Genetics Education and Equity in Maternal Fetal Medicine: A Pilot Feasibility Randomized Controlled Trial to Assess Impact of a Video Education Tool on Decisional Conflict Among Prenatal Patients (GEM)

Protocol ID: 1721550

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Of note, Part A and Part B of this IRB Submission were not clinical trials. Part C (started on page 12) reflects the clinical trial portion of our protocol which has been registered with ClinicalTrials.gov

Development and Assessment of Educational Video to Impact Prenatal Genetic Screening Knowledge Among Pregnant Patients

Principal Investigators: Margaret Thorsen, MD and Melissa Russo, MD

Study ID: 1721550-13

PART A: A Survey to Assess Obstetric Provider's Knowledge of, Perceived Barriers to, and Confidence in Providing Prenatal Genetic Counselling

Overview:
We will perform a REDCap survey of 59 prenatal care providers regarding knowledge of prenatal genetic aneuploidy testing, confidence in counseling skills, and barriers to adequate counselling. These providers will be emailed a link to the consent to participate in the study. The survey will be available to them via email in a link via REDCap.

Eligibility: Academic prenatal care providers working within our hospital system. A list of key providers who work in this clinical setting and provide prenatal care has been generated:

Study Aim:
The objective of this part of the study is to identify maternity care provider gaps in knowledge about prenatal genetic testing and perceived barriers to counselling to inform the development of a video-based intervention.

Introduction:
Counselling regarding prenatal genetic screening poses a challenge for maternity care providers. Explaining screening and diagnostic options ideally centers on an understanding of a patient's baseline health literacy and exploration of their values. Providers are stretched thin when it comes to time dedicated to discuss these topics. In a 2016 cohort study analyzing transcripts of over 200 first prenatal visits, only 1.5% of all conversations between providers and their pregnant patients were comprehensive and representative of ACOG prenatal genetic screening recommendations (Collicha et al)[1]. This study also highlighted significant variation in providers' prenatal genetic counseling practices. Previous studies have shown that ob/gyn resident physicians lack standardized genetics curricula and may feel uncomfortable providing genetic counselling (Macri 2003[2], Dotters-Katz 2019[3]).

Furthermore, genetic testing options have become increasingly complex, and it is not known if providers are comfortable counseling with new technologies (Musci 2013)[4] or regarding

[1] 1. Colicchia LC, Holland CL, Tarr JA, Rubio DM, Rothenberger SD, Chang JC. Patient-health care provider conversations about prenatal genetic screening. In: *Obstetrics and Gynecology*.Vol 127.; 2016:1145-1152. doi:10.1097/AOG.0000000000001433.

[2] Macri CJ, Gaba ND, Sitzer LM, Freese L, Bathgate SL, Larsen JW. Implementation and evaluation of a genetics curriculum to improve obstetrician-gynecologist residents' knowledge and skills in genetic diagnosis and counseling. Am J Obstet Gynecol. 2005;193(5):1794-1797. doi:10.1016/j.ajog.2005.08.003.d

[3] Dotters-Katz SK, Vora N, Kuller J. Genetics for the Women's Health Trainee: A Five-Module Curriculum. *MedEdPORTAL J Teach Learn Resour*. 2019;15:10797. doi:10.15766/mep_2374-8265.10797.

[4] Musci TJ, Fairbrother G, Batey A, Bruursema J, Struble C, Song K. Non-invasive prenatal testing with cell-free DNA: US physician attitudes toward implementation in clinical practice. *Prenat Diagn*. 2013;33(5):424-428. doi:10.1002/pd.4091.

emerging genetic data privacy concerns (Parobek et al, 2021)[5]. To complicate matters of informed consent and patient autonomy, timing of counseling about genetic testing is somewhat inflexible, given that potential interventions can be time-sensitive.

Literature on maternity care providers' experiences providing prenatal genetic counselling is sparse and data that do exist may be outdated due to rapid changes within the field. It is important to establish provider gaps in knowledge and barriers to genetic counselling in order to establish solutions that meet both patient and provider needs. Additionally, assessing knowledge and sentiments among providers in our community will allow us to specifically target solutions that will serve providers and patients at the Obstetrics and Gynecology Care Center (OGCC) and Providence Community Health Center (PCHC).

Impact:
This portion of our study serves as a needs assessment of providers to help inform and guide development of a video-based intervention for patients.

Research Design:
Fifty-nine local prenatal care providers will be sent a link to a survey via REDCap regarding knowledge of prenatal genetic aneuploidy testing, confidence in counseling skills, and barriers to adequate counselling. These providers will be emailed a link to the consent to participate in the study. The survey will be available to them via email in a link via REDCap. The survey will be anonymous.

This study will use Care New England's instance of REDCap for the collection and storage of data. The study will not collect or store any actual data within REDCap until the project has been moved into REDCap's production environment. REDCap is a secure, web-based application developed by Vanderbilt University for building and managing surveys and databases. It is primarily designed to support online or offline data capture for research studies, quality improvement, and operations. REDCap provides easy data manipulation (with audit trails for reporting, monitoring and querying patient records), real-time data entry validation, and an automated export mechanism to common statistical packages.

