

BMJ Open Linking genetic counseling communication skills to patient outcomes and experiences using a community-engagement and provider-engagement approach: research protocol for the GC-PRO mixed methods sequential explanatory study

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ABSTRACT

Introduction In over 50 years since the genetic counseling (GC) profession began, a systematic study of GC communication skills and patient-reported outcomes in actual sessions across multiple clinical specialties has never been conducted. To optimize GC quality and improve efficiency of care, the field must first be able to comprehensively measure GC skills and determine which skills are most critical to achieving positive patient experiences and outcomes. This study aims to characterise GC communication skills using a novel and pragmatic measure and link variations in communication skills to patient-reported outcomes, across clinical specialties and with patients from diverse backgrounds in the USA. Our community-engagement and provider-engagement approach is crucial to develop recommendations for quality, culturally informed GC care, which are greatly needed to improve GC practice.

Methods and analysis A mixed methods, sequential explanatory design will be used to collect and analyze: audio-recorded GC sessions in cancer, cardiac, and prenatal/reproductive genetic indications; pre-visit and post-visit quantitative surveys capturing patient experiences and outcomes and post-visit qualitative interview data. A novel, practical checklist will measure GC communication skills. Coincidence analysis will identify patterns of GC skills that are consistent with high scores on patient-reported measures. Two-level, multilevel models will be used to evaluate how GC communication skills and other session/patient characteristics predict patient-reported outcomes. Four community advisory boards (CABs) and a genetic counselor advisory board will inform the study design and analysis.

Ethics and dissemination This study has been approved by the single Institutional Review Board of the University of Minnesota. This research poses no greater than minimal

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will link genetic counseling (GC) communication skills with patient outcomes and experiences, filling a significant gap in the literature by identifying the most critical aspects of GC that contribute to positive patient experiences within a diverse sample.
- ⇒ Community-advisory and practitioner-advisory boards will inform the study design and analyses in order to develop recommendations for quality, culturally informed GC care.
- ⇒ A primary limitation of this study is that only patients who attend GC appointments will be approached for recruitment, leading to the potential for a sample that is not representative of the US population (e.g., predicted higher health literacy, greater trust in the US medical system, etc. amongst our participant sample).
- ⇒ Many patient outcome and experience measures used in this study have never been employed in GC research, which may lead to difficulty in capturing the nuances and variations in participants' GC experiences.

risk to participants. Results from this study will be shared through national and international conferences and through community-based dissemination as guided by the study's CABs. A lay summary will also be disseminated to all participants.

INTRODUCTION

As demand for genetic services increases, the genetic counseling (GC) field has worked towards expanding access to care and

optimizing efficiency without compromising the quality of services or increasing counselor burnout.^{1–5} Though expansion of GC services is ideal to meet the needs of the growing precision medicine field, it is unclear which elements of GC visits are essential to provide quality patient care, positive patient experiences, and genetic counselor satisfaction. Elucidating the GC communication skills used in sessions is critical as these skills are the basis for assessing the quality and effectiveness of GC services.^{6–8} In addition, given well-documented disparities in access to and utilization of GC services among historically under-represented racial and ethnic minority groups, integrating diverse perspectives to define quality GC services is a crucial step to reduce health disparities within the GC field.^{9–12} In over 50 years since the GC profession began, a systematic study of GC communication skills and patient-reported outcomes in actual sessions across multiple clinical specialties has never been conducted. To optimise GC quality and improve the efficiency of care, the field must first be able to comprehensively measure GC skills and determine which skills are most critical to achieving positive patient experiences and outcomes.

