

Development of FOCUS-GC: Framework for Outcomes of Clinical Communication Services in Genetic Counseling

Deborah Cragun¹ · Heather Zierhut²

Received: 7 December 2016 / Accepted: 11 August 2017 / Published online: 12 October 2017
© National Society of Genetic Counselors, Inc. 2017

Abstract Conceptual frameworks bring together existing theories and models in order to identify, consolidate, and fill in gaps between theory, practice, and evidence. Given the vast number of possible outcomes that could be studied in genetic counseling, a framework for organizing outcomes and postulating relationships between communication services and genetic counseling outcomes was sought. Through an iterative approach involving literature review, thematic analysis, and consolidation, outcomes and processes were categorized to create and define components of a conceptual framework. The final product, “Framework for Outcomes of Clinical Communication Services” (FOCUS) contains the following domains: communication strategy; communication process measures; patient care experience, patient changes, patient health; and family changes. A website was created to allow easier access and ongoing modifications to the framework. In addition, a step-by-step guide and two examples were created to show flexibility in how the framework can be used. FOCUS may help in conceptualizing, organizing and summarizing outcomes research related to risk communication and counseling in genetic service delivery as well as other healthcare settings.

Keywords Evaluation · Patient outcomes · Genetic services · Genetic counseling · Patient communication · Family communication · Cascade testing

✉ Deborah Cragun
dcragun@health.usf.edu

¹ Department of Global Health, University of South Florida, 3720 Spectrum Boulevard, IDR B 304, Tampa, FL 33612, USA

² Department of Genetics, Cell Biology, and Development, University of Minnesota, Twin Cities, Minneapolis, MN, USA

Introduction

Measuring the impact of genetic counseling (GC) on patient outcomes is critical for improving patient care and establishing the added value and quality of care provided by genetic counselors. Clinical communication encompasses many of the education, counseling, and care coordination processes that genetic counselors perform. Clinical communication is a critical component of patient-centered care and may influence patient health outcomes indirectly through cognitive, emotional, or behavioral patient changes that occur as a result of clinical services (Epstein and Street 2007; Street 2013; Street et al. 2009).

We and other researchers have recognized that a comprehensive conceptual framework would be helpful in promoting the use of theory in practice and research related to clinical communication processes and outcomes (McAllister et al. 2016). A framework can be defined as “a structure, overview, outline, system or plan consisting of various descriptive categories, e.g. concepts, constructs or variables...that are presumed to account for a phenomenon” (Nilsen et al. 2015). A framework could help guide hypothesis driven research, selection of outcome measures, and the development of a systematic approach to evaluate the impact of a communication strategy on patient outcomes. Furthermore, use of a conceptual framework helps ensure that potentially important factors have been considered as part of an outcomes assessment (Glanz and Bishop 2010). Finally, a framework can help in hypothesizing and testing proposed relationships between GC communication processes and outcomes (Glanz and Bishop 2010).

Prior efforts to develop a conceptual framework for evaluating genetic service delivery have been made using different approaches. Wang et al. reviewed the scientific literature and developed a basic framework by outlining goals of genetic

counseling as well as some examples of process variables and outcome variables (Wang et al. 2004). In a separate effort, Veach et al. used information elicited from GC experts to develop the Reciprocal Engagement Model (REM) of genetic counseling practice which outlines tenets, goals, strategies, and behaviors relevant to the GC profession along with a few outcomes (Veach et al. 2007). Efforts to systematically or comprehensively identify important genetic services outcomes have been conducted by several groups. Two groups in the United Kingdom analyzed qualitative patient data and independently defined similar sets of outcomes that are important to patients (Marion McAllister et al. 2007, 2008; Pithara 2014). One of these groups subsequently developed and validated the Genetic Counseling Outcomes Scale to assess the overarching construct of patient empowerment, defined as “*a set of beliefs that enables a person from a family affected by a genetic condition to feel they have some control over and hope for the future*” (McAllister et al. 2011). In the United States (U.S.), the Western States Regional Genetics Collaborative developed a menu of outcomes related to genetic service delivery in clinical and public health settings (Silvey et al. 2009). In another effort, a multidisciplinary group of health care professionals from the U.S. and United Kingdom identified and prioritized a set of “quality indicators” for clinical genetics (Zellerino et al. 2009). Based on a literature review of outcome measures, a group in the United Kingdom identified 19 key domains captured by genetic service outcomes measures and asked patients and providers to determine which are most appropriate to measure (Payne et al. 2007a; Payne et al. 2007b). Most recently, work by U.S. researchers in collaboration with a National Society of Genetic Counselors (NSGC) sub-committee has generated outcomes specific to genetic counseling sessions (Redlinger-Grosse et al. 2015; Zierhut et al. 2016).

Recognizing the need to cohesively synthesize prior efforts, our initial aim was to develop a framework that: 1) organizes, consolidates, and conceptualizes clinical outcomes; 2) postulates how these outcomes connect to GC skills and processes that can be combined to form an overall communication strategy; and 3) aligns framework components with possible measures that have previously or could be used in conducting genetic counseling outcomes research. The framework intentionally concentrates on clinical communication services in GC and does not encompass other medical aspects of genetic service delivery which were outside the scope of this project. In this paper we describe framework development and the creation of a website prototype to house information about the framework. We also illustrate how to tailor the framework for practical use in considering genetic counseling-specific outcomes using a step-by-step guide. Finally, we discuss future directions for using and refining the framework and how it may help in gathering an evidence base for defining quality in genetic counseling.

Methods

Overview of Framework Development and “Outcomes” Categorization

Models, theories and frameworks are all tools for conceptualizing, evaluating, and understanding phenomena; and distinctions between these three terms are not critical for our purposes. Terminology for the components of a framework can vary, but we use the terms constructs (abstract ideas or concepts) and domains (groupings of similar or related constructs).

In developing the framework we drew upon our collective training and experience related to: 1) clinical genetic counseling practice and research; 2) existing behavioral or communication models and published literature from several targeted reviews; and 3) a list of nearly 200 outcomes generated as part of prior and ongoing efforts to elicit GC outcomes (Redlinger-Grosse et al. 2015). We began by grouping the list of “outcomes” into broad domains using a modified logic model approach beginning with the most distal patient outcomes and working backwards toward “outcomes” that would be more directly influenced by GC (Kenyon et al. 2015). An initial attempt to further categorize and consolidate these was taken by the first author and then audited by the other author. Discrepancies in categorization and in domain and construct labels were discussed until a consensus was reached between authors. Framework development was iterative and involved weekly discussions between the authors over a period of approximately 2 years, with additional revisions over the course of several months.

Early in our process we defined several framework domains. The first, which we ultimately called “*patient health*”, reflects changes in patients’ mental, physical, or social health that are hypothesized to be indirectly influenced by genetic counseling. We then worked backwards to propose how genetic counseling might mediate (i.e., influence or lead to) patient health. Using the “*Direct and Indirect Pathways from Communication to Health Outcomes*” model (Street 2013; Street and Epstein 2007; Street et al. 2009), Wang’s framework for evaluating genetic services (Wang et al. 2004), Donabedian’s Model of Quality Care (Donabedian 1988), and the National Quality Measures Clearinghouse (“National Quality Measures Clearinghouse 2017) to guide our efforts, we defined three additional domains, which we ultimately called: “*process measures*”; “*patient care experience*”; and “*patient changes*”. We also added a “*family changes*” domain to reflect findings that genetic services can impact outcomes for other family members (Marion McAllister et al. 2007; Payne et al. 2007a, 2007b). During this process we further categorized and re-categorized “outcomes” using thematic analysis and then defined constructs using emergent themes and prior work by other researchers

(McAllister et al. 2011; Epstein and Street 2007; Payne et al. 2007a, 2007b; Pithara 2014; Silvey et al. 2009; Street 2013; Wang et al. 2004). We also added constructs from several widely used theories or frameworks such as the Health Belief Model, Theory of Planned Behavior, Self-determination Theory, and Extended Parallel Process Model, (DiClemente et al. 2009; Glanz and Bishop 2010; Witte 1992). To preserve parsimony in an already complex framework, we combined constructs we deemed to have substantial overlap and selected or created labels we agreed were most descriptive of blended or newly created constructs.

Linking “Outcomes” to Communication Skills and Processes

When considering how genetic counseling might influence various outcomes, we extracted several lists of behaviors, techniques, processes, and communication functions from the REM (Veach et al. 2007), GC competencies (Accreditation Counsel for Genetic Counseling 2015), framework for evaluating genetic services (Wang et al. 2004), Direct and Indirect Pathways to Patient Outcomes model (Epstein and Street 2007; Street 2013; Street et al. 2009), Social Support Theory (House 1981), Motivational Interviewing (Lundahl et al. 2013; Miller and Rollnick 2013), Self-determination Theory (SDT) (DiClemente et al. 2009), the Ottawa Decision Making Framework (Légaré et al. 2006), GC research (Hallowell et al. 2005; Lerner et al. 2015; Meiser et al. 2008; Roter et al. 2006), and widely used GC texts (Hartmann et al. 2015; Uhlmann et al. 2009; Veach et al. 2010; Veach et al. 2003). Using a similar iterative approach used to organize outcomes, we categorized items on these lists using thematic analysis and then consolidated them into communication skills categories that are each comprised of several communication processes.

Our approach to link outcomes with communication skills and processes was largely influenced by the REM (Veach et al. 2007) and Direct and Indirect Pathways to Patient Outcomes model (Hoerger et al. 2013; Epstein and Street 2007; Street 2013; Street et al. 2009). Through co-opting, blending, and modifying visual representations of patient-centered communication illustrated by (Hoerger et al. 2013) and (Street 2013; Street et al. 2009), we depicted the following framework components: 1) influence of patient and provider goals; 2) skills and processes that comprise a communication strategy; 3) reciprocal communication that occurs between genetic service providers and patients, which is central to the REM; and 4) possible links by which hypothesized strategies may improve the patient care experience and lead to desired cognitive, emotional, or behavioral changes in patients or their family members.

Considering Context

To complete the framework, we followed Epstein and Street’s recommendation to consider the important influence of individual-, family-, cultural-, institutional-, or policy-level factors that may influence patient outcomes (Epstein and Street 2007). Examples of these include; sociodemographics of both the patient and genetic service provider as well as disease-related factors, patient’s illness representation, health literacy and numeracy, family structure, social distance from family members, health insurance status and type, social support, cultural context, policies, laws, health care system factors, and provider self-awareness. Although contextual factors could mediate or moderate proposed relationships between many of the framework constructs, these are external to the main framework domains.

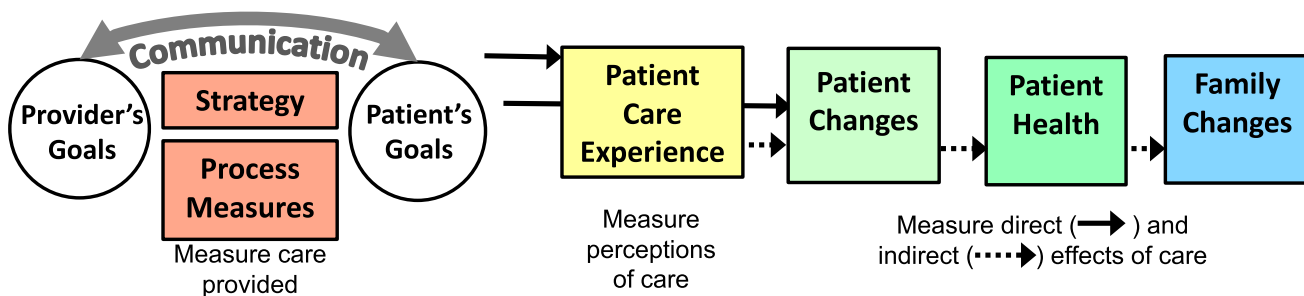
Creation of a Website, Concrete Examples, and Step-by-Step Guide

Due to the large amount of content in the framework and the foreseeable need to continue making ongoing modifications or updates, an on-line website was created under the domain <https://www.focusoutcomes.com/>. The website was designed to assist in disseminating the framework and to help people navigate framework content while minimizing the likelihood they will be overwhelmed with too much information at one time. Concrete examples were created to illustrate how components of the framework can be combined in different ways to illustrate different outcomes. Finally, a step-by-step guide was also created to help demonstrate one way in which the framework can be used to develop a plan for evaluating genetic counseling services or conducting a research study.

Results

General Framework

The title we selected, “Framework for outcomes of clinical communication services (FOCUS),” reflects the framework’s general purposes which are to: 1) organize and consolidate outcomes to help researchers and health care providers select and focus on outcome(s) they are interested in evaluating; 2) hypothesize how the outcomes may relate to each other and to various skills and processes that may be employed as part of a communication strategy in clinical settings; and 3) align framework components with possible measures. The general relationships between domains that comprise FOCUS and patient and provider goals are depicted in Fig. 1. FOCUS domains include: 1) communication strategy (i.e., the overall combination of skills and processes employed to achieve the goals); 2) communication process measures; 3) patient care



Cragun & Zierhut 2016

Fig. 1 Framework For Outcomes In Clinical Communication Services (FOCUS)

experience; 4) patient changes; 5) patient health; and 6) family changes. The resulting framework provides clinicians and researchers with flexibility to combine communication skills in various ways in order to design a strategy hypothesized to achieve specific outcomes of interest.