Care New England's instance of REDCap is hosted within the Care New England data center in Warwick, RI. This REDCap instance is role-based and is fully integrated with CNE's Active Directory structure. It enjoys 24/7/365 enterprise-level support and security inherit to CNE's HIPAA-compliant data center. Network transmissions (data entry, survey submission, and web browsing) to and from REDCap are protected via TLS 1.2 encryption. REDCap's data is stored on encrypted servers within CNE's data center.

The REDCap Consortium is composed of thousands of active institutional partners in over one hundred countries who utilize and support REDCap. REDCap was developed specifically around

[5] Parobek, Christian M. MD, PhD; Russo, Melissa L. MD; Lewkowitz, Adam K. MD, MPHS Privacy Risks in Prenatal Aneuploidy and Carrier Screening, Obstetrics & Gynecology: May 06, 2021 - Volume Latest Articles - Issue - 10.1097/AOG.0000000000004387

HIPAA-Security guidelines, and more information about the consortium and system security can be found at http://www.projectredcap.org/.

Providers who participate will be given the option to receive an unsigned hard copy of the consent.

A verbal reminder about this voluntary survey will be given to OGCC resident physicians after core didactics by Margaret Thorsen. This reminder will be given once during the week that the survey link is sent out. When the residents are reminded in person, a QR code to access the link to the anonymous RedCap survey will be shared with them for ease of access to the survey.

All participants will be offered the option of being entered into a raffle for a $50 Amazon gift card. The drawing will be random (via computer program to choose a participant) at the conclusion of the data collection period.

Analysis Plan:
We plan to analyze average scores on each quantitative item of our survey to better understand providers' knowledge base and barriers to genetic counseling. We will also conduct a thematic analysis of the qualitative question in the survey: "What would be your hope/wishes for an educational tool for patients surrounding prenatal genetic testing?" This cross sectional data will be used to help us to inform the content of our video intervention for patients.

Part B: A Series of Semi-Structured Interviews to Assess English and Spanish Speaking Patients' Perceptions of Prenatal Genetic Counseling and Prototype Video Educational Tool

Overview:
We plan to conduct a series of semi-structured interviews to assess our patient population's perceptions of prenatal genetic counseling and perspectives on a proposed video educational tool (VET) for prenatal genetic screening.

Eligibility:
Inclusion criteria (to be confirmed via chart review): Pregnant patients ≥ 18 years of age presenting to the Obstetrics and Gynecology Care Center (OGCC) or Providence Community Health Center (PCHC) for dating ultrasound appointment, fluency in English or Spanish, singleton pregnancy, who have not yet had genetic screening or counseling during this pregnancy.

Exclusion criteria are known fetal anomalies or known abnormal nuchal translucency, donor oocyte used, and early pregnancy loss in current pregnancy.

We will use a convenience sample based on research staff's availability to recruit and consent eligible patients at the dating ultrasound appointment at either the OGCC or PCHC. The electronic medical record schedule will be used to review the schedule of when patients are presenting for this reason.

Study Aims:
Our primary research objectives are to:

1. Understand patient experience of prenatal genetic counseling including perceptions of, concerns about, and barriers to prenatal genetic testing.
2. Elucidate preferences regarding how genetic counseling information is presented to inform patient consent or refusal.
3. Receive constructive feedback from our patient population on structure, content, and language of our proposed video educational tool.

Secondary research objectives are to:

1. Understand how patients use social media and existing technology-based resources to inform prenatal care decisions.
2. Explore patient attitudes about data privacy in prenatal genetics.

Development and Assessment of Educational Video to Impact Prenatal Genetic Screening Knowledge Among Pregnant Patients

Introduction:

The American College of Obstetrics and Gynecology (ACOG) and the Society of Maternal Fetal Medicine (SMFM) recommend that all pregnant patients are offered prenatal genetic testing regardless of risk factors,[6,7] and that patients are provided the necessary counseling in order to give informed consent or refusal.[8] ACOG advocates for patient-centered prenatal genetic counseling discussing the relative risks, benefits, and limitations of available screening and diagnostic testing.[9] Given time constraints and the increasing complexity of testing options, including emerging options like cell free DNA, providers struggle to keep up with current recommendations and may face challenges in providing standardized counseling. In a study analyzing 210 first prenatal visits, only 1.5% of conversations included all ACOG recommended prenatal genetics counseling topics.[10]

This lack of standardization manifests in known disparities, both racial-ethnic and socioeconomic, in the uptake of prenatal genetic testing, the understanding of whether screening and diagnostic prenatal testing is optional, and the recall regarding whether screening had already been performed in the pregnancy.[11,12]

