Satisfaction of pain relief during labor and delivery following access to new educational materials.

PROTOCOL TITLE:

Satisfaction of pain relief during labor and delivery following access to new educational materials.

PRINCIPAL INVESTIGATOR:

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1.0 Objectives

1.1. This project is intended to evaluate an educational website, thepainlesspush.com, especially with respect to its influence on parturients' satisfaction with particular aspects of the delivery process.

1.2. The investigators hypothesize that parturients with access to the website will exhibit greater satisfaction.

2.0 Background

2.1 Prior studies have shown variance in overall satisfaction scores for labor and delivery regardless of analgesic approach, implicating that multiple factors other than pain relief alone are involved in the childbirth experience. [1-3]

2.2 No preliminary data have been obtained. The investigators created the website under review, and intend to test its effect on patient satisfaction.

3.0 Inclusion and Exclusion Criteria

3.1. All patients who are admitted to the UMNH Labor and Delivery Floor and will be progressing to active labor during that admission will be considered for eligibility. As part of standard practice, anesthesiology is knowledgeable about patients who are likely to progress to active labor and delivery. These patients will be considered eligible and offered enrollment into the study.

3.2. All English- or Spanish-speaking pregnant patients who are admitted to UNMH Labor and Delivery for planned progression to active labor will be eligible for inclusion. All pregnant patients will be eligible, no matter what gestational age, how many previous deliveries, or planned induction. Exclusions include age under 18 years, those unable to provide consent for medical procedures, and women who do not speak either English or Spanish.

3.3. Special populations:

- Adults unable to consent: Excluded
- Individuals who are not yet adults (infants, children, teenagers): Excluded
- Pregnant women: Included
- Prisoners: Excluded

3.4. No particular racial or ethnic group will be excluded.

4.0 Study-Wide Number of Subjects

4.1. This is not a multicenter study.

4.2. The investigators plan to recruit up to 150 patients. The target sample size after attrition is approximately 100 completed surveys, but if actual attrition is less than anticipated, data may be obtained on up to 150 participants.

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4.3. The target sample size should be sufficient at α=0.05 and 80% power to detect a difference between group means equal to approximately 58% of the standard deviation.

5.0 Study-Wide Recruitment Methods

This is not a multicenter study.

6.0 Multi-Site Research

6.1 NA; this is not multi-site research.

7.0 Study Timelines

7.1 The duration for an individual's active participation in the research will be from the time they sign the consent form until after they have delivered their baby and completed the satisfaction survey. Depending on speed of labor progression and the delivery, this could be hours or days. The investigators anticipate that enrollment will take approximately six months, with another six months for data analysis.

8.0 Study Endpoints

8.1 Enrollment will terminate upon completion of the intended sample size.

8.2 The investigators have not identified any safety or exploratory endpoints.

9.0 Procedures Involved*

9.1 This is a prospective randomized study of an educational website.

9.2 Potential participants will be offered participation in the study. If they choose to participate, they will be enrolled following the consent process. They will be randomized into either control group or intervention group. Control group participants will receive usual care and routine hospital pain-relief information. Intervention group participants will receive usual care, plus one hour in which to view the patient education website thepainlesspush.com, on an iPad provided by the Anesthesiology department for this purpose. After their delivery and transfer to the mother/baby unit, participants will complete a satisfaction survey brought to them by a study team member. Participants will complete the survey following their delivery and prior to discharge. Their active participation in the study will be complete at this time.

9.3 After a participant completes the satisfaction survey, research team members will collect demographic information and relevant obstetric/medical history information from the electronic medical record.

10.0 Data and Specimen Banking

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10.1 Identifiable data will not be banked for future use. Deidentified data may be retained indefinitely for use as pilot data for future studies. Any such future study would only proceed with separate HRRC approval.

11.0 Data and Specimen Management

11.1 Demographic and medical-history data will be described with routine descriptive statistics. Survey data will be reported with appropriate crosstabulations. The two study arms will be compared on the survey questions with routine Wilcoxon-Mann-Whitney test.

11.2 The target sample size should yield sufficient power at $\alpha=0.05$ and 80% power to detect a difference between group means equal to approximately 58% of the standard deviation.

11.3 All study team personnel carry all appropriate HIPAA and HITECH certifications as required by UNM HSC, as well as CITI human-subjects research certification. Data forms will be kept only temporarily, until deidentified data are entered onto a spreadsheet stored on secure UNM HSC servers. Temporary usage of identifiers is necessary in order to permit accurate linkage of survey responses to arm assignment and electronic medical record information. Investigators may notify one another of recent enrollments by use of the *secure* function in UNM Health Sciences Center email or the TigerConnect communication system, both of which are HIPAA-compliant and appropriate for internal exchange of PHI according to the UNM Health System IT Security group and the HSC Chief Information Officer. Remaining study records will be maintained for at least 3 years after study closure.