Patient and provider goals within the context of genetic counseling have been described or studied previously by other researchers (Bernhardt et al. 2000; Hartmann et al. 2015; Peters and Petrill 2011; Veach et al. 2007; Wang et al. 2004). Our targeted literature review revealed that goals vary from patient to patient in different subspecialty settings (Peters and Petrill 2011) and many patients are unaware of what to expect from genetic counseling and therefore lack well-defined goals (Bernhardt et al. 2000). Genetic counseling goals from the REM fall into four main categories: 1) understanding and appreciation; 2) support and guidance; 3) facilitative decision-making; and 4) patient-centered education (Hartmann et al. 2015). These goals are similar to the three overarching goals of genetic counseling described by Wang et al., which include: 1) educate and inform, 2) provide support and help cope, and 3) facilitate informed decision-making (Wang et al. 2004).

A communication strategy is a plan or method for achieving patient and provider goals and positively influencing patient care experiences, changes, and/or health. A strategy can be created by combining various communication skills and processes that are categorized in Table 1. Communication process measures reflect the clinical communication services that take place. Processes can be measured using checklists, chart reviews, or third-party observation to document use of communication skills, adherence to professional guidelines, patients' level of involvement, and other components of care. Constructs within the communication process domain and some example measures that may assess these constructs are listed in Table 2.

Patient care experiences consist of different types of feedback from patients and their families or caregivers about the delivery of patient care. Some of the examples listed in Table 3 include: meeting patient needs, perceptions of the patient/provider relationship,

perceptions of communication, and perceptions of information received. These reflect the level of patient-centered care and may influence other downstream changes.

Patient changes are cognitive, emotional or behavioral factors that change during or after the visit with the healthcare provider as a direct or indirect result of the care they received. These are listed in Table 4 along with a few examples of possible measures that have or could possibly be used to measure these changes.

Patient health includes both objective and patient reported changes in mental, physical, or social health that result from the clinical care received. In the case of clinical communication services, changes in patient health are more likely to occur indirectly as the result of upstream influences services may have on patient care experiences or patient changes. Patient health outcomes are listed in Table 5 along with some measures to serve as examples.

Family changes consist of factors that change among the patient's family as an indirect result of health services provided to a patient. These can include: family communication, family functioning, family member access to appropriate care, and caregiver burden detailed in Table 6. Several of these changes may be important contributors to improved health outcomes among family members.

FOCUS-GC Step-by-Step Guide and Examples

Two concrete examples of how FOCUS can be applied to genetic counseling were created. The first example, entitled "*FOCUS on Genetic Counseling to Improve Family Risk Communication and Appropriate Uptake of Health Services*", is illustrated in Fig. 2 and described briefly below. This example could be useful for researching the effectiveness of genetic counseling interventions on conditions, such as hereditary cancer syndromes and familial hypercholesterolemia, where genetic testing/screening can empower family members to access genetic services and take appropriate actions that

Table 1 Communication skills used to create strategies as part of the Framework for Outcomes in Clinical Communication Services (FOCUS)

Communication skills categories ^a	Description of skills and processes	Hypothesized to influence patient experience, changes and health
Building rapport (i.e., establishing a professional relationship and mutual respect) [1, 5–7, 10]	<p>Ask how the patient prefers to be addressed (use their own language and words if appropriate).</p> <p>Attend to the patient's physical comfort and other needs.</p> <p>Place yourself on the same level as the patient, with no barriers between you.</p> <p>Be sincere, respectful, & culturally responsive (e.g., use person-first or identity-first language).</p> <p>Avoid interruptions and remain flexible in altering your approach to meet the patient's needs.</p> <p>Open up two-way communication (patient is given opportunities and encouraged to talk, ask questions, voice concerns, discuss options, and share information with the provider).</p> <p>Engage in active listening (e.g., maintain eye contact (in Western cultures), lean forward, attend to verbal and non-verbal cues, restate what the patient says to confirm understanding of the patient's perspective).</p> <p>Take an empathic, non-judgmental, and genuine approach.</p> <p>Demonstrate unconditional positive regard and appreciation of patient strengths.</p> <p>Consider how provider's own personal experiences or attitudes could impact communication.</p> <p>Recognize that provider's self-disclosure or intense emotional responses can shift the focus away from the patient.</p> <p>Maintain professional boundaries and objectivity.</p>	<p>Meet patient needs/expectations</p> <p>Perception of patient-provider relationship</p> <p>Perceptions of information provided</p>
Mutual agenda setting (i.e., contracting) [1–4]	<p>Elicit patient's expectations, goals, and reason for the visit</p> <p>Summarize patient's perspective.</p> <p>Explain or clarify health provider's goals & understanding of the reason for the visit.</p> <p>Prioritize patient's goals and needs and develop a mutually agreed upon agenda.</p> <p>Manage patient expectations – (If patient's needs/expectations cannot realistically be met, explain why & provide alternative means by which patients may meet their needs).</p> <p>Reassess the patient's needs throughout the encounter.</p>	<p>Meeting patient needs and expectations</p> <p>Perceptions of patient-provider relationship</p> <p>Perceptions of information provided</p>
Gathering medical and psychosocial information	<p>Gather medical records and/or ask patient questions about health history (e.g., symptoms, pregnancy history, family history, developmental history, and/or health behaviors).</p> <p>Use open-ended questions and reflections to elicit patient needs, concerns, perspectives, values, health beliefs, and psychological/social context.</p>	<p>Meeting patient needs and expectations</p> <p>Perceptions of patient-provider relationship</p> <p>Accurate diagnosis</p>
Responding to emotions [1, 3–7, 9, 11, 14–16]	<p>Elicit, clarify and acknowledge patient's emotions (e.g., express empathy by reflecting patient's thoughts/feelings, develop or reduce emotional intensity).</p> <p>Provide emotional support (e.g., supportive comments, encouragement, or validation; normalize; limit liability, give positive feedback).</p>	<p>Perception of patient-provider relationship</p> <p>Empowered to make decisions</p> <p>Empowered to cope with emotions</p>
Educating and checking for understanding [1, 2, 5–8]	<p>Elicit patient's beliefs about the condition/risks while listening for inaccuracy.</p> <p>Assess patient education level, health literacy level and information preferences.</p> <p>Modify the level of information and amount of detail provided to align with patient's education/literacy/numeracy levels and preferences.</p> <p>Use plain language and avoid complex terms or jargon (be clear, concise and specific).</p> <p>Use visual aids; organize and "chunk" information.</p> <p>Provide accurate information in a manner that is sensitive to cultural beliefs and values.</p> <p>Check patient understanding (e.g., use the "teach back method"; ask patients to describe what the information means for them personally and/or their family and how they plan to use the information or not).</p> <p>Summarize, clarify and highlight key points and take home messages.</p>	<p>Perceptions of information provided</p> <p>Patient knowledge</p> <p>Feeling informed</p> <p>Perceived severity of condition</p> <p>Attitudes, beliefs, feelings about options and anticipated outcomes</p> <p>Quality health decisions</p>

Table 1 (continued)

Communication skills categories ^a	Description of skills and processes	Hypothesized to influence patient experience, changes and health
Communicating risk [3, 4, 8, 9]	<p>Review relevant medical history, family history, and test results with the patient.</p> <p>Provide personalized risk information based on genetic, environmental, and lifestyle risks.</p> <p>Discuss risk implications for both the patient and their family members (if appropriate).</p> <p>Use natural frequencies, round numbers, and common denominators to decrease numeracy demands.</p> <p>Assess and re-assess patient's risk perceptions.</p> <p>Clarify risks.</p>	<p>Perceptions of information provided</p> <p>Perceived risk and susceptibility</p> <p>Patient knowledge</p> <p>Feeling informed</p> <p>Empowered to make decisions</p> <p>Accurate diagnosis</p> <p>Risk communication among family members</p>
Communication framing and format [10–13]	<p>Present risks as both the chance the patient will have the condition and chance the patient will not have it to reduce framing bias.</p> <p>Present balanced information: include “best case”, “worst case”, and “most likely” scenarios.</p> <p>Focus on the “most likely” outcome. Highlight the most effective or feasible options.</p> <p>Explain all versus a subset of anticipated signs and symptoms of the disease/condition.</p> <p>Disclose (or not) scientific uncertainty regarding risks and anticipated outcomes.</p> <p>Use authority (or not) in explaining the available medical evidence and what actions are anticipated to achieve optimal health outcomes.</p> <p>Restate a situation in a more favorable light (reframing).</p> <p>Tailor information to the patient.</p> <p>Use narratives (stories) to promote understanding or to elicit emotions.</p> <p>Use appropriate decision aids and visual aids (e.g., graphs, tables, pictographs).</p>	<p>Perceptions of information provided</p> <p>Patient knowledge</p> <p>Feeling informed</p> <p>Perceived severity and risks associated with the condition</p> <p>Attitudes, beliefs, feelings about options and outcomes</p> <p>Empowered to make a decision</p> <p>Empowered to cope with emotions</p> <p>Risk communication among family members</p>
Mobilizing patient strengths, resources, support [1, 4, 8, 9, 15]	<p>Encourage patient self-reflection.</p> <p>Point out specific patient strengths (praise, affirmation).</p> <p>Elicit how the patient dealt with other difficult situations or medical issues before and identify what strengths, skills, and support the patient drew upon.</p> <p>Help the patient define his/her current support network.</p> <p>Explore whether coping mechanisms have resulted in positive or negative outcomes.</p> <p>Encourage positive appraisal of the patient's situation (reframing, re-appraisal).</p> <p>Describe positive coping mechanisms that other patients may have used and why they were helpful (if the patient desires this information).</p>	<p>Empowered to cope with emotions</p> <p>Empowered to access resources</p> <p>Empowered to make decisions</p>
Engaging patient in decision making [1, 3, 4, 7, 10, 11, 15, 16, 18]	<p>Assess patient decision-making style; encourage participation, while respecting patient's preferred level of involvement.</p> <p>Determine who else in their life may be important to their decision making process and include them if the patient desires or encourage the patient to verbalize what they believe the other(s) would want them to do and why.</p> <p>List options and allow patient to overtly express pros and cons related to them.</p> <p>Explore patient's cognitive and emotional responses to options</p> <p>Assess patient's outcome expectations; help align expectations with the most likely outcomes or range of possible outcomes; provide anticipatory guidance.</p> <p>Explain the reasons why some patients tend to choose various different options.</p> <p>Recognize and acknowledge ethical challenges and/or uncertainties related to the decision.</p> <p>Help the patient clarify his/her values and underlying beliefs or emotions.</p> <p>Align options with patient's values and goals.</p>	<p>Perception of patient-provider relationship</p> <p>Perceptions of information provided</p> <p>Empowered to make decisions</p> <p>Attitudes or perceptions about options action plan and anticipated outcomes</p> <p>Adherence / self-management</p> <p>Quality health decisions</p>

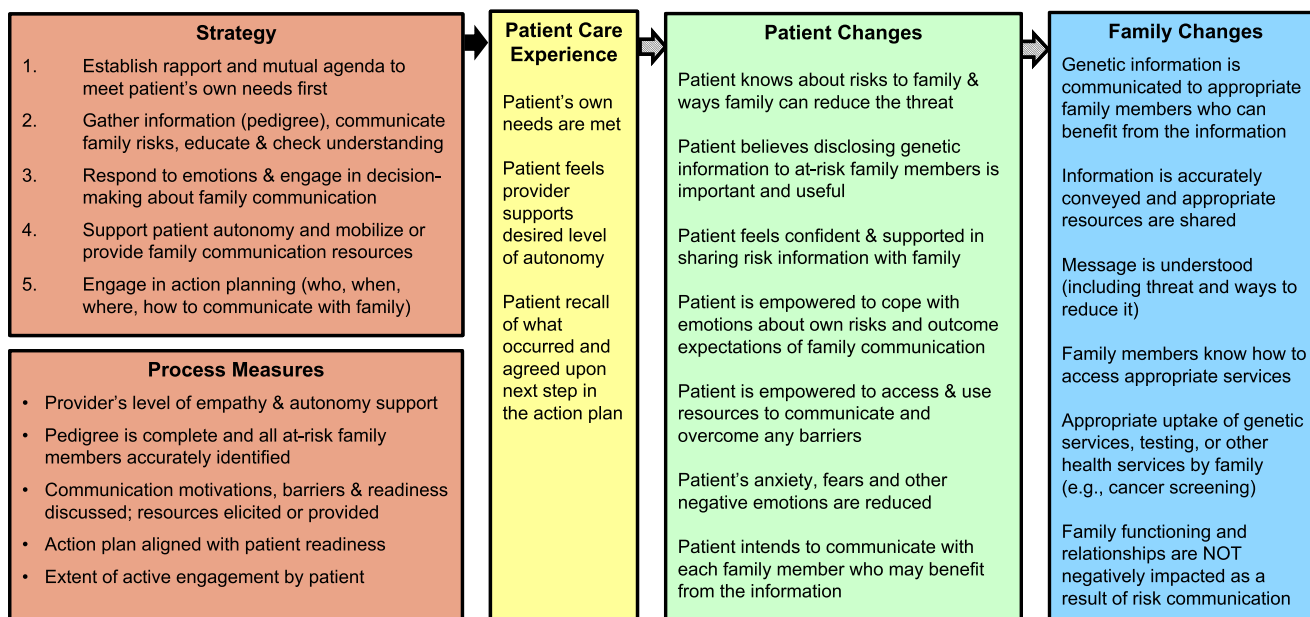
Table 1 (continued)