Preliminary data from our institution, Women and Infants Hospital, suggest gaps in patient knowledge regarding prenatal genetic screening that are consistent with the existing literature. At the Prenatal Diagnosis Center, 20% of English-speaking pregnant patients are unaware as to whether and what type of genetic screening they have had. We have not yet studied, but suspect that non-English speaking patients face similar if not greater patient knowledge gaps. Across the country, Latina women are less likely than non-Latina identifying women to undergo prenatal genetic testing. Studies have shown that lower uptake of prenatal genetic screening by minority patient populations is not a reflection of negative attitudes about testing, but rather a reflection of lower rates of informed choice.[13]

Educational interventions that standardize counseling in patients' preferred language may help to address these disparities.[14,15] Our research team will produce an educational video intervention for Spanish- and English-speaking patients. We will ensure that our educational tool meets current identified gaps as demonstrated in the literature, including discussion of genetic data

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[6] ACOG, 2007
[7] SMFM et al, 2016
[8] ACOG practice bulletin 226
[9] ACOG practice bulletin 226
[10] Colicchia LC, Holland CL, Tarr JA, Rubio DM, Rothenberger SD, Chang JC. Patient-Health Care Provider Conversations About Prenatal Genetic Screening: Recommendation or Personal Choice. *Obstet Gynecol*. 2016;127(6):1145-1152. doi:10.1097/AOG.0000000000001433
[11] Elizabeth Dormandy, Susan Michie, Richard Hooper, Theresa M Marteau, Low uptake of prenatal screening for Down syndrome in minority ethnic groups and socially deprived groups: a reflection of women's attitudes or a failure to facilitate informed choices?, International Journal of Epidemiology, Volume 34, Issue 2, April 2005, Pages 346–352, https://doi.org/10.1093/ije/dyi01
[12] Bryant AS, Norton ME, Nakagawa S, et al. Variation in women's understanding of prenatal testing. *Obstet Gynecol*. 2015;125(6):1306-1312. doi:10.1097/AOG.0000000000000843
[13] Dormandy E, Michie S, Hooper R, Marteau TM. Low uptake of prenatal screening for Down syndrome in minority ethnic groups and socially deprived groups: A reflection of women's attitudes or a failure to facilitate informed choices? *Int J Epidemiol*. 2005;34(2):346-352. doi:10.1093/ije/dyi021.
[14] de Leeuw RA, van der Horst SFB, de Soet AM, et al. Digital vs face-to-face information provision in patient counselling for prenatal screening: A noninferiority randomized controlled trial. *Prenat Diagn*. 2019;39(6):456-463. doi:10.1002/pd.5463.
[15] Bryant AS, Norton ME, Nakagawa S, et al. Variation in women's understanding of prenatal testing. *Obstet Gynecol*. 2015;125(6):1306-1312. doi:10.1097/AOG.0000000000000843

privacy with regarding to cell free DNA[16], offering both diagnostic and screening testing for all patients, and context for understanding residual risk.[17] In order to inform the patient-centered development of this resource, we will elucidate patient understanding, preferences, and perceptions of prenatal genetics and receive iterative feedback on structure, content, and tone of our prototype video educational tool.

Limited studies that have included Spanish-speaking women have demonstrated that not only knowledge about testing options, but also opinions of family and friends and religious

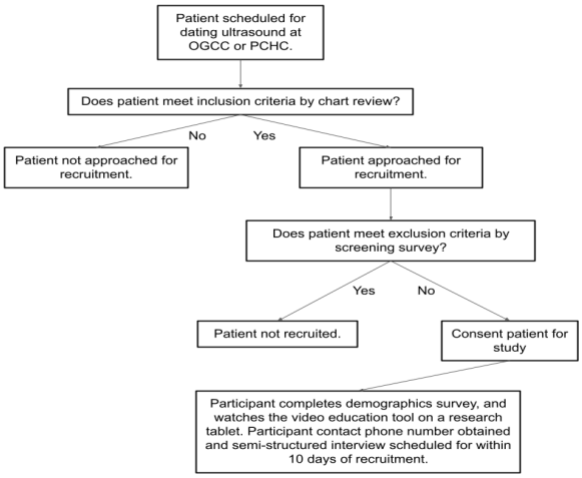
Additionally, little is known about our target population's preferences regarding counseling, including tone, medium, content and directional style. While the ACOG endorses a shared identification, may impact decisions about prenatal genetic screening.[18,19,20 ,21] None of these studies have included a patient population in the Northeast. In order to create a patient-centered, acceptable, and effective educational intervention, it is critical that patient voices and preferences are taken into account. decision-making approach to prenatal genetic diagnostic testing,[22,23] studies have shown that patients differ in their preferences for participation in clinical decision making. [24,25,26] Studies conducted using only English-speaking patients have shown that video resources regarding prenatal genetic screening are of added value to patient knowledge and receive the same level of patient satisfaction in comparison to face-to-face counseling.[27,28] Semi-structured interviews with members of our target patient population will help us to elucidate these preferences.

