additionally, she will be asked to complete the STAI questionnaire again. Finally, she will be asked to complete the post procedural questionnaire. At that point the parturient's participation in the study will be complete.

The provider or research team member will be asked to fill out the Participant's Demographics Information form.

The provider placing the labor epidural catheter will be asked to evaluate his/her ability to palpate landmarks for placement, the positioning of the patient, and overall perceived difficulty with the epidural placement, using a VAS from 0-100mm for each, which will be kept confidential. Additionally, they will complete a short series of questions focusing on

the presence of a companion for the procedure. No identifying information from the provider will be recorded on this form.

DATA AND SPECIMEN BANKING:
N/A

DATA AND SPECIMEN MANAGEMENT:
Group sample sizes of 75 and 75 achieve 81% power to show a difference in means when there is a difference of 4.7 between the null hypothesis mean difference of 0.0 and the actual mean difference of -4.7 at the 0.050 significance level (alpha) using a two-sided Mann-Whitney-Wilcoxon Test.

The acquired data forms will be kept in folders with only the study ID number as an identifier. These folders will be placed in a secure, locked cabinet in the Office of the Section of Obstetrical Anesthesiology. Only those researchers directly analyzing these data will have access to the files. Any electronic communication regarding the study will be conducted using the secure Northwestern email service. Computerized data forms will be password protected. Only the study ID number will be used to identify participants during data analysis. The data will be stored until the completion of the study, including the final data analysis. Members of the anesthesia team collecting these data will be educated on the process prior to approaching prospective participants.

These data collected from each participant will include:
- STAI forms before and after epidural placement
- Pre and post procedure questionnaire
- VAS scoring of satisfaction and pain perception following the procedure
- Newest Vital Sign form completed before epidural placement
- Pain Catastrophizing Score form completed before epidural placement
- Relation of the support person to the parturient
- Support person and parturients preference completed before epidural placement
- Post procedure questionnaire from the Resident/Fellow Physician
- Post procedure questionnaire from the Attending Physician

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS:
N/A

WITHDRAWAL OF PARTICIPANTS:
Participants will be withdrawn from the study if the companion is required to leave due to violation of directions. These include entering the room before the procedure is completed if he/she is in the partner out group, getting up from the chair or attempting to watch the procedure after a warning in the partner in group. When a participant withdraws, data collected up to that point will be retained and analyzed at the end of the study to determine if there is an identifying characteristic that predisposes to inability to follow instructions for safe participation with the epidural procedure.

RISKS TO PARTICIPANTS:
Risks to the parturients participating in this study are the same risks as those electing to have neuraxial labor analgesia not involved in the study. The placement of a labor epidural catheter includes specific risks, which are communicated to the parturient before obtaining informed consent for the procedure. These include bleeding, infection, nerve injury, post-dural puncture headache, hypotension, fetal bradycardia, nausea, vomiting, and very rarely seizures and cardiac arrhythmias.

There is the potential for feeling emotionally uncomfortable answering some of the questionnaires.

There is the potential for loss of confidentiality even though there are strict measures in place to prevent occurrence.

The risks to the companion include a vasovagal response and loss of consciousness. To best prevent this risk he/she will be seated in front of the parturient, unable to directly witness the placement of the labor epidural catheter. Additionally, he/she will be placed on a seat that does not have wheels and cannot move.

POTENTIAL BENEFITS TO PARTICIPANTS:
The potential benefit to the parturient is an improvement in both satisfaction and anxiety during the procedure, through the presence of a familiar companion.

VULNERABLE POPULATIONS:
The study is designed to evaluate an intervention during labor and is therefore, by definition, involving pregnant women. The study itself does not change whether neuraxial analgesia will be offered to an individual for labor pain. The HRP-412 Checklist has been reviewed and there are no conflicts noted.