Communication skills categories ^a	Description of skills and processes	Hypothesized to influence patient experience, changes and health
Supporting patient autonomy [1, 9, 11, 16–18]	<p>Ask patients what they want to achieve and encourage exploration and questions.</p> <p>Evoke the patient's own reasons for wanting to take action.</p> <p>Elicit (or provide if patient desires) several options for achieving the patient's goal(s).</p> <p>Remind them they have choices & you are there to help them figure out what is best for them.</p> <p>Give patient time to consider choices and allow them time to provide input.</p> <p>Explore patient's ambivalence about taking action or committing to a decision; acknowledge the patient may not be ready; normalize ambivalence and decision making difficulty.</p> <p>Use autonomy-supportive phrases rather than controlling language (e.g., "here are some things that may help you" instead of "do this for me, or you must...").</p> <p>Get permission before providing advice.</p> <p>Affirm patient's competence and confidence.</p> <p>Refrain from judgment or evaluation.</p>	<p>Perception of patient-provider relationship</p> <p>Empowered to make decisions</p> <p>Empowered to access support</p> <p>Empowered to cope with emotions</p>
Action planning [15–18]	<p>Summarize what is most important to the patient and evoke their possible next steps.</p> <p>Assess patient's readiness to: implement their decision, take the next step toward their goal, or follow a medical recommendation.</p> <p>Help patient identify barriers and facilitators that may influence their ability to take action.</p> <p>Engage patient in solution finding to overcome barriers and elicit what would work for them.</p> <p>Support patient in developing a detailed plan for achieving their goal, including how and when they plan to complete the next step.</p> <p>Create contingency plans if needed (i.e., alternatives); assure patient you will help if things don't work according to plan.</p> <p>Help patient strengthen their commitment and identify ways to monitor their progress.</p>	<p>Empowered to make decisions</p> <p>Empowered to access support</p> <p>Adherence / self-management</p>
Skill-building [8, 10, 11, 15]	<p>Engage the patient in coping skills exercises or interventions.</p> <p>Help the patient identify and challenge negative self-talk.</p> <p>Teach problem-solving strategies/critical thinking skills.</p> <p>Model ways the patient can communicate and disclose information to others.</p> <p>Practice or role play relevant scenarios.</p> <p>Teach self-management skills.</p>	<p>Empowered to access resources</p> <p>Empowered to cope with emotions</p> <p>Coping and psychological outcomes</p> <p>Adherence / self-management</p> <p>Risk communication among family members</p>
Care coordination and provision of resources [19]	<p>Coordinate testing.</p> <p>Ensure appropriate testing is ordered.</p> <p>Determine insurance eligibility for testing or medical care.</p> <p>Help the patient navigate the health care system (e.g., provide referrals, schedule medical appointments, help them enroll in a clinical trial).</p> <p>Communicate directly with the patient's other healthcare providers (with patient's permission).</p> <p>Identify and provide informational materials (e.g., decision aids, handouts, brochures, patient letters, family letters).</p> <p>Help patients find appropriate services and resources.</p> <p>Provide contact information for support/advocacy groups</p> <p>Assist in arranging follow-up appointments.</p> <p>Medical documentation to ensure accuracy and completeness.</p> <p>Test results tracking, follow-up and disclosure.</p>	<p>Accurate diagnosis</p> <p>Empowered to cope with emotions</p> <p>Empowered to access resources</p> <p>Risk communication among family members</p> <p>Accessed appropriate care</p>

^a Communication skills can be combined to create a strategy for achieving patient and provider goals and positively influencing patient experiences, patient health, and/or family changes.

References

- [1] Veach, P. M., Bartels, D. M. & Leroy, B. S. (2007). Coming full circle: A reciprocal-engagement model of genetic counseling practice. *Journal of Genetic Counseling*, 16(6), 713–728. <http://www.ncbi.nlm.nih.gov/pubmed/17934802>.
- [2] Hoeger, M., Epstein, R. M., Winters, P. C., Fiscella, K., Duberstein, P. R., Gramling, R., Butow, P. N., Mohile, S. G., Kaesberg, P. R., Tang, W., Plumb, S., Waleczak, A., Back, A. L., Tancredi, D., Venuiti, A., Cipri, C., Escalera, G., Ferro, C., Gaudion, D., Hoh, B., Leatherwood, B., Lewis, L., Robinson, M., Sullivan, P. & Kravitz, R. L. (2013). Values and options in cancer care (VOICE): study design and rationale for a patient-centered communication and decision-making intervention for physicians, patients with advanced cancer, and their caregivers. *BMC Cancer*, 13, 188. <http://www.ncbi.nlm.nih.gov/pubmed/23570278>.
- [3] Uhlmann, W. R., Schutte, J. L. & Yashar, B. M. (2009). *A guide to genetic counseling*, 2nd (ed.). Hoboken: Wiley-Blackwell.
- [4] Veach, P. M., LeRoy, B. S. & Bartels, D. M. (2003). *Facilitating the genetic counseling process: A practice manual*. New York: Springer-Verlag.
- [5] Street, R. L., Makoul, G., Arora, N. K. & Epstein, R. M. (2009). How does communication heal? Pathways linking clinician-patient communication to health outcomes. *Patient Education and Counseling*, 74(3), 295–301. <http://www.ncbi.nlm.nih.gov/pubmed/19150199>.
- [6] Street, R. L. (2013). How clinician-patient communication contributes to health improvement: Modeling pathways from talk to outcome. *Patient Education and Counseling*, 92(3), 286–291. <http://www.ncbi.nlm.nih.gov/pubmed/23746769>.
- [7] Street, R. L. & Epstein, R. M. (2007). *Patient-Centered Communication in Cancer Care: Promoting Healing & Reducing Suffering*. Bethesda: NIH Publication. http://appliedresearch.cancer.gov/areas/pcc/communication/pcc_monograph.pdf.
- [8] Ha Dinh, T. T., Bonner, A., Clark, R., Ramsbotham, J. & Hines, S. (2016). The effectiveness of the teach-back method on adherence and self-management in health education for people with chronic disease: A systematic review. *JBHI Database of Systematic Reviews and Implementation Reports*, 14(1), 210–247. <https://www.ncbi.nlm.nih.gov/pubmed/26878928>.
- [9] Accreditation Counsel for Genetic Counseling. (2015). Practice-Based Competencies for Genetic Counselors Accreditation Council for Genetic Counseling. http://www.gceducation.org/Documents/ACGC_Core_Competencies_Brochure_15_Web.pdf.
- [10] Veach, P. M., LeRoy, B. & Bartels, D. M. (2010). *Genetic counseling practice: Advanced concepts and skills*. Wiley-Blackwell.
- [11] Weil, J. (2000). Psychosocial genetic counseling, 1st (ed.). New York: Oxford University Press.
- [12] Kirklin, D. (2007). Framing, truth telling and the problem with non-directive counselling. *Journal of Medical Ethics*, 33(1), 58–62. <http://www.ncbi.nlm.nih.gov/pubmed/17209114>.
- [13] Kreuter, M. W., Green, M. C., Cappella, J. N., Slater, M. D., Wise, M. E., Storey, D., Clark, E. M., O'Keefe, D. J., Erwin, D. O., Holmes, K., Hinyard, L. J., Houston, T. & Woolley, S. (2007). Narrative communication in cancer prevention and control: A framework to guide research and application. *Annals of Behavioral Medicine*, 33(3), 221–235. <http://www.ncbi.nlm.nih.gov/pubmed/17600449>.
- [14] McCaffery, K. J., Holmes-Rovner, M., Smith, S. K., Rovner, D., Nutbeam, D., Clayman, M. L., Kelly-Blake, K., Wolf, M. S. & Sheridan, S. L. (2013). Addressing health literacy in patient decision aids. *BMC Medical Informatics and Decision Making*, 13(Suppl 2), S10. <http://www.ncbi.nlm.nih.gov/pubmed/24624970>.
- [15] Wang, C., Gonzalez, R. & Merajver, S. D. (2004). Assessment of genetic testing and related counseling services: Current research and future directions. *Social Science & Medicine*, 58(7), 1427–1442. <http://www.ncbi.nlm.nih.gov/pubmed/14759687>.
- [16] DiClemente, R. J., Crosby, R. A. & Kegler, M. (2009). *Emerging theories in health promotion practice and research*, 2nd (ed.). San Francisco: Jossey-Bass.
- [17] Miller, W. R. & Rollnick, S. (2013). *Motivational interviewing: helping people change*, 3rd (ed.). New York: The Guilford Press.
- [18] Murray, A., Hall, A. M., Williams, G. C., McDonough, S. M., Ntoumanis, N., Taylor, I. M., Jackson, B., Matthews, J., Hurley, D. A. & Lonsdale, C. (2015). Effect of a self-determination theory-based communication skills training program on physiotherapists' psychological support for their patients with chronic low back pain: A randomized controlled trial. *Archives of Physical Medicine and Rehabilitation*, 96(5), 809–816. <https://www.ncbi.nlm.nih.gov/pubmed/25433220>.
- [19] House, J. S. (1981). *Work stress and social support*. Addison-Wesley Pub Co.



Context: Gender of patient and family members, family roles and dynamics, social and physical distance from relatives, and nature of the genetic condition

Fig. 2 FOCUS on genetic counseling to improve family communication and appropriate service utilization

can ultimately reduce morbidity and mortality (George et al. 2015).

The second example uses the step-by-step guide to illustrate how FOCUS can be applied in designing research studies and is summarized in Fig. 3. To complete the first step, we selected our primary goal and used Tables 4 and 5 to identify indicators or outcomes related to the goal. The primary goal was “to promote quality health

decisions”; and the primary indicators/outcomes, selected to reflect the extent to which this goal is achieved, include: 1) patient makes an informed decision; 2) the decision is based upon best available evidence; 3) the decision aligns with the patient’s values and goals; and 4) the decision can be put into action.

In the second step we created a strategy for the intervention by listing communication skills from Table 1 that

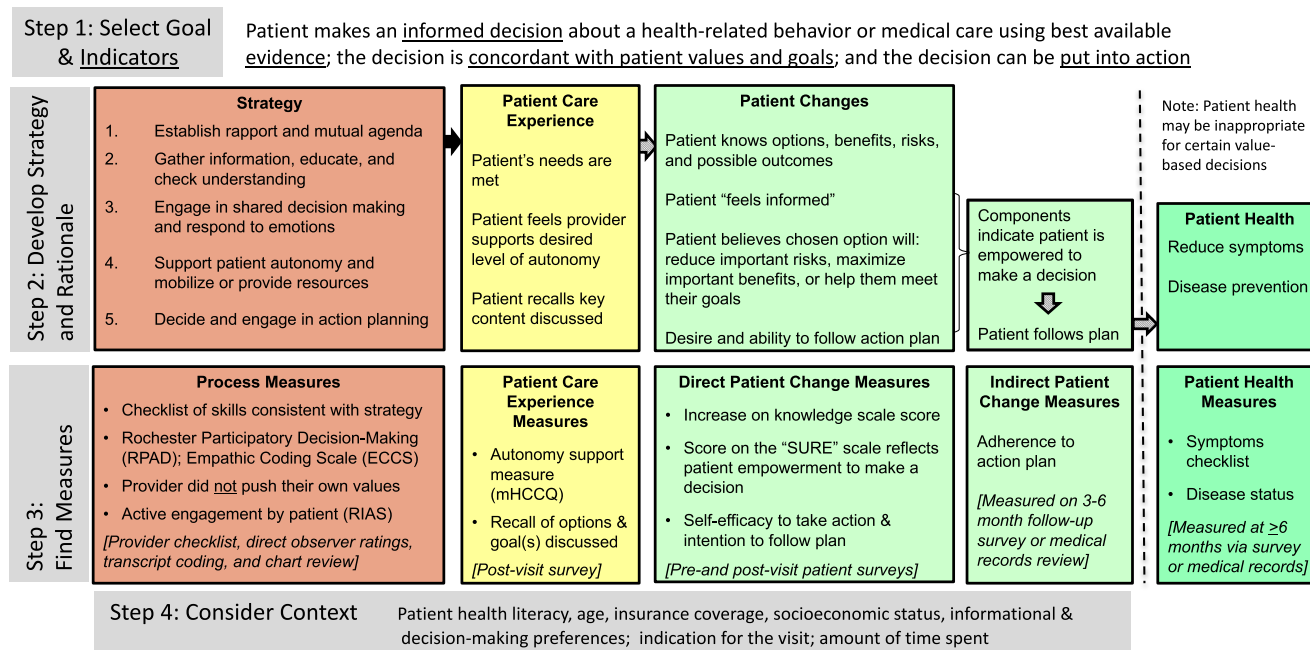


Fig. 3 FOCUS on genetic counseling to promote quality health decisions

Table 2 Communication process measures from the Framework for Outcomes in Clinical Communication Services (FOCUS)