Impact: Data gathered from semi-structured interviews of our target population, both English and Spanish speaking patients seeking prenatal care, will serve as formative research to guide

[16] Parobek CM, Russo ML, Lewkowitz AK. Privacy Risks in Prenatal Aneuploidy and Carrier Screening: What Obstetricians and Their Patients Need to Know. Obstet Gynecol. 2021 Jun 1;137(6):1074-1079. doi: 10.1097/AOG.0000000000004387. PMID: 33957653.
[17] Colicchia LC, Holland CL, Tarr JA, Rubio DM, Rothenberger SD, Chang JC. Patient-Health Care Provider Conversations About Prenatal Genetic Screening: Recommendation or Personal Choice. *Obstet Gynecol*. 2016;127(6):1145-1152. doi:10.1097/AOG.0000000000001433
[18] Garza et al, 2020 Garza G, Hodges-Delgado P, Hoskovec J, Palos G, Wagner C, Zacharias N, Noblin SJ. Exploring experiences and expectations of prenatal health care and genetic counseling/testing in immigrant Latinas. J Genet Couns. 2020 Aug;29(4):530-541. doi: 10.1002/jgc4.1261. Epub 2020 Apr 17. PMID: 32302061.
[19] Seth et al. 2011 Seth, S. G., Goka, T., Harbison, A., Holllier, L., Peterson, S., Ramondetta, L., & Noblin, S. J. (2011). Exploring the role of religiosity and spirituality in amniocentesis decision-making among Latinas. Journal of Genetic Counseling, 20, 660– 673. https://doi.org/10.1007/s10897-011-9378-5
[20] Farrell et al. 2015, Griffiths & Kuppermann 2008, Suther & Kiros, 2009
[21] Kuppermann, Miriam PhD, MPH1,2,4; Learman, Lee A. MD, PhD1,2; Gates, Elena MD1; Gregorich, Steven E. PhD3,4; Nease, Robert F. Jr PhD5; Lewis, James MD6; Washington, A Eugene MD, MS1,2 Beyond Race or Ethnicity and Socioeconomic Status, Obstetrics & Gynecology: May 2006 - Volume 107 - Issue 5 - p 1087-1097 doi: 10.1097/01.AOG.0000214953.90248.db
[22] Prenatal diagnostic testing for genetic disorders. ACOG Practice Bulletin No. 162. American College of Obstetricians and Gynecologists. Obstet Gynecol 2016;127:108–22.
[23] Screening for fetal aneuploidy. ACOG Practice Bulletin No. 163. American College of Obstetricians and Gynecologists. Obstet Gynecol 2016;127:123–37.
[24] Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). Soc Sci Med 1997;44:681–92. [PubMed: 9032835] Molina et al. Page 9 Patient Educ Couns. Author manuscript; available in PMC 2020 March 01.
[25] Committee on Quality Health Care in America, Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century Washington (DC): National Academy Press; 2001.
[26] Sheridan SL, Harris RP, Woolf SH, Shared decision making about screening and chemoprevention. a suggested approach from the U.S. Preventive Services Task Force. Am J Prev Med 2004;26:56–66. [PubMed: 14700714]
[27] de Leeuw RA, van der Horst SFB, de Soet AM, et al. Digital vs face-to-face information provision in patient counseling for prenatal screening: A noninferiority randomized controlled trial. *Prenat Diagn*. 2019;39(6):456-463. doi:10.1002/pd.5463.
[28] Mulla BM, Chang OH, Modest AM, Hacker MR, Marchand KF, O'Brien KE. Improving Patient Knowledge of Aneuploidy Testing Using an Educational Video: A Randomized Controlled Trial. *Obstet Gynecol*. 2018;132(2):445-452. doi:10.1097/AOG.0000000000002742.

content, structure, language, and tone of the proposed educational video intervention for prenatal genetic counseling. This study will secondarily serve as an opportunity to explore emerging topics in prenatal genetics - including how pregnant patients use social media and technology-based resources and attitudes about genetic data privacy.

Semi-Structured Interview Recruitment Schematic:
Outline of Study Schematic:



STEP ONE: <u>Pre-screening chart review</u> from EMR for eligibility
Patient presenting to the Obstetrics and Gynecology Care Center (OGCC) or Providence Community Health Center (PCHC) for dating ultrasound will have chart reviewed to determine if eligible based on the following inclusion criteria:

1. Patient ≥ 18 years of age
2. Preferred language English or Spanish
3. Singleton pregnancy
4. No documentation of genetic screening results or counseling during **this** pregnancy

At the Providence Community Health Center, key study personnel will pre-screen charts of patients presenting for a dating ultrasound to determine eligibility. At the OGCC, key study personnel, Dr. Margaret Thorsen or Research Assistant, Rose Mahoney, will pre-screen charts to determine eligibility.

Patients who meet eligibility criteria, as above, will be approached for enrollment in the study by key study personnel. We will attempt to enroll participants at their dating ultrasound appointment in order to schedule a semi-structured interview prior to their New OB appointment, when they will receive genetic counseling for this pregnancy. If unable to approach or consent an eligible patient during the dating ultrasound appointment (e.g. due to participant or recruiter time constraints) they will be approached at the new OB appointment.

STEP TWO: If eligible, patient approached and offered an opportunity to enroll in study.