COMMUNITY-BASED PARTICIPATORY RESEARCH:
N/A

SHARING OF RESULTS WITH PARTICIPANTS:
N/A

SETTING:
- The research will be conducted on the Labor and Delivery ward 8th floor at Prentice Women's Hospital
- The research team will identify and recruit potential participants on the Labor and Delivery ward at Prentice Women's Hospital
- Research procedures will be performed in the Labor Suites on the Labor and Delivery ward at Prentice Women's Hospital
- There is no plan to create a community advisory board at this time

RESOURCES AVAILABLE:

- The labor epidural catheter placement will be conducted by a resident physician, fellow physician, or attending physician, who has completed sufficient training in neuraxial labor analgesia and deemed to be qualified to place labor epidurals by the Department of Obstetrical Anesthesiology at Northwestern.
- The member of the anesthesia team recruiting the participants will be educated in the use of the STAI, pre and post procedure, Newest Vital Sign, and Pain Catastrophizing questionnaires prior to enrolling participants. The primary recruitment will be by the anesthesia research nursing staff that has extensive experience in recruiting participants to various studies.
- We expect to recruit 2-4 participants on a daily basis, as the number of labor epidural catheters placed during a given 24 hour period well exceeds 20. By recruiting 1 participant every day (<5% of laboring parturients each day), or 7 in a week period, the data collection would take 22 weeks, which is within the proposed 3-5 month recruitment period.
- This research will be conducted primarily by Feyce Peralta, M.D. and Eric Morell, M.D. the latter of which is the current Fellow in Obstetrical Anesthesiology and has 3 months of devoted time during this fellowship year for research.
- While the collection of data will occur in the Labor Suite on the Labor and delivery ward, the analysis of these data collected during the study will be analyzed in the Office of Obstetrical Anesthesiology 9th floor Prentice as well as in the main Anesthesiology Office in Arkes 10th floor. These locations are restricted to personnel in the Department of Anesthesiology and are not located in patient care areas.
- Participants will have access to the members of both the research and anesthesia teams on call, before and after placement of the labor epidural catheter, who can answer any questions they may have regarding the procedure.
- Prior to recruiting participants, the study protocol will be reviewed by the anesthesia research study team.
- The provider placing the labor epidural catheter will be informed of which group the parturient was randomized into just before entering the room for the procedure. At that time they will either ask the companion to leave the room or ensure that there is a non-mobile seat for the companion in front of the parturient.

PRIOR APPROVALS:

Department of Anesthesiology Research Committee

RECRUITMENT METHODS:

Participants will be recruited on the Labor and Delivery Ward 8th floor of Prentice Women's Hospital. They will be approached regarding participation if they meet inclusion criteria during chart review or initial pre-anesthesia interview. Both patients in spontaneous labor and those scheduled for induction of labor will be approached if they meet criteria. The GE Centricity computerized board that lists all active laboring parturients is available in the anesthesia work room for review of the current Labor and Delivery census. If the patient is nulliparous she will be approached by a member of the

research team with regard to enrollment in the study. No reimbursement will be offered for participation.

NUMBER OF LOCAL PARTICIPANTS:
A total of 150 participants will complete the study. Half of the participants (n=75) will be randomized to the "companion in the room" group and half (n=75) will be randomized to the "companion out of the room" group. We are anticipating minimal patients who enroll to become ineligible during the study, since the total duration of enrollment is likely less than a couple hours, however we will attempt to recruit 180 participants in total to allow for a 20% drop-out rate, either by choice or by protocol violation.