Categories of communication process measures ^a	Description	Example Measures ^b
Use of communication skills	<p>Fidelity to a specific counseling or educational technique, approach, or strategy (i.e., extent to which skills were implemented as intended).</p> <p>List of skills and processes that are checked if completed.</p> <p>Samples of processes that could be on a checklist include:</p> <ol style="list-style-type: none"> 1) Open-ended questions used to elicit patient needs, perspectives, concerns, values, or social context 3) Three- or four-generation family history was completed 4) Patient risk perceptions were elicited 5) Personalized risk information was given (visuals used) 6) Beliefs/emotions about health condition were discussed 7) All reasonable options were considered 8) Patient's attitudes/feelings about options were elicited 9) Anticipatory guidance was provided 11) Discussed implications and risks for family members 12) Provider used active listening skills; few interruptions 13) Provider's statements conveyed empathy versus unsolicited advice and judgmental comments 14) Patient's goals or outcome expectations were elicited 15) "Teach back" used correctly to check understanding 17) Patient's readiness to take action was determined 18) Barriers to the decision or action were identified and ways to overcome them identified 19) Pain was assessed (if applicable) 	<p>Rochester Participatory Decision-Making Scale (RPAD) (Shields 2005) measures patient-physician collaborative decision-making (observer coded) [1]</p> <p>Informed decision making coding (Braddock, 1999) measures degree to which physician recommendations satisfy informed decision making (observer coded) [2]</p> <p>Empathic Communication Coding System (ECCS) (Bylund and Makoul 2002) (observer coding) [3]</p> <p>Roter Interaction Analysis System (RIAS) (Roter and Larson 2002) identifies information seeking and information-giving utterances (observer coding) [4]</p> <p>Physician-Patient Verbal Coding Scheme (Gordon, Street, Sharf, and Souček, 2006) measures physician information giving across several categories (observer coding) [5]</p> <p>The 5-As model (Glasgow, Emont, and Miller 2005) measures 4 steps to physician facilitation of patient health behavior change: ask, advise, assess, assist, and arrange follow-up. [6]</p> <p>Empowering Health Counseling scale (Kettunen 2006) completed by patient & provider [7]</p>
Appropriateness of testing and accuracy of results interpretation [8]	<p>Reliable and clinically valid testing was offered (if appropriate).</p> <p>Test results were interpreted accurately by the provider, taking into consideration the medical and family history.</p>	<p>Proportion of cancer patients who have a variant of uncertain significance who are told their family history should determine cancer risk screening and management options (and the test result does not change their risks or management options).</p> <p>Proportion of patients with a variant of uncertain significance result who are inappropriately informed that this result means they are at increased risk for disease</p> <p>Proportion of prenatal patients who are told that results of noninvasive prenatal screening should be confirmed with amnio or CVS.</p>
Appropriateness of informational content	<p>Information provided was up to date, accurate, and culturally appropriate. Information was tailored to the patient's health literacy and education levels as well as the patient's needs and desired amount of detail.</p>	<p>Experts can evaluate information accuracy.</p> <p>Compare patient reported preferences for information to actual information that was provided:</p> <p>Information Styles Questionnaire (Cassileth Zapkis 1980) [9];</p> <p>Information Preference Scale (Blanchard et al. 1988) [10];</p> <p>Willingness to discuss psychosocial and physical aspects of health (Street et al. 1995) [11];</p> <p>Preferences for discussing prognostic information (Hagerty 2004) [12].</p>
Patient involvement (e.g., reciprocity of communication and content of patient responses) [13]	<p>Extent to which the patient actively communicated as evidenced by how often the patient talked, asked questions, offered opinions or beliefs, stated preferences, introduced topics for discussion, expressed emotions, and disclosed concerns.</p> <p>Certain content of patient utterances may be predictive of key changes or outcomes.</p>	<p>Analyzing Patient Participation in Medical Encounters (Street and Millay 2001) observer coding [14]</p> <p>Proportion of patients who offer their opinions or state their preferences and values.</p> <p>Motivational interviewing commitment language by the patient (especially at the end of the session) is strongly correlated with behavior change.[15]</p>

Table 2 (continued)

Categories of communication process measures ^a	Description	Example Measures ^b
Care was coordinated & resources or follow-up provided	Whether and how the provider helped the patient navigate the healthcare system or share information with family members and what support resources, referrals, or written information were provided to patients. Provider followed up as planned in a timely fashion.	AHRQ Care of Coordination Measure Atlas. [16] Proportion of individuals with a new diagnosis who are given information about support or advocacy groups. Proportion of individuals sent a written summary of visit. Timeliness of follow-up task completion by the provider.
Followed professional guidelines and ethical practices [16–18]	Appropriate options and medical management recommendations were discussed in line with professional practice guidelines. Provider behaved ethically (e.g., was honest with the patient; did not push their own values on the patient).	Comprehensive family medical history completed according to standardized nomenclature. [20] Checklist documenting that important points identified in an evidence-based practice guideline were completed. Proportion of patients who meet certain criteria and receive appropriate evidence-based care.
Accurate diagnosis	An accurate diagnosis is necessary for the patient to access appropriate care and make quality health decisions. An inaccurate diagnosis can lead to more costly and inappropriate medical care, which can negatively impact patient health outcomes.	Proportion of patients seen by a genetic counselor who received an accurate diagnosis.

^a Communication process measures, in general, reflect the healthcare services provided to a patient (including what occurred during the communication process and whether strategies were implemented as originally prescribed or intended). Several process measures are expected to influence patient care experiences and may contribute to other changes

^b Types of process measures include: checklists, chart reviews, observer coding documenting use of communication strategies, and adherence to professional guidelines. Measures can be based on coding by a third party observer during or after the visit (if it is audio recorded) or through medical record checklists completed by providers

References

- [1] Shields, C. G., Franks, P., Fiscella, K., Meldrum, S., & Epstein, R. M. Rochester Participatory Decision-Making Scale (RPAD): reliability and validity. *Annals of Family Medicine*, 3(5), 436–442. <http://www.ncbi.nlm.nih.gov/pubmed/16189060>.
- [2] Braddock, C. H., Edwards, K. A., Hasenberg, N. M., Laidley, T. L., & Levinson, W. Informed decision making in outpatient practice: time to get back to basics. *JAMA*, 282(24), 2313–2320. <http://www.ncbi.nlm.nih.gov/pubmed/10612318>.
- [3] Bylund, C. L., & Makoul, G. (2002). Empathic communication and gender in the physician-patient encounter. *Patient Education and Counseling*, 48(3), 207–216. <http://www.ncbi.nlm.nih.gov/pubmed/12477605>.
- [4] Roter, D., & Larson, S. (2002). The Roter interaction analysis system (RIAS): Utility and flexibility for analysis of medical interactions. *Patient Education and Counseling*, 46(4), 243–251. <http://www.ncbi.nlm.nih.gov/pubmed/11932123>.
- [5] Gordon, H. S., Street, R. L., Sharf, B. F., & Soucek, J. (2006). Racial differences in doctors' information-giving and patients' participation. *Cancer*, 107(6), 1313–1320. <http://www.ncbi.nlm.nih.gov/pubmed/16909424>.
- [6] Glasgow, R. E., Emont, S., & Miller, D. C. (2006). Assessing delivery of the five 'as' for patient-centered counseling. Health Promotion International, 21(3), 245–255. <http://www.ncbi.nlm.nih.gov/pubmed/16751630>.
- [7] Kettunen, T., Liimatainen, L., Villberg, J., & Perko, U. (2006). Developing empowering health counseling measurement. Preliminary results. *Patient Education and Counseling*, 64(1–3), 159–166. <http://www.ncbi.nlm.nih.gov/pubmed/16469473>.
- [8] Payne, K., Nicholls, S. G., McAllister, M., MacLeod, R., Ellis, I., Donnai, D., & Davies, L. M. (2007). Outcome measures for clinical genetics services: A comparison of genetics healthcare professionals and patients' views. *Health Policy*, 84(1), 112–122. <http://www.ncbi.nlm.nih.gov/pubmed/17485130>.
- [9] Cassileth, B. R., Zupkis, R. V., Sutton-Smith, K., & March, V. (1980). Information and participation preferences among cancer patients. *Annals of Internal Medicine*, 92(6), 832–836. <http://www.ncbi.nlm.nih.gov/pubmed/7387025>.
- [10] Blanchard, C. G., Labrecque, M. S., Ruckdeschel, J. C., & Blanchard, E. B. (1988). Information and decision-making preferences of hospitalized adult cancer patients. *Social Science & Medicine*, 27(11), 1139–1145. <http://www.ncbi.nlm.nih.gov/pubmed/3206248>.

- [11] Street, R. L., Cauthen, D., Buchwald, E. & Wiprud, R. Patients' predispositions to discuss health issues affecting quality of life. *Family Medicine*, 27(10), 663–670. <http://www.ncbi.nlm.nih.gov/pubmed/8582560>.
- [12] Haggerty, R. G., Butow, P. N., Ellis, P. A., Lobb, E. A., Pendlebury, S., Leigh, N., Goldstein, D., Lo, S. K. & Tattersall, M. H. N. (2004). Cancer patient preferences for communication of prognosis in the metastatic setting. *Journal of Clinical Oncology*, 22(9), 1721–1730. <http://www.ncbi.nlm.nih.gov/pubmed/15117995>.
- [13] Street, R. L. & Epstein, R. M. (2007). *Patient-Centered Communication in Cancer Care: Promoting Healing & Reducing Suffering*. Bethesda: NIH Publication. http://appliedresearch.cancer.gov/areas/pec/communication/pec_monograph.pdf.
- [14] Street, R. L. & Millay, B. (2001). Analyzing patient participation in medical encounters. *Health Communication*, 13(1), 61–73. <http://www.ncbi.nlm.nih.gov/pubmed/11370924>.
- [15] Miller, W. R., Moyers, T. B., Ernst, D. & Amrhein, P. (2008). Manual for the Motivational Interviewing Skill Code (MISC). [Online] Available: <http://casaa.unm.edu/download/misc.pdf>.
- [16] McDonald, K. M., Schultz, E., Albin, L., Pineda, N., Lonnert, J., Sundaram, V., Brunstrom, J., Malcolim, E., Rohn, L. & Davies, S. (2014). Care Coordination Measures Atlas Update. [Online] Available: <http://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/atlas2014/index.html>.
- [17] Veach, P. M., Bartels, D. M. & Leroy, B. S. (2007). Coming full circle: A reciprocal-engagement model of genetic counseling practice. *Journal of Genetic Counseling*, 16(6), 713–728. <http://www.ncbi.nlm.nih.gov/pubmed/17934802>.
- [18] Silvey, K., Stock, J., Hasegawa, L. E. & Au, S. M. (2009). Outcomes of genetics services: Creating an inclusive definition and outcomes menu for public health and clinical genetics services. *American Journal of Medical Genetics. Part C, Seminars in Medical Genetics*, 151C(3), 207–213. <http://www.ncbi.nlm.nih.gov/pubmed/19621453>.
- [19] Accreditation Counsel for Genetic Counseling. (2015). Practice-Based Competencies for Genetic Counselors Accreditation Council for Genetic Counseling. http://www.gceducation.org/Documents/ACGC_Core_Competences_Brochure_15_Web.pdf.
- [20] Bennett, R. L., Steinhaus, K. A., Ulrich, S. B., O'Sullivan, C. K., Resta, R. G., Lochner-Doyle, D., Markel, D. S., Vincent, V. & Hamanishi, J. (1995). Recommendations for standardized human pedigree nomenclature. Pedigree standardization task force of the National Society of genetic counselors. *American Journal of Human Genetics*, 56(3), 745–752. <http://www.ncbi.nlm.nih.gov/pubmed/7887430>.

together would likely help achieve the primary goal (either directly or indirectly). As part of this step we also began developing a rationale for choosing these specific skills based on logic, empirical research findings and other frameworks or theories in order to explain why and how combining these communication skills in a specific way would be expected to improve the select indicators and outcomes. The skills we combined to create our strategy included: 1) establish rapport and a mutual agenda; 2) gather information, educate, and check understanding; 3) respond to emotions and engage patient in decision making; 4) support patient autonomy and mobilize or provide resources; 5) decide and engage in action planning. These skills are each comprised of several processes, including several from the Ottawa Decision-making Framework and those that were identified as critical to shared decision making in a review article (Légaré et al. 2006; Makoul and Clayman 2006). We then mapped out direct and indirect pathways through which our strategy may influence the patient care experience as well as cognitive, emotional or behavioral changes among the patient.

To complete step 3 we identified measures to ensure that the strategy was implemented with fidelity (process measures). Measures were also selected for inclusion on patient surveys in order to evaluate the patient care experience and measure direct patient changes (Fig. 3). Additionally, indirect patient changes and patient health measures were considered for inclusion on a follow-up survey and medical record review 3–6 months later. Finally, to complete step 4 we considered some of the general contextual variables that might modify or confound decision making studies and are therefore important to measure so that they can be used as covariates in the analysis. Although we elected to create a somewhat general decision-making example, literature on a specific type of decision and/or specific setting in which it occurs may identify other important contextual variables.