Comprehensive and pragmatic measures may help define and clarify the essential skills performed in GC sessions. Without systematic measures in natural settings, it is difficult to compare variability in GC sessions across clinical settings and across providers or determine how counselors adapt their sessions for patient needs.¹³ The body of the literature on GC communication has been built from analyses generated by the Roter Interaction Analysis System (RIAS)^{4 14} and the Genetic Counseling Video Project.¹⁴ The RIAS codes for affective and social communication patterns as well as instrumental and informational communication units in medical interactions. The Genetic Counseling Video Project recruited genetic counsellors who completed simulated prenatal and cancer pretest counselling cases. Given the many changes in GC practice since 2003, including the explosion of service delivery alternatives resulting in increased access to diverse patient populations, a reassessment of the GC health communication skills used in real sessions is far overdue.^{14 15}

Other health communication measurement tools have been used to study elements of GC communication strategies but the literature is limited.^{16–21} A combination of constructs most relevant to GC is ideal for a more accurate and specific assessment of GC communication skills. The Genetic Counseling Skills Checklist (GCSC) is a novel process measure specific to the GC field that aims to address missing elements of previous checklists and is based on findings from existing patient communication checklists; the Framework for Clinical Communication Services; communication and counseling theories; interviews with genetic counselors; and research findings on patient-centered care, patient education, and shared decision-making.^{7 22–24}

Accurate characterization of GC communication skills represents a first step towards identifying which skills are

essential for quality GC care. However, it is particularly important to elucidate how GC communication skills specifically lead to patient-reported outcomes and experiences. GC outcomes studies to date have been conducted within majority White patient populations and have shown that counseling is safe, impacts patient changes (e.g., improves patient empowerment), and may ultimately impact patient health outcomes.^{12 25–27} Given the findings of a systematic review showing limited research has been conducted on GC outcomes among racially/ethnically diverse populations, further research is needed to determine whether similar positive outcomes are reported for more diverse patients. Identifying positive and negative patient outcomes among diverse populations, and linking these outcomes to specific GC communication skills, has not been attempted in actual GC sessions across clinical specialties.

To ensure findings are culturally informed, and future applications are feasibly implementable into practice, community members and genetic counselors must be engaged in shaping the strategies used in GC research. While participatory research is not common in GC studies,^{28–32} engaging key stakeholders throughout the research process using community-based participatory research (CBPR) approaches can improve the reliability and equity of research, as well as increase the applicability and dissemination of research findings that could be implemented to reduce health disparities in GC.^{33 34}

The objective of the Genetic Counseling Processes Result in Outcomes (GC-PRO) study is to characterize GC communication skills using a novel and pragmatic measure and link variations in communication skills and session characteristics to patient-reported outcomes in a diverse sample. The study incorporates the expertise of community and genetic counselor advisory boards to help define quality GC practice from the diverse patient and genetic counselor perspectives.

METHODS

Study design

The specific study aims are (1) to collect and analyse pre-session and post-session surveys and audio-recordings of actual GC sessions from patients to identify which GCSC categories impact corresponding patient experience and outcome measures using coincidence analysis (CNA) and (2) to conduct multilevel modeling to evaluate how session characteristics and GC communication skills employed affect patient outcomes. These aims will be achieved through a multi-site, multi-discipline, mixed method sequential explanatory design with quantitative survey data collected first followed by qualitative interview data to interpret the quantitative results (figure 1). Study sites include the University of Minnesota, University of South Florida and Genome Medical.

