

Mobile Video Education to Improve Patient Clinician Communication During Prenatal  
Clinic Visits

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## 1. Background

### a. Value of communication skills

- i. The communication between clinicians and parents is a partnership; the family caregivers are equally important, as are their behaviors.
- ii. Especially important are parents' active behaviors, such as asking questions, introducing topics for discussion, expressing concerns, and sharing opinions.
- iii. Active patients receive more information and support from clinicians, are more satisfied with the care, and experience better outcomes than passive patients.

### b. Importance in the context of fetal anomalies

- i. Parents who have pregnancies diagnosed with a fetal anomaly are often overwhelmed by new medical information while they are in the process of grieving a normal pregnancy.
- ii. Often during this stressful time, medical decisions need to be made which are preference sensitive. Families and clinicians need to be able to work together to achieve a treatment plan that best fits a family's values.

### c. Proposed intervention

- i. We intend to address this problem by creating a short, animated Art of Medicine video delivered via text messages.
- ii. The goal of our educational intervention is to improve clinician-patient communication by equipping families with evidence-based skills that they can implement during medical encounters.
- iii. Our research team has developed a smartphone-based text-video educational platform with NIH support to prepare pregnant women for premature birth. We intend to use this platform to improve clinician-patient communication by disseminating concise, memorable, and immediately actionable education.

## 2. Aim:

- a. Determine the effect of the educational intervention on parents' communication during a fetal concerns appointment.

## 3. Study design

- a. The proposed intervention is to be implemented as randomized controlled study.

## 4. Study population

- a. A pregnant patient referred to Children's Wisconsin Fetal Concerns Center for a prenatal diagnosis.
- b. Own a smartphone
- c. 18 years of age or older
- d. Able to speak and understand English
  - i. Currently, the intervention is only available in English.

- e. Exclusion criteria:
  - i. Pregnant patient's appointment at Children's Wisconsin Fetal Concerns center is not for a fetal anomaly (e.g., screening only, past pregnancy with anomaly the only cause of appointment)
  - ii. Pregnant patient is considering termination of pregnancy.
- 5. Enrollment and consent
  - a. Upcoming Children's Wisconsin FCC appointment schedules will be screened by study team.
  - b. Eligibility will be discussed with a clinical team member (e.g., medical director Dr. Jessica Smith, a nurse care coordinator). Prior to the first scheduled visit to the FCC clinic, the patient will be approached with a study introduction from the clinical team member through one or more of the following: encrypted email, phone call, or MyChart message. This introduction will assess patient interest in participation.
  - c. If interested, patients will be provided more study information and be invited to review an informational letter in REDCap. A waiver of documentation of consent is requested.
  - d. Participants will be invited to complete an enrollment questionnaire in REDCap prior to randomization and intervention delivery.
- 6. Randomization
  - a. Participants will be randomized 1:1 to receive either the video intervention or a control.
  - b. Randomization list will be generated by MCW Quantitative Health Sciences and will be implemented by study staff via REDCap.
- 7. Intervention & control
  - a. Intervention video development
    - i. We will develop the intervention's video objectives using published literature. Topics may include preparing questions for the appointment, summarizing using teach back, and participating in shared decision making.
    - ii. The video will be developed in a collaborative and iterative manner. After creating the script to meet the video's learning objectives, we will create the animation and audio using the software Vyond and Audacity, respectively. Professional voiceovers will provide narration and dialogue.
    - iii. The video will run approximately 10 minutes long and feature a diverse representation of families.
    - iv. This plan for creating and testing videos is similar to the procedure followed by Dr. Basir's team, which successfully generated over 50 videos through user feedback.
  - b. Control education materials
    - i. Control education includes links to publicly available webpages from Children's Wisconsin describing the Fetal Concerns Center to

familiarize them with the clinic and prepare them for the appointment.

c. Education distribution plan:

- i. For participants randomized to the video intervention: After enrollment, participants will be registered to the Art of Medicine platform and be sent the video link by text message to their smartphone.
- ii. For participants randomized to the control: After enrollment, participants will be sent links to the Children's Wisconsin webpages by email or text message, depending on participant preference. After follow up assessment, control participants will also be sent the animated video.

8. Data collection

a. Medical record data

- i. After pregnant patients are enrolled, we will gather data from their medical records.
- ii. Data includes their date of birth, estimated due date, primary diagnosis / reason for referral, and obstetric history.

b. Website data

- i. Using tracking software already developed and utilized in Dr. Basir's previous project, we will collect information regarding the number of video links sent, the number of links clicked, the number of complete and partial viewing of the video, and timestamps of views.

c. Questionnaires

- i. Participants will be asked to complete two questionnaires during the study, one at enrollment and one the day after their fetal concerns appointment.
- ii. The enrollment questionnaire will include a survey collecting information regarding sociodemographics, experience with healthcare providers, smartphone information, and a health literacy assessment (the HL6, see Supporting Documents).
- iii. The follow up assessment will include self-report items of participants describing their behavior before and during their appointment (see Supporting Documents).

9. Compensation

- a. For completing the follow up assessment, participants will receive \$20 in gift cards.

10. Data management

- a. All data will be stored securely at the Medical College of Wisconsin in REDCap. Only study team members will have access to identifiers.

11. Statistical analysis plan

- a. Missing data

- i. Logistic regression will be used to investigate the missing data pattern. In general, we will assume data are missing at random (MAR).
      - ii. We plan to use random effects models with maximum likelihood estimation for repeated measures and multiple imputations for items. We may miss obtaining some survey results or observe dropout for follow-up and will perform sensitivity analysis allowing for different assumptions.
    - b. Tracked video viewing data will be analyzed and correlated with study assessments and participant characteristics.
      - i. To examine relationships between assessment scores, participant characteristics, and tracked viewing data, we will use a generalized linear model, with link functions such as a negative binomial considered.
    - c. For patient participants, scoring of the follow up assessment will be calculated as percentage of communication behaviors self-reported as having occurred.
      - i. The primary outcome is a comparison of total follow up assessment scores in the video intervention group compared to the control.
      - ii. The analysis will include consideration of covariates, e.g., health literacy, income.
      - iii. Tracked video viewing data will be similarly analyzed.
12. Risks and benefits
- a. Potential risks
    - i. There is a minimal risk of mental distress while reviewing the video material or completing the questionnaires as reminders of a potentially distressing clinic appointment.
    - ii. There is a minimal risk of breach of confidentiality if (1) the security of data storage is violated, (2) the data is shared by people other than designated researchers and professionals, or (3) the result is reported in a manner that could reveal the identity of the participants.
    - iii. Physical risks or discomfort to the participants are minimal. No physical interventions are being undertaken.
  - b. Potential benefits
    - i. The potential benefits of the communication education for participants outweigh the minimal risks.
    - ii. This study will allow us to determine best methods of preparing parents to communicate during an appointment with complex medical information and shared decision making.