Discussion

The unique contribution of FOCUS is that it consolidates prior models, published literature, and professional experience into a more comprehensive framework that defines terms and helps postulate general mechanisms by which clinical communication services (including genetic counseling, health coaching and care-coordination) may influence patients and families either directly or indirectly and result in improved care experiences and health outcomes. FOCUS is purposefully agnostic to any specific outcome or context in order to maintain flexibility and applicability to a variety of clinical settings in which GC

Table 3 Patient care experience from the Framework for Outcomes of Clinical Communication Services (FOCUS)

Patient care experience categories ^a	Description	Example measures	Hypothesized to influence other outcomes
^b Satisfaction with support personnel and logistics of care	Appointment and registration personnel were courteous, respectful, and helpful. Facilities/amenities were perceived favorably (comfortable, clean, etc). Wait times to be seen in clinic were reasonable to the patient.	Proportion of patients who report the amenities were clean. Proportion of patients who report that the wait time to be seen for an appointment was not too long.	Patient satisfaction with these and other aspects of care is one indicator of patient-centered care and therefore considered quality care.
^b Meeting patient needs & expectations [1]	Patient's perception that expectations are met, needs are addressed, and provider spent enough time with them.	Proportion of persons who report that their health care providers always spent enough time with them. Several of these concepts are captured as part of Genetic Counseling Satisfaction Scales [2, 3]	Meeting patient needs may influence patient empowerment and adherence/self-management.
Perceptions of provider communication	Patient reports their provider communicated well. Patient recalls discussion of certain topics such as: available options (including risks and benefits) or who in the family may also be at risk for the genetic condition. Patient recalls provider asked about patient's preferences, values and opinions. Patient feels that the provider involved them in the interaction. Patient recalls provider followed up with patient as planned (e.g., called out test results, verified insurance, communicated with other providers). Patient's perceptions of degree to which clinical providers worked together.	Proportion of persons who report their health care provider always asked them to describe how they will follow the instructions. Proportion of persons who report that their health care providers always involved them in decisions about their health care as much as they wanted, Perceived involvement in Care Scale (patient involvement subscale) [4].	Improved recall is expected to increase how informed patients feel and their perceptions of both the information received and the patient-provider relationship. If patients don't recall what occurred, it may hinder their ability to make quality health decisions or negatively impact self-efficacy to take action. Patients' perceptions that staff worked together for their health care is strongly correlated with overall evaluations of care.
^b Perceptions of patient-provider relationship [2-4]	Feeling understood and respected. Perceptions of trust and confidence in the provider. Perceptions of emotional support from the provider. Perceptions of autonomy support from provider.	Captured as part of the Genetic Counseling Satisfaction Scale [2, 3] Patient Reactions Assessment subscale "affective communication" measures patient perceptions of physician's respect and concern for the patient [8]. Proportion of persons who report that their health care providers always listened carefully to them. Health Care Climate – patient feels provider supports autonomy [9]. Patient Reactions Assessment (PRA) subscale, "information" -- measures patient's perception of physicians' information-giving [8].	Patients who positively perceive their relationship with their provider are more likely to make quality health decisions and adhere to health recommendations.
^b Perceptions of information	Although "experts" can evaluate whether the information is accurate, the patient is perhaps the best person to evaluate information clarity.		Perceptions that information is appropriate and relevant indicate patient-centered care.

Table 3 (continued)

Patient care experience categories ^a	Description	Example measures	Hypothesized to influence other outcomes
	amount, appropriateness, and relevance for themselves.	Proportion of persons who report their health care provider always gave them easy to understand instructions [or information] about their health condition.	Positive perceptions about information may improve how informed patients feel, quality health decision, adherence/self-management, and communication with family.

^a Patient experience measures reflect patient-centeredness which is one of the six quality health domains

^b Although more specific, these categories may encompass some aspects of what people have referred to as “patient satisfaction”

References

- [1] Wang, C., Gonzalez, R. & Merajver, S. D. S. D. (2004). Assessment of genetic testing and related counseling services: Current research and future directions. *Social Science & Medicine*, 58(7), 1427–1442. <http://www.ncbi.nlm.nih.gov/pubmed/14759687>.
- [2] DeMarco, T. A., Peshkin, B. N., Mars, B. D. & Tercyak, K. P. (2004). Patient satisfaction with cancer genetic counseling: A psychometric analysis of the genetic counseling satisfaction scale. *Journal of Genetic Counseling*, 13(4), 293–304. <http://www.ncbi.nlm.nih.gov/pubmed/19736695>.
- [3] Shiloh, S., Avdor, O. & Goodman, R. M. (1990). Satisfaction with genetic counseling: Dimensions and measurement. *American Journal of Medical Genetics*, 37(4), 522–529. <http://onlinelibrary.wiley.com/doi/10.1002/ajmg.1320370419abstract;jsessionid=0D869F79210E85EC865859AE4B3F00A8.f03402>.
- [4] Lerman, C. E., Brody, D. S., Caputo, G. C., Smith, D. G., Lazaro, C. G. & Wolfson, H. G. Patients' Perceived Involvement in Care Scale: relationship to attitudes about illness and medical care. *Journal of General Internal Medicine*, 5(1), 29–33. <http://www.ncbi.nlm.nih.gov/pubmed/2299426>.
- [5] Street, R. L., Makoul, G., Arora, N. K. & Epstein, R. M. (2009). How does communication heal? Pathways linking clinician-patient communication to health outcomes. *Patient Education and Counseling*, 74(3), 295–301. <http://www.ncbi.nlm.nih.gov/pubmed/19150199>.
- [6] Street, R. L. (2013). How clinician-patient communication contributes to health improvement: Modeling pathways from talk to outcome. *Patient Education and Counseling*, 92(3), 286–291. <http://www.ncbi.nlm.nih.gov/pubmed/23746769>.
- [7] Street, R. L. & Epstein, R. M. (2007). *Patient-Centered Communication in Cancer Care: Promoting Healing & Reducing Suffering*. Bethesda: NIH Publication. http://appliedresearch.cancer.gov/areas/pcc/communication/pcc_monograph.pdf
- [8] Galassi, J. P., Schanberg, R. & Ware, W. B. (1992). The patient reactions assessment: A brief measure of the quality of the patient-provider medical relationship. *Psychological Assessment*, 4(3), 346–351. <http://doi.apa.org/getdoi.cfm?doi=10.1037/1040-3590.4.3.346>
- [9] Zohar, D., Livne, Y., Tenne-Gazit, O., Admi, H. & Donchin, Y. (2007). Healthcare climate: A framework for measuring and improving patient safety. *Critical Care Medicine*, 35(5), 1312–1317. <http://www.ncbi.nlm.nih.gov/pubmed/17414090>.

Table 4 Patient changes from the Framework for Outcomes in Clinical Communication Services (FOCUS)

Patient change categories ^a	Description	Example measures	Hypothesized relationships with other patient changes, patient experiences, or health outcomes
Knowledge	Objective knowledge about health topics (e.g.): 1) the condition for which the person is at risk; 2) level of risks and options for oneself or one's family members; 3) benefits and limitations of the various options; 4) treatment or action plan and procedural knowledge (i.e., how to take action).	Proportion of individuals who can accurately recall information about the benefits and limitations of their genetic testing options. Proportion of patients who can accurately recall which relatives are at risk for a genetic condition. Knowledge scales specific to: HBOC [1]–[3] Lynch syndrome [4] Thalassaemia [5] Fragile X [6] Maternal Serum Screening [7]	Knowledge is often necessary but may be insufficient for other patient changes (e.g., access to care, quality health decision, adherence, and communication with family members.)
^b Feeling informed [8]–[16]	Belief that one has sufficient information about the personal and family implications of the health condition/risks as well as information about available options for managing, clarifying, or dealing with the condition/risks.	Proportion of individuals who feel like they have enough information about a medical condition. Cognitive Control- Genetic Counseling Outcomes Scale [10]. Decisional Conflict Scale: Inverse of the “feeling uninformed” subscale [17, 18]	Feeling informed is likely necessary but may be insufficient to facilitate other patient changes (e.g., access to care, quality health decision, adherence, and communication with family members.)
Perceptions of health risks	Genetic risk perceptions - patient beliefs about how likely it is that they have a genetic predisposition. Perceived disease susceptibility - perception about how likely they are to develop symptoms associated with a condition. Perceived severity - perception of ‘how bad’ the condition seems. Overall appraisal of health risks, conditions, or situations as positive or negative. Levels of uncertainty about the condition.	Patient's perception about their risk for cancer (can be absolute risk or relative to a reference group). Susceptibility and severity scales have been created based on the Health Belief Model and Extended Parallel Process Model [19, 20]. Primary and secondary stress appraisals can be measured based on Lazarus and Folkman's Transactional Model of Stress and Coping. Transactional theory and research on emotions and coping [21]. Uncertainty in illness scale [22, 23].	Together perceived risks, susceptibility and severity create a perception of threat and this can motivate or hinder access to care, adherence or self-management. Individuals who can reframe a situation and recognize or focus on positive aspects of a health risk or condition may experience fewer negative emotions and better mental health. Strategies to manage uncertainty can improve symptoms and may decrease negative emotions.
Beliefs, motivations, & emotions about: 1) a decision, 2) behavior, or 3) anticipated outcomes	Attitudes, emotions, motivation, and perceived barriers related to the behavior or decision. Anticipated outcomes (i.e., behavioral expectancies, perceived benefits, response efficacy, anticipated emotions). Beliefs about what healthcare providers and significant others want the patient to do. Perceived importance of the decision or behavior. Confidence in one's ability to take action and overcome barriers to do so (i.e., self-efficacy).	Several example scale measures to assess changes in this category are available based on commonly used health models like the Health Belief Model; Theory of Planned Behavior; Transtheoretical model (decisional balance); Self-determination theory; Extended Parallel Process Model; Social Cognitive Theory [19, 20, 24–26].	Low perceived barriers as well as positive attitudes and emotions about both the behavior or decision and the expected outcomes may lead to a quality health decision and improve adherence/self-management. Intrinsic motivation and high perceived benefits increase the likelihood of long term adherence/self-management. If significant others and/or trusted healthcare providers are supportive of an action it may be more likely that the patient will take that action. Self-efficacy is often a very strong correlate of behavior. Decisional empowerment contributes to whether a quality health decision is made and adhered to.
^c Empowered to make quality decisions [8, 14–16, 27, 28]	Feeling supported, confident in and control over one's ability to make decisions that: 1) will maximize health and well-being and; 2) are consistent with the	Decisional Conflict Scale (DCS) measures uncertainty in decision making (opposite of empowered to make a decision). [17, 18]	

Table 4 (continued)

Patient change categories ^a	Description	Example measures	Hypothesized relationships with other patient changes, patient experiences, or health outcomes
	values and interests of oneself and perhaps one's family.	SURE scale measures certainty in decision making, perception of understanding of risks and benefits, clarity of which risks/benefits matter, perceived level of support/advice [29]. Decisional regulation sub-scale of the Genetic Counseling Outcomes Scale [10]. Decisional control from perceived personal control scale [15]. Self-regulation and competence scales based on Self Determination Theory [30]. Proportion of patients who are clear about the role their values may play in making a decision.	
^d Empowered to access resources and/or engage in self-management [8, 10, 14, 15, 27, 28, 30]	Feeling supported, confident in, and control over one's ability to effectively access and use medical and social support resources and engage in self-management.	Behavioral control subscales from either the perceived personal control [15] or GC outcomes scale [10]. Illness management self-efficacy scales: Self-Efficacy for Managing Chronic Disease 6-Item Scale [32] Self-efficacy and Quality of Life among People with Bipolar Disorder [33]. Perceived competence scales based on Self Determination Theory [30]. PROMIS measures: Emotional support, informational support, and instrumental support – assesses availability of information, and availability of assistance with tasks [34–35]. PROMIS measures: Self-efficacy for managing chronic condition [37].	This is expected to improve adherence, self-management, and effective coping.
^e Empowered to cope with emotions and uncertainty [8, 10, 14, 27, 28] Behavioral or decisional intention [38, 39]	Feeling supported, confident in and control over one's ability to cope by effectively managing emotions & dealing with uncertainty. Intention, desire, willingness to follow through with a decision or a particular action plan (e.g., proceed with testing).	Emotional regulation subscale in GC outcomes scale [10]. Emotional self-efficacy scale [38]. Behavioral intention measures using 5 or 7-point Likert scale [41].	This is expected to improve effective coping and reduce negative emotions. Although intentions and desires do not always lead to action, those who lack intention or are ambivalent are extremely unlikely to follow-through.
Quality health decision [11–13]	Informed decision about a health behavior or medical care is made based on best available evidence; the decision is concordant with patient values & goals; and the decision can be implemented.	Proportion of <i>BRCA</i> mutation carriers who elect to have a prophylactic oophorectomy, believe they are ready to do so, and feel like potential benefits outweigh potential harms. Proportion of individuals whose decisions match their reported values. Proportion of individuals who were able to act on their decision. Multidimensional Model of Informed Choice [42].	Quality health decisions can increase survival, reduce symptoms, and contribute to other health outcomes. A person can make a quality health decision, but still regret that decision later. Regardless, decisional regret can negatively impact health.