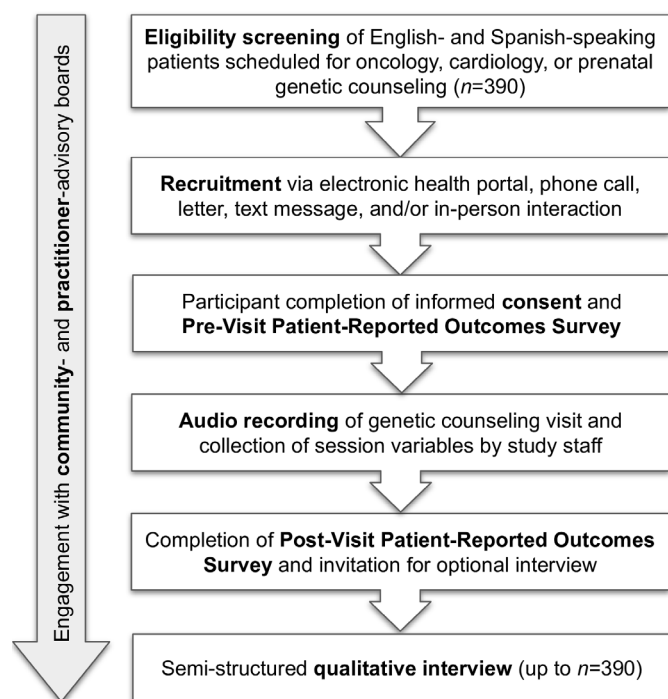


Figure 1 Genetic Counseling Processes Result in Outcomes study schema.

Community-engagement and provider-engagement approaches

Community advisory boards

We will incorporate a CBPR approach using four ethnic CABs and involve research team members who are also members of understudied communities in the USA, including Black/African American, Latino, Somali and Hmong communities. The Black/African American CAB at 'Faith Works: Connecting for a Healthier Community' organization affiliated with the University of Utah and the University of Kansas Medical Center (KUMC) is an established, faith-based group that has familiarity with GC and testing. The 'JUNTOS Center for Advancing Latino Health' is an established CAB group through KUMC focusing on health issues impacting the Latino community.^{35–39} The Somali CAB will be a new group consisting of key stakeholders and community members in Minnesota who have differing experiences with healthcare and genetics. The Hmong CAB is an iteration of a previous CAB involved in genetic research^{29 40 41} with new members joining the CAB through individual outreach.

The CABs will meet two to three times per year to provide input on study design, recruitment strategies, surveys and study materials, definition of key outcomes, interpretation of findings and dissemination plans. Some board members may transition into official research team member roles to support additional study activities, such as reviewing interview data. Representatives from each CAB will also be invited to participate in a cross-CAB meeting to discuss similarities and differences in themes arising from each CAB as well as a survey of their experience as CAB members in this study.

Genetic Counselor Advisory Board

A GCAB, consisting of lead genetic counselors from each clinical specialty at all three study sites, will meet one to two times per year. The GCAB will provide input on study processes, identify inconsistencies in data patterns, and interpret study findings from GC practitioner viewpoints.

Patient and public involvement

As outlined in section the Community-Engagement and Provider-Engagement Approaches, this study incorporates a CBPR approach through the use of community-advisory and provider-advisory boards. CABs contain members of the public, including patients with personal experience with GC. CABs were first involved in the research after the study goals and design were generated by the research team but before the initiation of the study. The research questions were informed by CAB leaders, several of whom are research team members. Each CAB will determine relevant goals for this research collaboration, which are expected to inform future research questions and directions. CAB members informed recruitment strategies but will not directly participate in recruitment or conduct of the study. CABs will inform prioritization of which patient-reported outcome and experience measures are most important from the patient's perspective. CABs will inform dissemination plans through the identification of relevant community-based settings and audiences that may desire education on the findings of this study. The GCAB, made up of genetic counselors, will also provide input on recruitment strategies, dissemination plans, and future research directions.

Setting and participants

Patient participants

The study will recruit approximately 390 English-speaking or Spanish-speaking adult patients or parents/legal guardians of underage patients referred for telehealth or in-person GC for a personal or family history of a cardiology, oncology, or prenatal/reproductive indication. Patients will be excluded from the study if they are unable to provide informed consent, cannot provide information for study surveys in English or Spanish, are under the age of 18 years, and/or are seeing a genetic counselor for other clinical indications beyond cancer, cardiology, or prenatal/reproductive genetics. In addition, for pediatric GC referrals, individuals who are not the parent or legal guardian of the child will be excluded. Patients will be recruited from two academic health centres (University of Minnesota-M Health Fairview and University of South Florida-Tampa General Hospital) and one telehealth GC company (Genome Medical, Inc.), providing a geographically diverse sample. We will include a variety of clinical indications from the three clinical disciplines, as well as pre-test and post-test counseling sessions.