STEP THREE: Screening questions via RedCap on tablet to assess via patient report for exclusion criteria:

1. In this pregnancy have you been diagnosed with a fetal anomaly, known abnormal nuchal translucency test, or fetal loss?
2. Did you use a donor oocyte (egg)?
3. Preferred language English or Spanish? *(will confirm here to ensure what is documented in the chart is accurate)*

STEP FOUR: Sign e-consent forms for study participation if patient agrees and is eligible.

STEP FIVE: Watch video educational tool on tablet.
Patients will watch the video on a research tablet in their preferred language(English or Spanish) at the time they consent for the study (in person). They will be informed that we will ask their input on the video when we call them to complete the semi-structured interview.

STEP SIX: Complete Pre-interview survey (see addendum attached).

After a patient consents to participate, they will be asked to fill out a RedCap survey requesting contact information including: patient phone number, consent to leave a voicemail, prefered language for the interview, and dates and times that they are available to be interviewed. We will attempt to schedule each semi-structured interview within ten days of consenting the patient.

Participants will also be asked to fill out a REDCap survey containing questions on demographics and prior pregnancies. The demographics questions will include age, educational attainment, languages spoken, preferred language, and self-identified race and ethnicity. Questions regarding prior pregnancies will include questions regarding: number of prior pregnancies, past pregnancy outcomes, and past experiences with prenatal genetic testing (including abnormal genetic test results in a prior pregnancy).

STEP SEVEN: Phone-based semi-structured interview
We chose to conduct phone interviews in order to avoid barriers to participating such as obtaining child care and transportation, or concerns regarding the COVID-19 pandemic.[29] We will conduct rolling enrollment until we have completed enough interviews to reach data saturation. Similar semi-structured interview studies have achieved data saturation after 10 or

[29] Garza G, Hodges-Delgado P, Hoskovec J, Palos G, Wagner C, Zacharias N, Noblin SJ. Exploring experiences and expectations of prenatal health care and genetic counseling/testing in immigrant Latinas. J Genet Couns. 2020 Aug;29(4):530-541. doi: 10.1002/jgc4.1261. Epub 2020 Apr 17. PMID: 32302061.

fewer interviews.[30,31] Our goal is to conduct 10 interviews with English-speaking patients and 10 interviews with Spanish-speaking patients for a total of 20 interviews.

The semi-structured interviews will be conducted by key research personnel, a Spanish-speaking research assistant, (key study personnel), will conduct interviews in Spanish and English-speaking research assistants (Dr. Margaret Thorsen and Rose Mahoney, both key study personnel) will conduct interviews in English. Research assistants will be trained in qualitative methodology.

Each interview will be scheduled for 60 minutes, but the ultimate length of each interview may vary depending on the interviewer and participant preferences. Participants will be informed that they may conclude the interview at any time and that they may choose not to answer any question.

The research personnel conducting the interview will guide the conversation via a semi-structured interview via phone with questions covering the following primary topics:

1. Patient experience of prenatal genetic counseling including perceptions of, concerns about, and barriers to prenatal genetic testing.
2. Patient preferences regarding how genetic counseling information is presented to inform patient consent or refusal.
3. Constructive feedback from our patient population on structure, content, and language of our proposed video educational tool.

The following secondary topics will also be explored in the interview.

1. How social media and existing technology-based resources are being used to inform patient's prenatal care
2. Patient attitudes about genetic privacy in prenatal care

STEP EIGHT: Participant <u>reimbursement</u> for their time/effort

Upon completion of the interview, the interviewer will provide participants with a code for a $50 Amazon gift card. If the participant does not have access to Amazon (e.g. poor access to Internet or no Amazon account), a Visa gift card for $50 can be given instead.

DATA ANALYSIS

The RedCap data from patient recruitment and patient enrollment, including e-consent forms and demographic survey will be stored in REDCap within a secured Care New England Network.

[30] Page RL, Murphey C, Aras Y, Chen LS, Loftin R. Pregnant Hispanic women's views and knowledge of prenatal genetic testing. J Genet Couns. 2021 Jun;30(3):838-848. doi: 10.1002/jgc4.1383. Epub 2021 Jan 26. PMID: 33496987.

[31] Garza G, Hodges-Delgado P, Hoskovec J, Palos G, Wagner C, Zacharias N, Noblin SJ. Exploring experiences and expectations of prenatal health care and genetic counseling/testing in immigrant Latinas. J Genet Couns. 2020 Aug;29(4):530-541. doi: 10.1002/jgc4.1261. Epub 2020 Apr 17. PMID: 32302061.

The phone interviews will be recorded and the audio files will be uploaded onto a secured Care New England Network.

The audio files will then be transcribed by NVivo transcription software. Identifiable data will be removed from the transcript by key study personnel. Transcript documents, with identifiable data removed, will be saved onto a secured Care New England Network. NVivo is a qualitative analysis software that has the ability to transcribe audio files in both Spanish and English. NVivo transcriptions are encrypted while in storage and intransit and both NVivo analysis and transcription services utilize security measures that are HIPAA compliant.