Table 4 (continued)

Patient change categories ^a	Description	Example measures	Hypothesized relationships with other patient changes, patient experiences, or health outcomes
Accessed appropriate care [11, 13, 30]	Patient receives appropriate follow-up care and/or testing. Patient receives services necessary to make appropriate transitions (e.g., adult health care, employment, long-term medical care).	Decision regret scale [43]. Proportion of children with developmental delays who receive appropriate therapies as the result of a genetics visit or accurate diagnosis.	Appropriate care can increase survival, reduce symptoms, or improve quality of life.
Adherence and self-management [11–13]	The patient follows through with health recommendations, action plan, or decisions, taking ownership of and being proactive about their care.	Proportion of patients with PKU who maintain phenylalanine levels within the medically accepted range. Self-care Behavior Inventory (McLaughlin 1985) [44]. Genetic Counselor involvement has been associated with increased adherence to provider recommendations [45].	Adherence and self-management can contribute to improvements in survival and other health outcomes.
Activated support resources [46]	Patient accesses or receives desired levels of social support, emotional support, or additional information related to the health issue/condition.	Of those individuals who desire more instrumental, emotional or informational support, the proportion who report accessing it as a result of their new diagnosis or health care received.	Patients who activate support resources may have improved mental and social health.
Reduction in negative emotions	Patient reduces negative emotions that are related to the health threat or diagnosis (e.g., anxiety, distress, anger, stigma, guilt, shame, worry, feeling overwhelmed).	Impact of events scale (measures distress related to a certain event or threat) [47]. Multidimensional Impact of Cancer Risk Assessment (MICRA) measures distress, uncertainty, and positive experience (the latter would fit within coping/adaptation). [48]. Psychosocial Illness Impact (negative item bank) PROMIS.	Reduction in these negative emotions can improve mental health.
Effective coping and adaptation [11–13, 46]	Patient uses coping mechanisms that are associated with better patient health outcomes. Over time a patient may even find a sense of purpose to the situation and/or they may experience personal growth or meaning from the health condition or threat.	Increase in the proportion of patients who use coping strategies that are helpful to them or promote positive health outcomes. Brief COPE [50]. Ways of coping scale [51]. Psychological Adaptation Scale (PAS)—measures extent to which condition has helped a patient grow or find meaning [52]. Psychosocial Illness Impact (positive item bank) PROMIS [53].	Effective coping and finding meaning in the situation contribute to a positive sense of well-being.
Reduction in use of unnecessary or more costly services	Patient does not seek care that is unnecessary	Proportion of individuals who have a known mutation in the family who undergo single site testing rather than full gene sequencing. [As prices of testing go down though, this will not result in much cost savings.]	Needs for emergency medical services are minimized when patients adhere to treatment plans. Correct diagnoses and accurate knowledge may reduce unnecessary health services.

Table 4 (continued)

Patient change categories ^a	Description	Example measures	Hypothesized relationships with other patient changes, patient experiences, or health outcomes
<p>Reduction in number of ER visits among patients with metabolic conditions.</p> <p>Reduction in unnecessary medical procedures among individuals found to be at low risk for disease based on genetic testing and/or family history assessment.</p>	<p>Reduction in number of ER visits among patients with metabolic conditions.</p> <p>Reduction in unnecessary medical procedures among individuals found to be at low risk for disease based on genetic testing and/or family history assessment.</p> <p>^a Patient changes are factors that change as a direct or indirect result of health services received. These are expected to influence patient health outcomes and/or family changes.</p> <p>^b This encompasses the concept of “understanding” from Pithara [8] and McAllister’s concept of “cognitive control” [27]. This term also encompasses aspects of “perceived personal control” [15]. Lastly, it is also the inverse of feeling uninformed, which is a component of “decisional conflict” [16].</p> <p>^c Inclusive of Pithara’s concept of “informed and shared decision making” [8] as well as McAllister’s concept of “decisional regulation” [27]. This term also encompasses aspects of perceived personal control [15] and decisional self-efficacy [28]. Finally, this construct is the inverse of several components of “decisional conflict” [16].</p> <p>^d Inclusive of Pithara’s concept of “enablement” [8] and McAllister’s concept “behavioral control” [27]. This term also encompasses aspects of “perceived personal control” [15] and “behavioral self-efficacy” [28].</p> <p>^e Inclusive of Pithara’s concept “reassurance” [8] and McAllister’s concept “emotional regulation” [27]. It is also similar to “emotional self-efficacy” [38].</p>		

References

- [1] Ondrusek, N., Warner, E. & Goel, V. (1999). Development of a knowledge scale about breast cancer and heredity (BCHK). *Breast Cancer Research and Treatment*, 53(1), 69–75.
- [2] Lerman, C., Biesecker, B., Benkendorf, J. L., Kerner, J., Gomez-Caminero, A., Hughes, C. & Reed, M. M. (1997). Controlled trial of pretest education approaches to enhance informed decision-making for BRCA1 gene testing. *Journal of the National Cancer Institute*, 89(2), 148–157.
- [3] Erblisch, J., Brown, K., Kim, Y., Valdimarsdottir, H. B., Livingston, B. E. & Bovbjerg, D. H. (2005). Development and validation of a breast cancer genetic counseling knowledge questionnaire. *Patient Education and Counseling*, 56(2), 182–191.
- [4] Bannon, S. A., Mork, M., Vilar, E., Peterson, S. K., Lu, K., Lynch, J. P. M., ... Putten, J. (2014). Patient-reported disease knowledge and educational needs in Lynch syndrome: findings of an interactive multidisciplinary patient conference. *Hereditary Cancer in Clinical Practice*, 12(1), 1.
- [5] Lee, Y.-L., Lin, D.-T. & Tsai, S.-F. (2009). Disease knowledge and treatment adherence among patients with thalassemia major and their mothers in Taiwan. *Journal of Clinical Nursing*, 18(4), 529–538.
- [6] Ames, A. G., Jaques, A., Ukoumunne, O. C., Archibald, A. D., Duncan, R. E., Emery, J. & Metcalfe, S. A. (2015). Development of a fragile X syndrome (FXS) knowledge scale: Towards a modified multidimensional measure of informed choice for FXS population carrier screening. *Health Expectations*, 18(1), 69–80.
- [7] Goel, V., Glazier, R., Holzapfel, S., Pugh, P. & Summers, A. (1996). Evaluating patient’s knowledge of maternal serum screening. *Prenatal Diagnosis*, 16(5), 425–430.
- [8] Pithara, C. (2014). Identifying outcomes of clinical genetic services: Qualitative evidence and methodological considerations. *Journal of Genetic Counseling*, 23(2), 229–238.
- [9] Payne, K., Nicholls, S. G., McAllister, M., MacLeod, R., Ellis, L., Donnat, D. & Davies, L. M. (2007). Outcome measures for clinical genetics services: A comparison of genetics healthcare professionals and patients’ views. *Health Policy*, 84(1), 112–122.
- [10] McAllister, M., Wood, A., Dunn, G., Shiloh, S. & Todd, C. (2011). The genetic counseling outcome scale: A new patient-reported outcome measure for clinical genetics services. *Clinical Genetics*, 79, 413–424.
- [11] Street, R. L., Makoul, G., Arora, N. K. & Epstein, R. M. (2009). How does communication heal? Pathways linking clinician-patient communication to health outcomes. *Patient Education and Counseling*, 74(3), 295–301.
- [12] Street, R. L. (2013). How clinician-patient communication contributes to health improvement: Modeling pathways from talk to outcome. *Patient Education and Counseling*, 92(3), 286–291.
- [13] Street, R. L. & Epstein, R. M. (2007). *Patient-Centered Communication in Cancer Care: Promoting Healing & Reducing Suffering*. Bethesda: NIH Publication.
- [14] McAllister, M., Dunn, G. & Todd, C. (2011). Empowerment: Qualitative underpinning of a new clinical genetics-specific patient-reported outcome. *European Journal of Human Genetics*, 19(2), 125–130.
- [15] Berkenstadt, M., Shiloh, S., Barkai, G., Katznelson, M. B. & Goldman, B. (1999). Perceived personal control (PPC): A new concept in measuring outcome of genetic counseling. *American Journal of Medical Genetics*, 82(1), 53–59.

- [16] Katapodi, M. C., Munro, M. L., Pierce, P. F. & Williams, R. A. Psychometric testing of the decisional conflict scale: genetic testing hereditary breast and ovarian cancer. *Nursing Research*, 60(6), 368–377.
- [17] (2015). Decisional Conflict Scale. The Ottawa Hospital. Available at https://decisionaid.ohri.ca/eval_des.html.
- [18] O'Connor, A. M. Validation of a decisional conflict scale. *Medical Decision Making*, 15(1), 25–30.
- [19] Cockburn, J., Fahey, P. & Sanson-Fisher, R. W. (1987). Construction and validation of a questionnaire to measure the health beliefs of general practice patients. *Family Practice*, 4(2), 108–116.
- [20] Witte, K., Cameron, K. A., McKeon, J. K. & Berkowitz, J. M. (1996). Predicting risk behaviors: Development and validation of a diagnostic scale. *Journal of Health Communication*, 1(4), 317–341.
- [21] Lazarus, R. S. & Folkman, S. (1987). Transactional theory and research on emotions and coping. *European Journal of Personality*, 1(3), 141–169.
- [22] Mishel, M. H. The measurement of uncertainty in illness. *Nursing Research*, 30(5), 258–263.
- [23] Lin, L., Acquaye, A. A., Vera-Bolanos, E., Cahill, J. E., Gilbert, M. R. & Armstrong, T. S. (2012). Validation of the Mishel's uncertainty in illness scale-brain tumor form (MUIS-BT). *Journal of Neuro-Oncology*, 110(2), 293–300.
- [24] Ajzen, I. Constructing a Theory of Planned Behavior Questionnaire. Available at <http://people.umass.edu/aizen/pdf/tpb.measurement.pdf>.
- [25] Self-Determination Theory Questionnaires. Available at <http://selfdeterminationtheory.org/questionnaires/>
- [26] Lent, R. W. & Brown, S. D. (2006). On conceptualizing and assessing social cognitive constructs in career research: A measurement guide. *Journal of Career Assessment*, 14(1), 12–35.
- [27] McAllister, M., Payne, K., Macleod, R., Nicholls, S., Donnai, D. & Davies, L. (2008). Patient empowerment in clinical genetics services. *Journal of Health Psychology*, 13(7), 895–905.
- [28] Bandura, A. (1997). *Self-efficacy: the exercise of control*, 1st (ed.). W.H. Freeman & Company.
- [29] Birmingham, W. C., Hung, M., Boonyasiriwat, W., Kohlmann, W., Walters, S. T., Burt, R. W., ... Kinney, A. Y. (2015). Effectiveness of the extended parallel process model in promoting colorectal cancer screening. *Psycho-Oncology*.
- [30] Ferron Parayre, A., Labrecque, M., Rousseau, M., Turcotte, S. & Légaré, F. (2014). Validation of SURE, a four-item clinical checklist for detecting decisional conflict in patients. *Medical Decision Making*, 34(1), 54–62.
- [31] Silvey, K., Stock, J., Hasegawa, L. E. & Au, S. M. (2009). Outcomes of genetics services: Creating an inclusive definition and outcomes menu for public health and clinical genetics services. *American Journal of Medical Genetics. Part C, Seminars in Medical Genetics*, 151C(3), 207–213.
- [32] Self-Efficacy for Managing Chronic Disease 6-Item Scale. Stanford Patient Education Research Center. Available at <http://patienteducation.stanford.edu/research/sect6.html>.
- [33] Abraham, K. M., Miller, C. J., Birgenheir, D. G., Lai, Z. & Kilbourne, A. M. (2014). Self-efficacy and quality of life among people with bipolar disorder. *The Journal of Nervous and Mental Disease*, 202(8), 583–588.
- [34] PROMIS. (2015). Emotional support. Available at <https://www.assessmentcenter.net/documents/PROMIS%20Emotional%20Support%20Scoring%20Manual.pdf>.
- [35] PROMIS. (2015). Informational support. Available at <https://www.assessmentcenter.net/documents/PROMIS%20Informational%20Support%20Scoring%20Manual.pdf>.
- [36] PROMIS. (2015). Instrumental support. Available at <https://www.assessmentcenter.net/documents/PROMIS%20Instrumental%20Support%20Scoring%20Manual.pdf>
- [37] PROMIS. (2015). Self-efficacy for managing chronic conditions a brief guide to the PROMIS self-efficacy instruments. Available at http://www.healthmeasures.net/images/promis/manuals/PROMIS_Self_Efficacy_Scoring_Manual.pdf.
- [38] Kirk, B. A., Schutte, N. S. & Hine, D. W. (2008). Development and preliminary validation of an emotional self-efficacy scale. *Personality and Individual Differences*, 45(5), 432–436.
- [39] Glanz, K. & Bishop, D. B. (2010). The role of behavioral science theory in development and implementation of public health interventions. *Annual Review of Public Health*, 31, 399–418.
- [40] Wang, C., Gonzalez, R. & Merajver, S. D. S. D. (2004). Assessment of genetic testing and related counseling services: Current research and future directions. *Social Science & Medicine*, 58, 1427–1442.
- [41] Vernon, S. W., Gritz, E. R., Peterson, S. K., Perz, C. A., Marani, S., Amos, C. I. & Baile, W. F. (1999). Intention to learn results of genetic testing for hereditary colon cancer. *Cancer Epidemiology, Biomarkers & Prevention*, 8(4 Pt 2), 353–360.
- [42] Michie, S., Dormandy, E. & Marteau, T. M. (2002). The multi-dimensional measure of informed choice: A validation study. *Patient Education and Counseling*, 48(1), 87–91.
- [43] Brehaut, J. C., O'Connor, A. M., Wood, T. J., Hack, T. F., Siminoff, L., Gordon, E. & Feldman-Stewart, D. Validation of a decision regret scale. *Medical Decision Making*, 23(4), 281–292.
- [44] McLaughlin, J. & Slepcevic, E. M. (1985). The self-care behavior inventory: A model for behavioral instrument development. Patient Education and Counseling, 7(3), 289–301.
- [45] Rutherford, S., Zhang, X., Atzinger, C., Ruschman, J. & Myers, M. F. (2014). Medical management adherence as an outcome of genetic counseling in a pediatric setting. *Genetics in Medicine*, 16, 157–163.
- [46] House, J. S. (1981). *Work stress and social support*. Addison-Wesley Pub Co.
- [47] Horowitz, M., Wilner, N. & Alvarez, W. (1979). Impact of subjective stress. *Psychosomatic Medicine*, 41(3), 209–218.