We will employ quota sampling to recruit a racially/ethnically diverse participant population, with a maximum of 50% of participants identifying as White (non-Hispanic) and an approximate goal for other

participants of at least 20% identifying as Black/African American, 20% Hispanic/Latino, and 10% Asian or other race/ethnicity (including multiracial individuals).

Genetic counselor participants

Genetic counselors ($n = 39$) will be recruited to allow audio-recording and analysis of 10 of their GC sessions. Genetic counselors must be adults, Board certified by the American Board of Genetic Counseling, provide services in English or Spanish, and counsel patients for cancer, cardiac, or prenatal/reproductive genetic indications. Genetic counselors will be excluded from study participation if they are not Board certified and/or if they exclusively provide GC services within other specialty settings. The study will aim to recruit a diverse sample of genetic counselors in terms of years of experience, race/ethnicity, age, gender, training program, and experience working with understudied populations; however, the majority of genetic counselors employed at each study site are White (non-Hispanic) females, which is representative of the GC field.⁴²

Power and sample size

We considered statistical power along with practical factors (e.g., financial costs and time to recruit participants and collect and process the study data) in determining an appropriate sample size for this exploratory study. Based on power analyses using the Optimal Design software, we will recruit 39 counselors and analyse 10 sessions per counselor.⁴³ In these power analyses, power was set at 0.80 to detect a moderate relationship between the eight dimensions of the GCSC and the three primary patient outcomes (including Patient Empowerment, Patient Activation, and Decisional Conflict). Power was sufficient when taking into account the degree of nesting as reflected in potential intraclass correlation coefficients < 0.10 . For multilevel modeling, the level-1 model will include GCSC categories as predictors and primary patient outcomes as dependent variables. Level-2 model variables will include genetic counselor variables. It is hypothesized that the effects between the GC communication skills and patients' outcomes may vary across counselors, so in the power analyses the variance of these effects was set to 0.05. Tests of significance will be set at the 0.05 level of significance for two-tailed tests.

Recruitment and consent

Patient recruitment and consent

Across all sites, study staff will review the upcoming schedules of participating genetic counselors to screen for eligible patients, enhanced to ensure diversity of participant demographics (including race/ethnicity, spoken language, etc.). At UMN-M Health Fairview, patients will be invited to participate via an electronic medical record portal message (i.e., Epic MyChart message) sent by the health system's research department. This approach may be acceptable and familiar to the majority of patients^{44 45}; however, if it is inadequate to recruit diverse patients,

additional outreach methods may be incorporated such as tailored phone calls, mailed letters, and text messages. At USF-Tampa General Hospital, eligible patients will be directly approached by the USF study staff through phone calls before their scheduled GC appointment and/or in-person recruitment right before the GC appointment (with additional messaging through MyChart). At Genome Medical, a GC assistant will call eligible patients prior to their GC appointment using a script to confirm appointment logistics and offer study participation.

Interested patients at all sites will be provided a link to the online consent form via email, in-person tablets, or telehealth platforms. The consent also asks participants whether they would like to opt into an optional follow-up phone or video call interview.

Genetic counselor recruitment and consent

Key stakeholders (e.g., clinic managers and research directors) at each study site were introduced to the study prior to initiation to ensure engagement and feasibility in genetic counselor recruitment. Genetic counselors will be invited to participate by clinical liaisons and study staff via group presentations and/or individual outreach. If more than the required number of genetic counselors volunteer, clinical liaisons will help select the final list of genetic counselors to maximise the diversity of genetic counselors as described above (section Genetic counselor participants). Genetic counselors will complete an online consent and a 2–5-min survey.