The de-identified transcripts from the Spanish interviews will be translated into English by Spanish-speaking KSP or a via certified Spanish interpreter. The transcript files will be uploaded into a secure NVivo database at which point a qualitative thematic analysis will be conducted. The relevant themes as described above and de novo themes will be coded and analyzed by two separate researchers. Discrepancies between the two researchers will be discussed with a third researcher to come to a consensus. Dr. Russo, Dr. Thorsen and Rose Mahoney will be performing the data analysis.

Development and Assessment of Educational Video to Impact Prenatal Genetic Screening Knowledge Among Pregnant Patients

Part C: The GEM Trial – Genetics Education and Equity in Maternal Fetal Medicine:
A Pilot Feasibility Randomized Controlled Trial (RCT) to Assess Impact of a Video Education Tool (VET) on Prenatal Genetics Knowledge Among Pregnant Patients

Overview:
At the time of new dating ultrasound appointment, we will enroll a total of 140 pregnant English or Spanish-speaking patients at the Obstetrics and Gynecology Care Center (OGCC) or Providence Community Health Center (PCHC) in Rhode Island. Participants who consent and enroll will complete a **baseline survey** regarding knowledge of prenatal genetics, prior experiences, and demographics. Participants will then be randomized to either the intervention (to watch our educational video) or control group (to receive standard care).

The patients in both groups will then undergo the typical new OB appointment. At the conclusion of that appointment (or via telephone or email follow up within 14 days of their new OB appointment), patients will be asked to answer **follow up survey #1** questions regarding: decisional conflict scale with respect to prenatal genetic testing decision, intended plan for testing, perception of likelihood of having a baby affected by a genetic problem, and implementation questions surrounding their experience of the intervention (if applicable).

Six to ten weeks from the second survey, **follow up survey #2** will be conducted in person at a follow up appointment or via telephone or email to assess: Provider patient communication, retention of genetics knowledge, patient recollection of testing performed, and self-reported out of pocket cost related to genetic testing.

Introduction:
According to the American College of Obstetricians and Gynecologists, prenatal genetic aneuploidy testing counselling should be offered to all pregnant patients[32] and standardization of what testing is offered to patients is essential to promote equitable care.[33] As genetic screening becomes more complex it is increasingly challenging for providers to give adequate information and obtain informed consent from patients for prenatal genetic testing at first prenatal appointment.

There are known disparities, both racial-ethnic and socioeconomic, in the understanding of whether screening and diagnostic prenatal testing is optional and of recall regarding whether screening had been done in the pregnancy[34]. Studies have shown that lower uptake of prenatal genetic screening by minoritized patient populations is not a reflection of negative attitudes about testing, but rather a reflection of lower rates of informed choice[35]. A lack of clear,

[32] Screening for Fetal Chromosomal Abnormalities. *Obstet Gynecol*. 2020;136(4):859-867. doi:10.1097/aog.0000000000004107.
[33] Committee Opinion No. 693 Summary: Counseling About Genetic Testing and Communication of Genetic Test Results. *Obstet Gynecol*. 2017;129(4):771-772. doi:10.1097/AOG.0000000000002011.
[34] Bryant AS, Norton ME, Nakagawa S, et al. Variation in women's understanding of prenatal testing. *Obstet Gynecol*. 2015;125(6):1306-1312. doi:10.1097/AOG.0000000000000843.
[35] Dormandy E, Michie S, Hooper R, Marteau TM. Low uptake of prenatal screening for Down syndrome in minority ethnic groups and socially deprived groups: A reflection of women's attitudes or a failure to facilitate informed choices? *Int J Epidemiol*. 2005;34(2):346-352. doi:10.1093/ije/dyi021.

culturally and linguistically appropriate prenatal genetic testing education may be a barrier to high-risk pregnant women making informed decisions[36].

Preliminary data from our institution, Women and Infants Hospital, suggest gaps in patient knowledge regarding prenatal genetic screening, consistent with the existing literature. At the Prenatal Diagnosis Center, 20% of English-speaking pregnant patients are unaware as to whether and what type of genetic screening they have had. We have not yet studied, but suspect that non-English speaking patients face similar if not greater patient knowledge gaps.

There is an urgent need for a solution that is both acceptable to providers and patients alike. A previous study among English-speaking patients, found that a prenatal genetic screening instructional video both increased patient knowledge and shortened the time providers spent counselling, while maintaining the same level of patient satisfaction[37]. Studies assessing Spanish-speaking women's attitudes towards and knowledge of prenatal genetic testing call for the adoption of mobile technology to provide pregnant patients with culturally appropriate education[38]. Electronic tools, including decision aids and educational videos[39],[40] are known to be acceptable to patients[41] and may allow for additional time spent building trust and clarifying patient values, essential components of this counselling[42]. Interactive decision tools have been studied among English speaking and Spanish speaking patients and have been found to enhance patient's informed choices in comparison to standard educational brochures[43],[44].

