SOUND CHECK-CORRELATION BETWEEN TRANSPERINEAL AND DIGITAL CERVICAL EXAM USING A POCKET ULTRASOUND IN 3RD TRIMESTER PREGNANCY

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Protocol & Statistical Analysis Plan

Patients in the third trimester that present to the obstetrical triage for assessment of labor (contractions or rupture membranes) as well as patients admitted for labor and delivery will be approached. After informed consent is obtained, Dr. Connell or I will perform a transperineal ultrasound (TPUS) using the glove-covered Butterfly iQ+. An independent, blinded examiner will then perform a traditional digital cervical exam (DCE). The study PI's will be blinded to the DCE measurement until the end of the study. The patient will act as their own control. The patient will then be asked to score discomfort on a scale of 0-3 and preference for a method, if any. After 30 patients are enrolled, the PI's will compare the TPUS dilation measurements to the DCE dilation measurements and calculate a simple correlation. The discomfort scale will be analyzed using a Wilcoxon Signed Rank test.

Inclusion Criteria:

Pregnant women in the third trimester presenting for assessment of labor or admitted for labor and delivery.

Exclusion Criteria:

Second trimester (less than 28 weeks) BMI>50 Does not wish to participate

Patients in the 3rd trimester that require a digital cervical exam (DCE) for assessment of labor will be approached. After informed consent is obtained, one of two study investigators will perform a transperineal ultrasound (TPUS) using the glove-covered Butterfly iQ+ probe. The Butterfly iQ+ does not have a transperineal probe or setting, therefore, the "bladder" preset setting will be used. The "bladder" setting has been predetermined to provide the best cervical images. This pocket ultrasound is FDA-approved and is the standard of care for point of care ultrasounds in many institutions and is already used in our department. The TPUS will be performed by 1 of the 2 investigators with digital calipers. There will be 3 measurements: dilation, effacement, and station. The dilation measurements with be made from the inside margins of the cervix . Effacement will be measured by marking the thinnest and most easily imaged lip of the cervix. Zero station will be assumed to be 5 cm above the perineum, with distances from 6-10 cm corresponding to -1 to -5 station clinically. An independent, blinded examiner will then perform a traditional digital cervical exam, which will be recorded in EPIC. The study investigators will be blinded to the DCE measurement until the end of the study. The patient will act as their own control. Additionally, we will collect EGA, race, ethnicity, age, BMI, and indication for assessment of the

cervix. The patient will then be asked to score discomfort on a scale of 0-3 (none-extremely). They will then be asked to state if they preferred the TPUS, DCE or have no preference. At the end of the study the TPUS exams will be compared to the DCE, and a simple correlation will be calculated.

Data Analysis

We chose a simple correlation r ($r=0.5$). Using a two-tailed test, 5% significance level test ($\alpha=0.05$) with power 80% power ($\beta=0.2$), the required sample size is approximately ($n=29$).

For the primary outcome, we will use the two-tailed test. For the secondary outcome (patient experience), we will use the Wilcoxon Signed Rank test.