Study procedures

Patient completion of surveys and audio-recorded GC visit

Consented participants are automatically routed to a 5–10-minute Pre-visit Survey to complete in REDCap (section Patient and genetic counselor outcome and experience measures). Once the survey is complete, study staff alert the participant's genetic counselor. When participants attend their GC appointment, study staff or the participating genetic counselor assures ongoing consent and then commences audio-recording of the session. Audio-recording was chosen rather than video recording to minimise intrusiveness and patient discomfort. Immediately after the GC visit, participants will be asked to complete a short Post-visit Survey (section Study procedures). Participants who complete both surveys and audio-recording of their GC visit will be emailed a \$30 gift card.

Semi-structured interviews with patient participants

The study will employ a mixed method sequential explanatory design in which qualitative interviews will help inform the interpretation of survey data and further elucidate which components of the GC visit were most and least beneficial. A semi-structured interview guide was developed that aligns with GCSC categories and investigates patient-reported outcomes and experiences. Patient participants who opt-in to a follow-up interview and complete all surveys will be invited to participate in

a 30-minute phone call or video interview after their GC appointment. Participants who complete the interview receive an additional \$25 gift card for a total of up to \$55 in gift card compensation.

Semi-structured interviews with genetic counselor participants

At the end of the study, genetic counselor participants will be invited to complete a semi-structured interview regarding their approach to medical education and psychosocial counseling. Additionally, we will gather practitioner perspectives about the GC outcomes they find most important and summary findings from GCSC coding of audio-recordings. Genetic counselors who complete the interview will receive a \$30 gift card.

Measures

Patient and genetic counselor outcome and experience measures

A combination of two short surveys (Pre-visit Survey: 52 items; Post-visit Survey: 83 items) will be used to collect patient-reported experiences and outcomes (table 1). The following measures and information will be collected: demographic information (including age, gender identity, race, ethnicity, education level, and income); awareness of GC; history of prior genetic testing; information preferences;^{46 47} baseline health literacy;⁴⁸ Information Overload;^{49 50} Working Alliance Inventory;^{51 52} CollaborRATE Shared Decision Making;^{53 54} Health Care Climate Questionnaire;⁵⁵ Genomics Outcomes Scale;^{56 57} Sure of myself, Understand information, Risk-benefit ratio, Encouragement (SURE) scale;⁵⁸ Patient Activation Measure;⁵⁹ Genetic Counseling Satisfaction Scale;⁶⁰ Patient-Centered Communication Scale;⁶¹ and a series of questions based on the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician & Group Survey Supplemental Items.^{62–64} Whenever possible, measures were used in their original form though several items were adapted to GC (eg, use the term genetic counselor instead of physician). Additionally, items that were not relevant to a GC encounter (questions about prescriptions, lifestyle, etc.) were removed from some measures.

A review of the psychometric evidence supporting the patient participant survey instruments was conducted and the surveys were then revised by a psychometrician, statistician, and communication expert, who made minor changes to capture GC outcomes and patient experiences. Subsequently, surveys were piloted by three non-participating genetic counselors at UMN, one JUNTOS Latino CAB member, and three Faith Works African American CAB members. Feedback from think-aloud piloting sessions informed item wording changes to increase clarity and understanding in the final survey versions (e.g., an item from the Working Alliance Inventory was changed from 'mutually agreed on management plan' to 'plan we both agree on').

All study materials were professionally translated into Spanish by KUMC JUNTOS Center for Advancing Latino Health through an iterative process involving multiple rounds of revisions from native Spanish-speaking staff

with experience translating research instruments for diverse audiences and a former GC patient. The translation process included (1) forward English-Spanish translation from an independent translator, (2) review of initial translation by a second translator, (3) harmonisation of both translations by the first and second translators who discussed disagreements until they reached consensus, (4) review of the harmonised version by a native Spanish-speaker with lived experience with GC and who viewed the translations through the lens of a patient, and (5) final review and editing from a fourth translator with expertise in the linguistic adaptation of behavioural interventions who compared the original English and patient-informed versions for consistency within and across instruments.