These studies have been promising, but few have integrated costs of testing and privacy of patient genetic information into conversations about various testing options presented in a values-based framework. Additionally, few of the existing resources are brief in nature and tailored to a population of patients with varying levels of health literacy. Studies have also found a preference for verbal, rather than written, dissemination of prenatal genetic counseling among Latina patients, suggesting patients may be more receptive to a video intervention than a text-based decision aid [45].

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[36] Page RL, Murphey C, Aras Y, Chen LS, Loftin R. Pregnant Hispanic women's views and knowledge of prenatal genetic testing. J Genet Couns. 2021 Jan 26. doi: 10.1002/jgc4.1383. Epub ahead of print. PMID: 33496987.

[37] de Leeuw RA, van der Horst SFB, de Soet AM, et al. Digital vs face-to-face information provision in patient counselling for prenatal screening: A noninferiority randomized controlled trial. *Prenat Diagn*. 2019;39(6):456-463. doi:10.1002/pd.5463.

[38] Page RL, Murphey C, Aras Y, Chen LS, Loftin R. Pregnant Hispanic women's views and knowledge of prenatal genetic testing. J Genet Couns. 2021 Jan 26. doi: 10.1002/jgc4.1383. Epub ahead of print. PMID: 33496987.

[39] Mulla BM, Chang OH, Modest AM, Hacker MR, Marchand KF, O'Brien KE. Improving Patient Knowledge of Aneuploidy Testing Using an Educational Video: A Randomized Controlled Trial. *Obstet Gynecol*. 2018;132(2):445-452. doi:10.1097/AOG.0000000000002742.

[40] de Leeuw RA, van der Horst SFB, de Soet AM, et al. Digital vs face-to-face information provision in patient counselling for prenatal screening: A noninferiority randomized controlled trial. Prenat Diagn. 2019;39(6):456-463. doi:10.1002/pd.5463.

[41] Knutzen D, Stoll K. Beyond the Brochure: Innovations in Clinical Counseling Practices for Prenatal Genetic Testing Options. *J Perinat Neonatal Nurs*. 2019;33(1):12-25. doi:10.1097/JPN.0000000000000374.

[42] Kuppermann M, Learman LA, Gates E, et al. Beyond Race or Ethnicity and Socioeconomic Status. *Obstet Gynecol*. 2006;107(5):1087-1097. doi:10.1097/01.aog.0000214953.90248.db.

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Impact: Ultimately, we aim to create a disseminable, visual educational resource in English and in Spanish that can be used as a tool to better support and educate our patients to promote informed consent and to empower them to make prenatal genetic testing decisions that are in line with their goals and values, while promoting health equity among our patients.

Study Aim/Hypotheses:
Our primary aim is to: determine the effect of video education tool (VET) on patient decisional conflict compared to usual care.

We hypothesize that patients randomized to the VET will have decreased decisional conflict on the Decisional Conflict Scale in comparison to patients who receive usual care.

Our secondary aim is to estimate the impact of video education tool on genetics knowledge retention.

Eligibility and Recruitment, Study Design:

STEP ONE: Pre-screening chart review from EMR for eligibility
Patient presenting to the Obstetrics and Gynecology Care Center (OGCC) or Providence Community Health Center (PCHC) for dating ultrasound will have chart reviewed to determine if eligible based on the following inclusion criteria:

- Patient ≥ 18 years of age
- Preferred language English or Spanish
- Singleton pregnancy
- No documentation of genetic screening results or counseling during **this** pregnancy
- Gestational age <24 weeks

At the Providence Community Health Center, key study personnel will pre-screen charts of patients presenting for a dating ultrasound to determine eligibility. At the OGCC, key study personnel, will pre-screen charts to determine eligibility.

Patients who meet eligibility criteria, as above, will be approached for enrollment in the study by key study personnel.

STEP TWO: If eligible, patient approached and offered an opportunity to enroll in study.

STEP THREE: Screening questions via RedCap on tablet to assess via patient report for exclusion criteria:

- In this pregnancy have you been diagnosed with a fetal anomaly, known abnormal nuchal translucency test, or fetal loss?
- Did you use a donor oocyte (egg)?
- If your preferred language English or Spanish?

- Have you been involved in any other research study regarding prenatal genetic testing in the past two years?*

* Part B and Part C of this study are being performed sequentially. The recruitment for each part of this study will be two separate groups from the same target population of pregnant women ≤ 24 weeks gestation. Therefore, participants in part B will not be enrolled in Part C.

STEP FOUR: Sign e-consent forms for study participation if patient agrees and is eligible. Participant phone number and email will be obtained. Name, email, and phone number will be stored in a RedCap database separate from all other data.

STEP FIVE: Patients complete questionnaire:

I. knowledge of prenatal genetics
II. prior experiences
III. demographics

STEP SIX:
Randomization: video vs standard care (no video)
If randomized to the intervention, patient will watch the video educational tool on a research tablet in their preferred language (English or Spanish) at the time they consent for the study (in person) prior to leaving their appointment. They will be given a pamphlet summarizing key points from the video intervention with a QR code links such thatparticipants can take home with them and share with family if they desire to rewatch the video series. This is optional.