11.4 A separate linking document will be used to link identifiers (medical record number) to study ID numbers. This document will be kept separately from study data, in a locked cabinet in an Anesthesiology Department office belonging to a study team member. Only study team members will have access to the linking document. It will be securely maintained until data collection is complete (up to approximately one year), at which point it will be securely shredded. The destruction of that linking document will deidentify the study data.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This study consists of exposure to an educational website, a satisfaction survey, and correlation of survey responses to arm assignment and basic demographic/medical information. The primary risk is confidentiality breach (see section 14 below). Identifiers will only be kept temporarily, and this study does not involve data typically seen as “sensitive.” The investigators thus believe that this study poses no more than minimal risk.

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13.0 Withdrawal of Subjects

13.1 The investigators have not identified any circumstances in which a participant may be withdrawn without their consent.

13.2 If any participants withdraw from the research, investigators will simply stop collecting data on them. Participants who do not with so continue participating may also elect to simply stop providing answers on the post-delivery survey.

14.0 Risks to Subjects

14.1 The only difference between study arms is the availability of an educational website. Therefore, the primary risk relates to potential loss of confidentiality. A reduced dataset of demographic and health-related information will be gathered to better understand patterns in the post-delivery satisfaction survey data. Similarly, identifiers will only be kept temporarily in order to accurately link arm assignment, demographic/health data, and satisfaction survey responses.

14.2 The investigators do not believe that the study procedures may reasonably be said to carry substantial unforeseeable risks: the study consists of access to an educational website (or routine information) and a satisfaction survey.

14.3 All subjects will be pregnant at the time of enrollment, but the investigators have not identified any risks to the fetus arising from reading an educational website. This project does not propose to modify any clinical decisions made by parturients, physicians, nurses, or midwives. The remaining study procedure, completing a satisfaction survey, occurs after delivery.

14.4 The investigators have not identified any risks to others arising from subjects' participation in this study.

15.0 Potential Benefits to Subjects

15.1 The main potential benefit that participants may experience would be an increased knowledge base and understanding of pain relief options during labor and delivery. This may help them feel more prepared for delivery and more comfortable with their various pain relief options. This knowledge may also be useful for any future pregnancies or deliveries.

16.0 Vulnerable Populations

16.1 The study targets pregnant women, but no other vulnerable group (prisoners, students, economically disadvantaged, etc). Pregnant women are regularly seen for labor and delivery at UNM Hospital. Dr. Reyes regularly treats laboring women as part of her routine clinical duties. This study does not modify any clinical decisions.

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As noted elsewhere, the only intervention is the selection of pain-relief educational materials: the existing materials in routine use, or the newly-developed website. The study thus presents minimal risk.

17.0 Community-Based Participatory Research

17.1 This project does not involve community-based participatory research.

18.0 Sharing of Results with Subjects

18.1 The investigators do not plan to share overall study results with participants. Others' satisfaction is not clearly relevant to participants' birth experience.

19.0 Setting

19.1 Research sites/locations:

- Potential participants will be recruited from the UNMH Labor & Delivery floor. All patients admitted to that unit who are expected to progress to active labor during that admission will be eligible for enrollment.
- All research procedures will occur at UNMH. Recruitment and patient education (routine or with the website being evaluated) will occur in the Labor & Delivery areas. The post-delivery satisfaction survey will occur in the Mother/Baby Unit. Collection of relevant data from the electronic medical record will occur at UNM HSC via workstations with regular access to the medical record.

20.0 Resources Available

20.1. PI Dr. Kathleen Reyes is a faculty member in the UNM Department of Anesthesiology & Critical Care Medicine, with all relevant licensures and credentials. Investigator Lauren Faber is a third-year medical student at the University of New Mexico School of Medicine. She has previous human-subjects experience at UNM SOM and Southwest Women's Health.

20.2. All medical decisions will be made by duly authorized and licensed personnel at UNM HSC, with input from participants as appropriate. The existence of this study does not modify any clinical decision.

20.3. The necessary resources are available, as noted below:

- UNMH serves thousands of parturients per year. Only a small percentage of them would need to complete this study for it to achieve its target sample size in less than one year.
- Dr. Reyes has regular nonclinical time that is intended for activities such as the planned project. Likewise, the two medical-student investigators are expected to participate in research as part of their curriculum. Adequate time is available.