Each genetic counselor participant will complete a demographic survey about age, gender identity, race/ethnicity, years of experience, and training program, and the Genetic Counseling Self-Efficacy Scale.⁶⁵

Collection of session characteristics

GC session variables collected by study staff will include genetic counselor, clinical specialty, modality of service delivery, allocated length of visit, total actual time spent counseling, pre-test or post-test counseling, and type of genetic result if post-test counseling.

GCSC coding

The GCSC captures eight categories of communication skills and strategies that may be employed by genetic counselors during patient sessions, including building rapport, mutual agenda setting and structuring, risk communication, recognising and responding to emotions and prior experiences, educating, checking for understanding, facilitating decision-making and promoting patient activation.²³ Detailed instructions are summarised in the checklist, training manual, and an online training module.

Planned statistical analysis

Confirmatory factor analysis

We will conduct confirmatory factor analysis and calculate Cronbach's alpha coefficients to verify the construct validity and reliability of the survey measures.

Coincidence analysis

In order to link GC communication skills to outcomes, CNA will be used to identify multiple complex patterns of conditions (e.g., individual patient characteristics and GC communication skills) that are consistently associated with an outcome of interest (e.g., patient-reported outcomes).⁶⁶ CNA is useful in evaluating complexities inherent in real-world settings where the effects of GC communication skills are not expected to act in isolation. A primary benefit of using CNA is its ability to identify conjuncts (or conditions that together may lead to an outcome but alone may be insufficient for the outcome). Furthermore, CNA can identify if there is more than one 'pathway' to achieve an outcome. For example, a certain combination of communication skills may lead to a positive outcome for specific patients, but an entirely different combination may be

Table 1 Patient and genetic counselor measures used in the GC-PRO Study

Measure	Number of items	Sample item	Response scale	Prior use in GC research
Patient-reported outcome and experience measures				
Baseline Health Literacy Assessment ^{*48}	3	How often do you have someone (like a family member, friend or caregiver) help you read medical information?	5-point Likert scale	Yes
Informational Styles and Preferences Questionnaire ^{*†46 47}	3	How much information about your healthcare options do you like to get from your healthcare provider?	5-point Likert response scale (1 item), 3-option multiple choice (2 items)	Yes
Genomics Outcomes Scale ^{†‡56 57}	17	I can explain what the health condition means to people outside my family who may need to know (e.g., teachers and social workers).	5-point Likert scale	Yes
Sure of myself, Understand information, Risk-benefit ratio, Encouragement Scale ^{‡58}	4	Are you clear about which benefits and risks matter most to you?	Yes/No multiple choice	Yes
Modified CAHPS Specialist Health Plan ^{†§62}	1	Using any number from 0 to 10, where 0 is the worst genetic counseling possible and 10 is the best genetic counseling possible, what number would you use to rate your genetic counseling?	11-point response scale (0 to 10)	No
State-Based Information Overload ^{†§49 50}	5	What we talked about in the visit left me feeling overloaded.	5-point Likert scale	No
CollaboRATE Shared Decision Making Scale ^{§53 54}	3	How much effort did the genetic counselor make to listen to the things that matter most to you about the health condition?	11-point response scale	Yes
Patient-Centered Communication Scale ^{§61}	7	How often did the genetic counselor give you the chance to ask all the health-related questions you had?	4-point Likert response scale	No
Genetic Counseling Satisfaction Scale ^{§60}	6	The genetic counselor helped me to identify what I needed to know to make decisions.	5-point Likert response scale	Yes
Healthcare Climate Questionnaire ^{†§55}	6	The genetic counselor tries to understand how I see things before suggesting a new way to do things.	7-point Likert response scale	No
Working Alliance Inventory-Short Revised Form ^{†§51 52}	10	The genetic counselor and I are working towards a plan we both agree on.	7-point Likert response scale	Yes
CAHPS Supplemental Health Literacy ^{†§64}	3	The genetic counselor used a lot of medical words I did not understand.	7-point Likert response scale	No
Patient Activation Measure-Short Form ^{†‡59}	10	I am confident that I can tell when I need to go get medical care and when I can handle the health condition myself.	5-point Likert response scale	Yes