STEP SIX: Chart review performed to look for the following variables:
zip code, insurance status

STEP SEVEN: Follow Up Survey #1
At the conclusion of the new OB appointment (or via telephone or email follow up within 14 days of their new OB appointment), patients will be asked to answer **follow up survey #1** questions regarding:

I. implementation questions surrounding their experience of the intervention
II. intended plan for testing
III. decisional conflict scale (limited literacy version) with respect to prenatal genetic testing decision
IV. perception of likelihood of having a baby affected by a genetic problem

STEP EIGHT
Patient Reimbursement
Patients will be compensated $10 per survey. They will be paid $30 in Amazon gift card at this time point ($10 for the completed baseline survey, $10 for the follow up survey, and $10 in advance for their commitment to complete the follow up survey #2).

STEP NINE – Chart Review

The following variables will be obtained: gestational age on date of follow up survey #1, obstetric history, routine screening via GAD 7 score (generalized anxiety disorder) from first trimester if obtained/documented, presence or absence of family history documented in OB chart

STEP TEN– Follow Up Survey #2
Six to ten weeks from the second survey, **follow up survey #2** will be conducted in person at a follow up appointment or via telephone or email to assess:

I. Provider patient communication
II. retention of genetics knowledge
III. patient recollection of testing performed
IV. self-reported out of pocket cost related to genetic testing
V. perception of genetic data privacy

Step ELEVEN - Chart Review
The following variables will be obtained: gestational age on date of follow up #2 survey, whether patient did carrier screening testing, type of genetic testing ordered and outcomes, whether and at what gestational age the patient saw a genetic counselor, whether or not post-natal genetic testing was ordered on the baby, and type of provider caring for patient during pregnancy.

Study Tools and EMR Data Abstraction

The knowledge-based portion of the survey was adapted from a similar measure created by Mulla et al[46]. The low literacy decisional conflict scale that we plan to use has previously been used in other research settings in English and in Spanish to assess "patient's uncertainty about the course of action to take…."[47] Decisional conflict is more common when patients are not provided with the adequate knowledge to make a decision[48] which is a known problem with prenatal genetics.

The EMR will be reviewed to determine with which practice group the patient has been following for the majority of prenatal care appointments. See data collection form entitled "Variables to Be Extracted" within IRBNet for the specifics of these variables.

All data (screening process, survey responses, and EMR data extraction) will be stored in REDCap within a secured Care New England Network. Consent forms will be signed and stored within REDCap. Participants will be given the option to receive an unsigned hard copy of the consent.

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[47] Légaré F, Kearing S, Clay K, et al. Are you SURE?: Assessing patient decisional conflict with a 4-item screening test. Can Fam Physician. 2010;56(8):e308-e314.
[48] Ferron Parayre A, Labrecque M, Rousseau M, Turcotte S, Légaré F. Validation of SURE, a four-item clinical checklist for detecting decisional conflict in patients. Med Decis Making. 2014 Jan;34(1):54-62. doi: 10.1177/0272989X13491463. Epub 2013 Jun 17. PMID: 23776141.

Video Production:
The content of the intervention video will include:

I. An explanation of the basics of chromosomal aneuploidy in pregnancy
II. Comparison of screening versus diagnostic testing options: pros/cons/alternatives
III. Emphasis on reflective questions that can guide informed patient choice
IV. Brief discussion of cost, patient privacy concerns, and logistics of testing

This video content will be guided by the American College of Obstetrics and Gynecology (ACOG) published clinical recommendations for prenatal genetic counselling and a review of the relevant literature. The video script and video itself will be submitted as an addendum to the IRB. Prior to implementing our intervention, we also plan to share the video in English and Spanish with two bilingual, Latina-identifying community healthcare workers at Progreso Latino for their feedback on acceptability, language, and tone of the video. Local genetic counselors at the Prenatal Diagnosis Center in Providence will also provide iterative feedback on our work. The final video will be produced in English and Spanish with the option for a voiceover in either language.

Sample Size: We plan to enroll 140 patients in this prospective randomized controlled trial.

Analysis Plan:
We plan to conduct a two-sample unpaired t-test to assess the difference in mean decisional conflict scores between intervention and control groups. We plan to use a significance level of alpha of 0.05 and a power of 80%. Based on prior studies on literature review for our primary outcome, we assume baseline decisional conflict is 20% and we expect
to
see a score of 10% decisional conflict with our intervention.

Expected outcomes: In order to ensure informed consent for prenatal genetic aneuploidy testing, patients must understand the information that is presented to them and have a framework to make the choice that is best for them. Through this study, we will determine if an educational video resource can improve patient decisional conflict about their choices for prenatal genetics. As secondary outcomes, we will also better understand if a video educational tool has an impact on type of testing chosen, patient-provider communication, recollection of testing performed, and patient knowledge retention over time. Ultimately, we hope that this study could support the use of an educational video as a way to standardize prenatal genetic counseling, thereby promoting health equity, and to improve patient knowledge and autonomy through informed consent.