- [48] Cella, D., Hughes, C., Peterman, A., Chang, C.-H., Peshkin, B. N., Schwartz, M. D., Wenzel, L., Lemke, A., Marcus, A. C. & Lerman, C. (2002). A brief assessment of concerns associated with genetic testing for cancer: The multidimensional impact of cancer risk assessment (MICRA) questionnaire. *Health Psychology, 21*(6), 564–572.
- [49] Biesscker, B. B. & Erby, L. (2008). Adaptation to living with a genetic condition or risk: A mini-review. *Clinical Genetics, 74*(5), 401–407.
- [50] Brief COPE measure. <http://www.psy.miami.edu/faculty/ccarver/sciBrCOPE.html>
- [51] Folkman, S. & Lazarus, R. (1988). *Ways of Coping Questionnaire*. Consulting Psychologists Press. Available at <http://www.selfcareinsocialwork.com/wp-content/uploads/2013/03/WAYS-OF-COPING-was-designed-by-Lazarus-and-Folkman.pdf>
- [52] Biesscker, B. B., Erby, L. H., Woolford, S., Adcock, J. Y., Cohen, J. S., Lamb, A., ... Reeve, B. B. (2013). Development and validation of the Psychological Adaptation Scale (PAS): use in six studies of adaptation to a health condition or risk. *Patient Education and Counseling, 93*(2), 248–254. <https://doi.org/10.1016/j.pcc.2013.05.006>
- [53] PROMIS Psychosocial Illness Impact (positive item bank) Available at <https://www.assessmentcenter.net/documents/PROMIS%20Psychosocial%20Illness%20Impact%20Positive%20Scoring%20Manual.pdf>.

or other communication intense health services are provided. The examples we created demonstrate how FOCUS can be tailored to examine different outcomes. Ultimately, this type of framework may help in designing studies to demonstrate and establish the gold standard of quality in genetic counseling and other healthcare communication services more generally.

The Institute of Medicine (IOM) has defined quality based on the extent to which health care services are patient-centered, equitable, effective, timely, safe and efficient (Committee on Quality of Health Care in America 2001). Development of quality measures begin with clinical research that links clinical care processes with the IOM quality indicators. The two examples we created using FOCUS can help conceptualize how GC may impact quality. Specifically, with regard to our first example, increasing family members' uptake of testing may improve *timeliness* of identifying at-risk family members and contribute to *effective* care through the prevention or early detection of disease. In addition, *efficiency* can be improved through ordering single site testing for family members (as opposed to full gene sequencing); and this is only possible if a patient accurately communicates test results to family members. In relation to our second example, using a shared decision-making strategy is considered high quality care because it takes into consideration the patients' needs, values, and goals and therefore the approach is *patient-centered*. Furthermore, a quality health decision is hypothesized to indirectly increase the *effectiveness* of care in some settings or contexts by improving patient adherence to evidence-based health recommendations.

Study Limitations

Despite the potential usefulness of FOCUS, there were limitations with the approach used to construct the framework. First, the process of developing the framework was not entirely systematic. However, it would have been impractical to review all literature within all relevant disciplines and to provide detailed examples or evidence for each of the proposed relationships between framework components. Thus, additional work is needed to comprehensively review research findings and to indicate the strength of evidence supporting or refuting the proposed relationships between constructs. Second, this framework was informed largely by the GC literature. As a result, some components of the framework may be less relevant to health service delivery that occurs outside the context of GC. Further, the process of consolidating and determining labels and definitions for FOCUS domains and constructs was challenging due to notable similarities between several outcomes or communication skills and

Table 5 Patient health outcomes from the Framework for Outcomes in Clinical Communication Services (FOCUS)

Patient health outcome categories ^a	Description (examples of relationship to patient changes)	Example Measures ^b
Survival [1–3] (i.e., reduced mortality)	Longer life as the result of diagnosing and managing a condition or risk factor. (Improving timely access to appropriate care can lead to increased survival. Quality health decisions and adherence or self-care can also improve survival.)	Overall survival; disease-free survival; net cancer-specific survival [4]. Survival has been proven to increase if patients with Lynch syndrome adhere to cancer screening/surveillance recommendations [5].
Symptoms and suffering [1–3] (i.e., reduced morbidity)	Reduction or prevention of disease-related symptoms or side effects of treatment (i.e., reduction in fatigue, pain, sleep disturbance, etc). (Eliciting information from the patient about side-effects may lead to a change in treatment and decrease in suffering. Discussing pain is critical to ensure appropriate medication is provided to reduce the pain. Sleep can be impacted by negative emotions related to a health risk, side effects of medication, or pain.)	Proportion of patients who report a reduction in physical suffering (scale measures how often symptoms were experienced and how much they bothered the patient) [6]. Proportion of patients who report a decrease in side effects of treatment. ^c PROMIS measures: Proportion of patients who report improvements in pain intensity or interference; or sleep disturbance, sleep-related impairment [7, 8].
Physical functioning [9] (includes physical aspects of Health Related Quality of Life (HRQoL) measures)	Ability to carry out activities that require physical actions (i.e., mobility levels, energy/vitality levels, self-care skills, sexual activity, exercise, work or school.) (Access to appropriate care, reductions in negative emotions, and increases in positive coping can improve physical functioning.)	Loss of function sub-scale of the SOS-V [10]. ^c PROMIS measures: Physical function [11] SF-36: Physical function, limitations to physical health, vitality subscales [12]. Global Assessment of Functioning (clinician rated) [13]. ^c PROMIS measure: Sexual function [14]. Days missed from work or school within a certain time period
Social functioning [9] (includes social health aspects of HRQoL measures)	Overall participation in social activities that a patient desires. Provision and receipt of support from family friends, and others. (Reductions in negative emotions, positive coping and feeling empowered to access support resources can improve social functioning.)	Social functioning from the SF-36 [12]. ^c PROMIS measures: Ability to participate in social roles/activities, social support, social isolation [16–18].
Cognitive functioning [1]–[3, 18]	Ability to concentrate and perform cognitive tasks that are desired by a patient. These include executing activities such as: logical speech, mental calculations, reading, learning, and work requiring cognitive functions. (An accurate diagnosis can reduce time spent worrying, thereby improving ability to concentrate on other tasks.)	Functional capacity in mental health [19].
Existential well-being [1–3, 5, 6]	Overall sense of purpose, hope, completeness, contentment, and satisfaction with life. (People who demonstrate positive coping behaviors and find a sense of purpose to their health situation may have improved overall well-being.)	Measure of “existential distress” which is the reverse of existential well-being [22]. ^c PROMIS measures for children: life satisfaction, meaning and purpose in life [23].
Mental Health [9] (includes mental health aspects of HRQoL measures)	Absence of psychological problems including anxiety and depression. (Having a diagnosis can reduce depression and anxiety even if there is no treatment because a diagnosis can help people cope, adapt, and access support resources.)	PROMIS measures: Anxiety and depression scales ^c [24, 25]. Overview of Measures of Anxiety [26]. State Trait Anxiety Inventory (STAI) [27]. Hospital anxiety and depression scale (HADS) [28]. Center for Epidemiological studies depression scale (CES-D) [29].

^a Patient Health Outcomes include changes in health and well-being that occur as a direct or indirect result of receiving health services

^b Measures are often patient reported, but can be performance-based measures, caregiver/proxy reported or direct observation

^c Patient reported outcomes measurement information system (PROMIS) has many assessment measures that reflect patient-reported health. These are calibrated item banks or scales, item pools or short forms http://www.nihpromis.org/Documents/InstrumentsAvailable_11516_508.pdf

References

- Street, R. L., Makoul, G., Arora, N. K. & Epstein, R. M. (2009). How does communication heal? Pathways linking clinician-patient communication to health outcomes. *Patient Education and Counseling*, 74(3), 295–301. <http://www.ncbi.nlm.nih.gov/pubmed/19150199>.
- Street, R. L. (2013). How clinician-patient communication contributes to health improvement: Modeling pathways from talk to outcome. *Patient Education and Counseling*, 92(3), 286–291. <http://www.ncbi.nlm.nih.gov/pubmed/23746769>.
- Street, R. L. & Epstein, R. M. (2007). *Patient-Centered Communication in Cancer Care: Promoting Healing & Reducing Suffering*. Bethesda: NIH Publication. http://appliedresearch.cancer.gov/areas/pcc/communication/pcc_monograph.pdf.