Continued

Table 1 Continued

Measure	Number of items	Sample item	Response scale	Prior use in GC research
CAHPS Patient Narrative Supplement†§ ⁶³	3	What do you wish had gone differently and/or what didn't you like during the genetic counseling visit?	Open-ended response	No
Genetic counselor measures				
Genetic Counseling Self-Efficacy Scale ⁶⁵	38	Please rate how certain you are that you can perform this competency today in a genetic counselling session: facilitate client decision-making that is consistent with the values of the client	100-point scale in increments of 10	Yes

Patient-reported outcome and experience measures, as well as genetic counselor participant measures, used in the Genetic Counseling Processes Result in Outcomes (GC-PRO) study. The assessment of each measures' use in other genetic counseling (GC) research studies was reviewed via an informal search of the literature in December 2023.

*Measure collected from patient participants in the Previsit Survey only.

†Modified from original measure for this study.

‡Measure collected from patient participants in both the Previsit and Postvisit Surveys.

§Measure collected from patient participants in the Postvisit Survey only.

CAHPS, Consumer Assessment of Healthcare Providers and Systems.

necessary for other patients. We will use CNA to uncover existing complex combinations of GC communication skills that make a difference in high scores on patient experience and patient change measures.

CNA will be conducted by Dr. Cragun using an R package designed specifically for CNA following best practices⁶⁶ and solution consistency and coverage (measures of model fit) will be reported.

Multilevel modeling

A series of two-level multilevel models, with level-1 representing session/patient variables (e.g., GCSC category scores) and level-2 representing counselor variables (e.g., years of experience), will be used to predict three primary patient outcome variables (Patient Empowerment, Patient Activation, and Decisional Conflict). For example, when examining Post-Session Patient Empowerment, the score for one of the GCSC categories 'facilitating decision-making' will be entered into the model as a predictor variable. One or more covariates will also be added to the model (e.g., patient age, Pre-Session Patient Empowerment) to evaluate the relation between the GCSC category and the outcome variable after controlling for relevant covariates. This modelling approach will be repeated for each of the GCSC categories for each of the primary outcome variables.

For the secondary outcomes (e.g., patient experience variables such as Information Overload, Patient-Reported Shared Decision Making, Satisfaction, Autonomy Support, Working Alliance, Perceived Health Literacy Demand of Appointment, Overall Patient-Reported Quality Rating of Appointment, and Patient-Centered Communication), we will use a similar approach that will include a series

of two-level multilevel models. We will build on these analyses to conduct exploratory two-level multilevel mediation models⁶⁷ to test how session characteristics (e.g., time in session) may affect GCSC category scores, which, in turn, may affect patient outcomes. These mediation models will be used to evaluate the direct and indirect effects of session characteristics and patient experience variables on patient outcomes. Standardized effect sizes and the explained variance of outcomes at level 1 will be calculated using methods proposed by Bosker & Snijders, 2011.⁶⁸ For all analyses, effect sizes will be calculated to complement the tests of significance. We will interpret tests of significance cautiously given that type 1 error increases with the number of tests of significance.

Thematic analysis of interviews

Participant and GC interviews will be transcribed and translated into English as necessary. Team members will evaluate the English transcripts using a reflexive thematic analysis. Reflexive thematic analysis is a constructivist approach used to analyse participant interviews by identifying patterns of meaning in the data to capture themes.^{69 70} Themes generated from patient and GC participant interviews will capture nuances in experiences, which can provide a deeper meaning related to patterns in GC communication skills and outcomes in participants' stories.