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- UNMH has adequate facilities to care for laboring women, and resources are available within the Anesthesiology department to ensure completion of the research, including IRB liaison, study design and statistical support, and manuscript preparation.
- The research consists of an educational opportunity and satisfaction survey. As a result, the investigators do not anticipate any need for medical or psychological resources resulting from consequences of participation.
- The study team is relatively small, and the research is to be conducted in one center. The HRRC-approved version of the protocol will be shared among the investigators prior to study commencement, and study procedures will be reviewed.

21.0 Recruitment Methods

21.1 Patients will be recruited following admission to the UNMH Labor & Delivery floor for expected delivery.

21.2 UNMH serves a large catchment area, and expectant mothers present daily for labor and delivery.

21.3 Physicians on the Obstetrics service routinely notify Anesthesiology of parturients expected to progress to active labor, in order for them to provide possible consultation and appropriate pain relief care. The study team will identify potential participants from among this patient population. Anesthesiology providers regularly review the medical records of this patient population upon receiving this notification, for purposes of clinical treatment. The investigators are requesting a partial waiver of HIPAA authorization requirements in order to permit the use of a subset of these records for purposes of verifying eligibility (i.e. that potential participants do not meet the few exclusion criteria). The research-related protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an opportunity to agree or object is not required by 45 CFR 164.512.

21.4 Recruitment will occur in person, and will not involve audio or video materials.

21.5 A recruitment flyer will be posted in patient areas of the Labor & Delivery floor, and copies of it may be distributed to potential participants.

21.6 Participants will not be paid.

22.0 Number of Subjects

22.1. This is not a multicenter study.

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22.2. The investigators plan to recruit up to 150 patients. The target sample size after attrition is approximately 100 completed surveys, but if actual attrition is less than anticipated, data may be obtained on up to 150 participants.

22.3. There is not a screening step between enrollment and determination of eligibility for procedures or data collection.

23.0 Provisions to Protect the Privacy Interests of Subjects

23.1 Investigators who will conduct recruitment and consent are already authorized for patient contact in this situation, so recruitment will not involve any extraneous or unexpected personnel.

23.2 Investigators are already experienced at interacting with patients during a time that is stressful in general (i.e. labor) and at specific moments during that time (i.e. between contractions). Recruitment and consent efforts will not interfere with these interactions, or be "forced" during contractions.

23.3 The PI is already authorized to contact these patients and review their records as part of medical practice.

23.4 The post-delivery satisfaction survey will occur in the Mother/Baby Unit prior to discharge, in order to provide some opportunity to recover from the stress of delivery.

24.0 Compensation for Research-Related Injury

24.1 This is a Minimal Risk study.

25.0 Economic Burden to Subjects

25.1 Participant costs will not be affected by the availability of these educational materials.

26.0 Consent Process

26.1 Consent will be obtained prior to enrollment. The investigators are requesting waiver of documentation of consent and HIPAA authorization, and use of an oral process for both consent and HIPAA authorization. As noted above, the research presents no more than minimal risk of harm to subjects. Similarly, it is routine to provide information on analgesia options and consultation to laboring women at UNMH. The educational website being evaluated is merely a specific option within the available educational materials. Healthcare satisfaction surveys (such as the Press Ganey healthcare satisfaction survey) are regularly conducted without formal written consent. For those reasons, the investigators believe that this project involves no procedures for which written consent is normally required outside the research context. The demographic and health information to be used in this study will be obtained from the electronic medical record by authorized personnel, and identifiers will be kept only temporarily. A script for an oral consent and

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HIPAA authorization process is included with this application, along with a post-participation informational handout. The oral consent/HIPAA script includes the usual elements of consent, as well as listing the PHI to be used for the study, referencing HIPAA and the requirement that patients give permission for use of PHI, and specifically asking for permission to "let us use your protected information."

- The consent process will occur in regular patient rooms on the UNMH Labor/Delivery floor, which are already sufficiently private for appropriately confidential doctor/patient conversations.
- The investigators believe that avoiding the requirement for prospective participants to read, comprehend, and sign a complicated consent/HIPAA document while in labor will better respect their privacy considerations. An oral process will be considerably less intrusive, while respecting patient autonomy and addressing all other required elements of consent and HIPAA authorization.
- Patients will be free to read the educational materials, or not, as they see fit; similarly, they can choose to decline to answer any or all of the satisfaction-survey questions. The investigators do not anticipate that ongoing consent will become an issue.

Non-English Speaking Subjects

- Most prospective participants speak English. The majority of the remainder speak Spanish.
- PI Dr. Reyes speaks some Spanish, and the educational website is available in Spanish. The consent process for these patients will occur in Spanish. Official UNM Hospital interpreters may be used to facilitate understanding.
- HRRC-approved Spanish-language documents will be used for patients who prefer to use Spanish.

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