Resident Participation: A total of 64 participants

Attending Physician: A total of 30 participants

Companion: A total of 150 participants

CONFIDENTIALITY:
Data will be stored in a department server which is password protected. Each study subject will be assigned a study code number. The code will be used to link study data to patient identification (name) in a separate database. Subject data will be stored on secured password protected computers at Northwestern University and Department of Anesthesiology servers. Paper data will be completed by research study team members and will be entered into REDCap. The paper folders will be stored in Arkes Pavilion 10th floor Department of Anesthesiology administrative office via key card controlled front door and key controlled closet. Data access will be password protected and only available to study investigators via REDCap. REDCap access will be controlled by the Principal Investigator. Data both electronic and paper will be destroyed 5 years after manuscript preparation.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS:
All parturients on the Labor and Delivery Ward at Prentice Women's Hospital receive an anesthesia consultation regardless of whether they are planning to have neuraxial labor analgesia, in anticipation of an unplanned surgical emergency requiring intervention by the anesthesia team. During the interview they are simply asked if they are planning to have neuraxial labor analgesia. This does not affect the remainder of the interview, except to explain to the parturient the steps involved in the placement of the labor epidural catheter, as well as the risks and benefits. During the study period, those parturients that fit the inclusion/exclusion restrictions will also be asked if they are interested in participating in a study that is "evaluating the impact of a companion's presence during the epidural procedure." Regardless of their response, if they are interested in receiving neuraxial labor analgesia and are an appropriate candidate for the procedure, they will receive a labor epidural catheter. It is rare on the Labor and Delivery Ward to receive a specific request of a certain level provider to place the labor epidural catheter, however it does happen. As is the case currently, the best effort will be made to honor the request, however due to staffing and volume of patients, this is

not always possible. There will be no difference in how these requests are treated in the study population.

The research staff will have access to the patient's EMR just as they do currently, and will use it in the same manner as it is currently used, to look up relative medical history as it relates to the patient's current labor event and to document a pre-anesthesia evaluation in the patient's chart. The patient's EMR will not be used in any greater capacity than is required to care for the patient during her labor. After the study data have been collected for each participant, it will be placed in a locked file that will only be accessed for data analysis.

COMPENSATION FOR RESEARCH-RELATED INJURY:
N/A

ECONOMIC BURDEN TO PARTICIPANTS:
Subjects will not be paid or charged extra for the care they receive as part of this study. All subjects will be charged for standard care they receive including the cost of the epidural labor analgesia that they would receive if they had not participated in this study. This cost will be billed to their insurance providers.

CONSENT PROCESS:
The consent process will take place in the Labor and Delivery Unit, 8th Floor, at Prentice Women's Hospital. There is no waiting period since subjects are in the hospital for delivery of their baby. SOP HRP 090 will be followed. The research study team will spend greater than 10 minutes discussing the study.

The consent will be discussed in full with the parturient prior to signing. The concept of randomization will be emphasized, and that although she may have a preference, this will not affect her grouping.

Between the times that the parturient agrees to participate, up to the time of the neuraxial procedure, she will be invited to discuss any part of the procedure or study with a member of the research or anesthesia teams. This is no different than the current protocol on the Labor and Delivery ward in which the parturients are invited to ask any questions they might have regarding the anesthesia for labor and cesarean delivery.

Ample time will be allowed for patient to answer questions regarding the study and the consent document. The subject will also be informed that there is no conflict of interest between the PI and the protocol. The PI will not receive financial remuneration nor will the study participation affect the subject's financial charges for their care.

For Non-English Speaking Participants
N/A

Waiver or Alteration of Consent Process:

N/A

Participants who are not yet adults (infants, children, teenagers)
N/A

Cognitively Impaired Adults
N/A

Adults Unable to Consent
N/A

PROCESS TO DOCUMENT CONSENT IN WRITING:
In addition to the standard consent for anesthesia required prior to receiving neuraxial labor analgesia, the participants will be required to sign a consent form for participation in the study. Prior to signing the study consent, they will be made aware of the questionnaires they will be asked to complete, as well as the randomization process that will be used to place them one of two groups. The study itself involves no more than minimal risk to the parturient, as the procedure to be performed will be the same as the currently performed for neuraxial labor analgesia. The only difference in the two procedures is the presence of a companion. She will still be asked to sign a consent form, however, that reiterates the study, and the grounds by which her companion will be asked to leave during the procedure, if he/she is randomized to the “companion in” group.

DRUGS OR DEVICES:
N/A