ETHICS AND DISSEMINATION

Ethical and safety considerations

This study has been approved under the single Institutional Review Board (IRB) of the University of Minnesota

(#00011241). We will seek approval for all protocol modifications to the IRB. This study poses no more than minimal risk to participants, as determined by the IRB and via an assessment by the Health Information Privacy and Compliance Office of the University of Minnesota. All participants will give informed consent before taking part in the research.

Study duration

We commenced study recruitment at the University of Minnesota in September 2023. The University of South Florida and Genome Medical began recruiting in December 2023 and January 2024. We anticipate closing study recruitment in August 2024 or when recruitment goals are met.

Dissemination of research findings

We will publish the results of this study in a peer-reviewed journal and present our findings at relevant scientific conferences and professional meetings. We will send a lay summary to all participants at study close, which will also be placed on the study's website. We will share findings with our CABs and GCAB, and anticipate disseminating results within relevant community-based settings as guided by the CABs.

DISCUSSION

The GC-PRO study will be the first systematic approach to linking GC communication skills with patient-reported outcomes and experience measures in real-life GC sessions across clinical specialties. By using an innovative analytic approach to identify causal complexity, this study will fill a 20-year gap in GC communication research and help build a more fully elucidated model of GC practice. In addition, through our mixed methods approach, we expect to provide an extensive review of the patient-reported experience and outcomes to capture patients' views of GC quality. The integration of key stakeholders from underrepresented communities and GC providers has the potential to identify findings that are culturally informed and could be successfully implemented into practice.

Our approach to linking GC communication skills with patient-reported outcomes builds on prior research in a variety of unique and novel ways. To date, the majority of GC studies were completed within only one clinical specialty and/or only analysed simulated cases. We chose three specialties to capture similarities and differences in GC communication skills that may present across differing specialties: oncology and obstetrical as the top two clinical specialties and cardiology as the fastest-growing specialty in GC.⁵ Due to the limited amount of comprehensive, validated patient experience/outcomes measures within GC research that reliably capture a multitude of GC patient experience domains, findings from this study may help better understand which outcome measures are most valuable from patients' perspectives and those

that reliably capture variations in patients' experiences. In addition, this is the first study to employ CNA to look for patterns of communication skills that consistently associate with positive GC outcomes and the first-time multilevel modeling will be used to determine variability in communication skills and outcomes across counselors and across sessions.

We designed the study to maximise diversity in clinical recruitment locations, service delivery models, enrolled participants, and CABs. The recruiting locations cover an expansive geographic area and involve differing GC practices within two academic medical centres and a private telehealth GC organization. We planned a unique combination of culturally informed recruitment methods to increase diversity in our sample, in order to identify a range of diverse patients' communication preferences and perspectives of GC quality. Finally, our community-engagement and provider-engagement approach involves Black/African American, Latino, Somali and Hmong community members as research team members and as CAB members, as well as genetic counselors who will participate as participants, research team members and advisors.

The primary limitation of this study is our sampling strategy, as only patients who attend GC appointments will be approached for recruitment. Patients who have higher health literacy and education, speak English or Spanish, have abilities and resources to navigate clinical specialty appointments, and higher trust in the US medical system are more likely to attend GC appointments.^{9–11} Other patient population limitations include the possibilities of higher representation of individuals who have health conditions that are less severe, who are less concerned about privacy/confidentiality, and/or who are generally motivated to participate in research. In addition, we expect that the majority of genetic counselor participants will be non-Hispanic White women, which is a limitation inherent in the racial/ethnic and sex constitution of the GC field.⁴² Genetic counselors were instructed not to alter their sessions but may have varied their patient communication approaches due to the session being recorded and analyzed. Given that some of these patient measures have never been used in GC research to date, outcome and experience measures may fail to capture the nuances and variations in participants' GC experiences. CNA analysis may fail to identify a highly consistent pattern of factors associated with high scores on patient outcome measures. To counteract this, we will use the qualitative interview data to supplement survey data and the CNA analysis, especially if we find contradictions to the identified patterns.

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