- [4] Measures of Cancer Survival. National Cancer Institute. [Online]. Available: <http://surveillance.cancer.gov/survival/measures.html>.
- [5] Renkonen-Sinisalo, L., Aarnio, M., Mecklin, J. P. & Järvinen, H. J. (2000). Surveillance improves survival of colorectal cancer in patients with hereditary nonpolyposis colorectal cancer. *Cancer Detection and Prevention*, 24(2), 137–142. <http://www.ncbi.nlm.nih.gov/pubmed/10917133>.
- [6] Schulz, R., Monin, J. K., Czaja, S. J., Lingler, J. H., Beach, S. R., Martire, L. M., Dodds, A., Hebert, R. S., Zdaniuk, B. & Cook, T. B. (2010). Measuring the experience and perception of suffering. *Gerontologist*, 50(6), 774–784. <http://www.ncbi.nlm.nih.gov/pubmed/20478899>.
- [7] Revicki, D. A. & Cook, K. F. (2015). PROMIS Pain-Related Measures: An Overview. [Online]. Available: <http://www.practicalpainmanagement.com/resources/clinical-practice-guidelines/promis-pain-related-measures-overview>.
- [8] Yu, L., Buysse, D. J., Germain, A., Moul, D. E., Stover, A., Dodds, N. E., Johnston, K. L. & Pilkonis, P. A. (2011). Development of short forms from the PROMIS™ sleep disturbance and sleep-related impairment item banks. *Behavioral Sleep Medicine*, 10(1), 6–24. <http://www.ncbi.nlm.nih.gov/pubmed/22250775>.
- [9] Health-Related Quality of Life and Well-Being. Healthy People. [Online]. Available: <https://www.healthypeople.gov/2020/about/foundation-health-measures/Health-Related-Quality-of-Life-and-Well-Being>.
- [10] Ruijs, K. D. M., Onwuteaka-Philipsen, B. D., van der Wal, G. & Kerkhof, A. J. F. M. (2009). Unbearability of suffering at the end of life: The development of a new measuring device, the SOS-V. *BMC Palliative Care*, 8, 16. <http://www.ncbi.nlm.nih.gov/pubmed/19887004>.
- [11] PROMIS. (2015). Physical Function. [https://www.assessmentcenter.net/documents/PROMIS Physical Function Scoring Manual.pdf](https://www.assessmentcenter.net/documents/PROMIS_Physical_Function_Scoring_Manual.pdf).
- [12] Brazier, J. E., Harper, R., Jones, N. M., O’Cathain, A., Thomas, K. J., Usherwood, T. and Westlake, L. (1992). Validating the SF-36 health survey questionnaire: New outcome measure for primary care. *BMJ*, 305(6846), 160–164. <http://www.ncbi.nlm.nih.gov/pubmed/1285753>.
- [13] Aas, I. H. M. (2011). Guidelines for rating global assessment of functioning (GAF). *Annals of General Psychiatry*, 10, 2. <http://www.ncbi.nlm.nih.gov/pubmed/21251305>.
- [14] PROMIS. (2015). Sexual Function and Satisfaction Measures User Manual. [https://www.assessmentcenter.net/documents/Sexual Function Manual.pdf](https://www.assessmentcenter.net/documents/Sexual_Function_Manual.pdf).
- [15] PROMIS. (2016). Ability to Participate in Social Roles and Activities. [Online]. Available: http://www.nihpromis.com/Science/PubsDomain/Socialroles_part.aspx?AspxAutoDetectCookieSupport=1
- [16] PROMIS. (2016). Social Support. [Online]. Available: http://www.nihpromis.com/science/PubsDomain/Social_support
- [17] PROMIS. (2015). Social isolation. [https://www.assessmentcenter.net/documents/PROMIS Social Isolation Scoring Manual.pdf](https://www.assessmentcenter.net/documents/PROMIS_Social_Isolation_Scoring_Manual.pdf).
- [18] Silvey, K., Stock, J., Hasegawa, L. E. & Au, S. M. (2009). Outcomes of genetics services: Creating an inclusive definition and outcomes menu for public health and clinical genetics services. *American Journal of Medical Genetics. Part C, Seminars in Medical Genetics*, 151C(3), 207–213. <http://www.ncbi.nlm.nih.gov/pubmed/19621453>.
- [19] Patterson, T. L. & Mausbach, B. T. (2010). Measurement of functional capacity: A new approach to understanding functional differences and real-world behavioral adaptation in those with mental illness. *Annual Review of Clinical Psychology*, 6, 139–154. <http://www.ncbi.nlm.nih.gov/pubmed/20334554>.
- [20] McAllister, M., Payne, K., Macleod, R., Nicholls, S., Donnai, D. & Davies, L. (2008). Patient empowerment in clinical genetics services. *Journal of Health Psychology*, 13(7), 895–905. <http://www.ncbi.nlm.nih.gov/pubmed/18809640>.
- [21] McAllister, M., Dunn, G. & Todd, C. (2011). Empowerment: Qualitative underpinning of a new clinical genetics-specific patient-reported outcome. *European Journal of Human Genetics*, 19(2), 125–130. <http://www.ncbi.nlm.nih.gov/pubmed/20924407>.
- [22] Lo, C., Panday, T., Zeppieri, J., Rydall, A., Murphy-Kane, P., Zimmermann, C. & Rodin, G. (2016). Preliminary psychometrics of the Existential Distress Scale in patients with advanced cancer. *European Journal of Cancer Care Centaur (England)*. <http://www.ncbi.nlm.nih.gov/pubmed/27778415>.
- [23] Ravens-Sieberer, U., Devine, J., Bevans, K., Riley, A. W., Moon, J., Salsman, J. M. & Forrest, C. B. (2014). Subjective well-being measures for children were developed within the PROMIS project: Presentation of first results. *Journal of Clinical Epidemiology*, 67(2), 207–218. <http://www.ncbi.nlm.nih.gov/pubmed/24295987>.
- [24] PROMIS. (2015). Anxiety. [https://www.assessmentcenter.net/documents/PROMIS Anxiety Scoring Manual.pdf](https://www.assessmentcenter.net/documents/PROMIS_Anxiety_Scoring_Manual.pdf).
- [25] PROMIS. (2015). Depression. [https://www.assessmentcenter.net/documents/PROMIS Depression Scoring Manual.pdf](https://www.assessmentcenter.net/documents/PROMIS_Depression_Scoring_Manual.pdf).
- [26] Julian, L. J. (2011). Measures of anxiety: State-trait Anxiety inventory (STAI), Beck Anxiety inventory (BAI), and hospital Anxiety and depression scale-Anxiety (HADS-A). *Arthritis Care & Research (Hoboken)*, 63(S11), S467–S472. <http://doi.wiley.com/10.1002/acr.20561>
- [27] The State-Trait Anxiety Inventory (STAI). American Psychological Association. [Online]. Available: <http://www.apa.org/pi/about/publications/caregivers/practice-settings/assessment/tools/trait-state.aspx>.
- [28] Zigmond, A. S. & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica*, 67(6), 361–370. <http://www.ncbi.nlm.nih.gov/pubmed/6880820>.
- [29] Lewinsohn, P. M., Seeley, J. R., Roberts, R. E. & Allen, N. B. (1997). Center for Epidemiologic Studies Depression Scale (CES-D) as a screening instrument for depression among community-residing older adults. *Psychology and Aging*, 12(2), 277–287. <http://www.ncbi.nlm.nih.gov/pubmed/9189988>.

processes as well as insufficient evidence to suggest that one label or description is superior to another. Subsequently, nuances in constructs and labels may have been lost during the consolidation process. Finally, there

are several important limitations related to the sample measures included in the FOCUS tables. Although researchers may find some of these measures useful, we did not use any type of systematic method in their

Table 6 Family changes from the Framework for Outcomes in Clinical Communication Services (FOCUS)

Family change categories ^a	Description	Example measures
Family communication [1, 2]	Open communication of accurate information that is understood by family members is necessary for family members to make their own informed decisions and lead to improved health outcomes for family members.	Self-reported family communication of test results. Family Communication Questionnaire (FCQ) [3]. Openness to Discuss Hereditary Cancer in the Family Scale [4].
Family members access appropriate services	Family member awareness of, interest in, and uptake of appropriate medical services.	Proportion of all at-risk, adult relatives of a patient with hereditary cancer who are aware of and who receive genetic risk assessment services. Proportion of family members of a person with a benign variant or variant of uncertain significance (VUS) who have <i>clinical</i> testing unnecessarily.
Family functioning and relationships [1, 2]	Patient health can change family functioning, roles, relationships, tension or conflict.	Psychosocial Adjustment to Hereditary Diseases: Burden of knowing and family connectedness [5]. Family adaptability and cohesion scale (FACES III) [6–9]. Cancer family impact scale [10]. Index of Family Relations [11].
Reduced caregiver burden & stress	Caregivers within the family face substantial stressors and may benefit from the provision of support resources or services. Caregiver burden may also decrease if positive patient changes occur.	Measure developed for caregivers of patients with Alzheimer's [12].
Family members' health and well-being	Changes in the health or well-being of the family members as the result of other family changes above.	See Patient Health (Table 5)

^a Changes among the patient's family as an indirect result of health services provided to a patient. These are important because they can lead to improved health outcomes among family members.

References

- [1] McAllister, M., Payne, K., Nicholls, S., MacLeod, R., Donnai, D. & Davies, L. M. (2007). Improving service evaluation in clinical genetics: Identifying effects of genetic diseases on individuals and families. *Journal of Genetic Counseling*, 16(1), 71–83. <http://www.ncbi.nlm.nih.gov/pubmed/17295055>.
- [2] Payne, K., Nicholls, S. G., McAllister, M., MacLeod, R., Ellis, I., Donnai, D. & Davies, L. M. (2007). Outcome measures for clinical genetics services: A comparison of genetics healthcare professionals and patients' views. *Health Policy*, 84(1), 112–122. <http://www.ncbi.nlm.nih.gov/pubmed/17485130>.
- [3] Hughes, C., Lerman, C., Schwartz, M., Peshkin, B. N., Wenzel, L., Narod, S., Corio, C., Tercyak, K. P., Hanna, D., Isaacs, C. & Main, D. (2002). All in the family: Evaluation of the process and content of sisters' communication about BRCA1 and BRCA2 genetic test results. *American Journal of Medical Genetics*, 107(2), 143–150. <http://www.ncbi.nlm.nih.gov/pubmed/11807889>.
- [4] Mesters, I., van den Borne, H., McCormick, L., Pruy, J., de Boer, M. & Imbos, T. (1997). Openness to discuss cancer in the nuclear family: Scale, development, and validation. *Psychosomatic Medicine*, 59(3), 269–79. <http://www.ncbi.nlm.nih.gov/pubmed/9178338>.
- [5] Watkins, K. E., Way, C. Y., Gregory, D. M., LeDrew, H. M., Ludlow, V. C., Esplen, M. J., Dowden, J. J., Cox, J. E., Fitzgerald, G. W. N. & Parfrey, P. S. (2013). Development and preliminary testing of the psychosocial adjustment to hereditary diseases scale. *BMC Psychiatry*, 1(1), 7. <http://www.ncbi.nlm.nih.gov/pubmed/25566359>.
- [6] FACES IV. Prepare/enrich. [Online]. Available: <http://www.facesiv.com/>.
- [7] Olson, D. H. (1986). Circumplex model VII: Validation studies and FACES III. *Family Process*, 25(3), 337–351. <http://www.ncbi.nlm.nih.gov/pubmed/3758310>.
- [8] Baptist, J. A., Thompson, D. E., Norton, A. M., Hardy, N. R. & Link, C. D. (2012). The effects of the intergenerational transmission of family emotional processes on conflict styles: the moderating role of attachment. *American Journal of Family Therapy*, 40, 56–73. http://www.buildingrelationships.com/facesiv_studies/baptist.pdf
- [9] Olson, D. (2011). Faces IV and the circumplex model: Validation study. *Journal of Marital and Family Therapy*, 3(1), 64–80. http://www.buildingrelationships.com/facesiv_studies/Validation_Study_JMFT_2011.pdf.
- [10] Sinicrope, P. S., Vernon, S. W., Diamond, P. M., Patten, C. A., Kelder, S. H., Rabe, K. G. & Petersen, G. M. (2008). Development and preliminary validation of the cancer family impact scale for colorectal cancer. *Genetic Testing*, 12(1), 161–169. <http://www.ncbi.nlm.nih.gov/pubmed/18373413>.
- [11] Hoge, R. D., Andrews, D. A., Faulkner, P. & Robinson, D. (1989). The family relationship index: Validity data. *Journal of Clinical Psychology*, 45(6), 897–903. <http://www.ncbi.nlm.nih.gov/pubmed/2613899>.
- [12] Davis, K. L., Marin, D. B., Kane, R., Patrick, D., Peskind, E. R., Raskind, M. A. & Puder, K. L. (1997). The caregiver activity survey (CAS): Development and validation of a new measure for caregivers of persons with Alzheimer's disease. *International Journal of Geriatric Psychiatry*, 12(10), 978–988. <http://www.ncbi.nlm.nih.gov/pubmed/9395929>.

selection and we created several of the measures to serve as examples. Consequently, we are unable to endorse any of the measures because we have not evaluated or generated evidence of their reliability or validity.

Practice Implications

FOCUS could be used to evaluate GC service delivery and help answer relevant clinical questions like: 1) How do genetic counselors contribute to improvements in patient care experiences and outcomes? and 2) What are best practices in genetic counseling? Professional consensus regarding terminology related to GC processes and outcomes together with widespread use of a consolidated framework (such as a modified version of FOCUS) may help move genetic counseling outcomes research ahead more quickly in order to build a strong evidence base for GC practice. Currently evidence supporting linkages between communication strategies and outcomes is somewhat limited in GC (Bettina Meiser et al. 2008; Paul et al. 2015). However, several propositions linking some of the FOCUS constructs do exist and provide rich areas of continued exploration. For example, patient-centered strategies based on Self-determination Theory, Motivational Interviewing techniques, and/or the Extended Parallel Process Model have increased autonomous motivation, improved perceived competence and self-efficacy, and/or changed cognitions, emotions or behaviors (DiClemente et al. 2009; Kinney et al. 2014; Lundahl et al. 2013; Miller and Rollnick 2013; Pengchit et al. 2011; Ruiters et al. 2014). These strategies consist of skills and techniques that are included in FOCUS such as asking the patient what she/he wants to achieve; refraining from judgment; encouraging questions; exploring and resolving ambivalence in decision making; altering risk perceptions; and/or promoting beliefs that certain actions or resources can help the patient effectively mitigate their risks.

Research Recommendations

In order for FOCUS to impact clinical practice, additional efforts are needed that go beyond the scope of the current study. Identifying appropriate outcome measures is still an important research area that will require additional efforts. A few articles have identified and reviewed measures that capture some GC outcomes (M McAllister and Dearing 2015; B Meiser et al. 2001; Payne et al. 2007a, 2007b) and we have included several other potential measures as examples. However, it will be critical to ensure these measures are well validated in a variety of GC contexts. Efforts will also be needed to further hypothesize and test specific direct and indirect relationships between constructs using methods such as structural equation modeling. As empirical evidence is gathered to support or refute hypothesized relationships, additional modifications to FOCUS may be

necessary. We also anticipate that constructs will be added to the framework over time and that FOCUS will be used in conjunction with other models and theories.

Conclusion

FOCUS provides a comprehensive way of thinking about clinical communication services and has the potential to help researchers: 1) develop ideas about how to evaluate clinical communication services (including genetic counseling); 2) organize, categorize, and define a broad array of possible outcomes; 3) select outcomes and measures; 4) hypothesize how communication strategies may positively impact health care quality; 5) guide comparative effectiveness research to determine whether and how differences in GC may or may not be associated with differences in patient outcomes. Use and refinement of this type of macro-level framework is expected to improve our ability to conceptualize and summarize genetic counseling outcome studies (both past and future) and help to collate much needed evidence on what communication strategies could be endorsed as best practices in GC. It is our hope that patients, healthcare providers, and researchers in many different areas may benefit from applying this type of framework in research and practice.

Acknowledgements Partial support for Deborah Cragun's time was provided during her postdoctoral training fellowship funded by a NCI R25 training grant awarded to Moffitt Cancer Center (5R25CA147832-05). However, this work reflects the authors' opinions and has neither been reviewed nor endorsed by the NCI or entities acknowledged below. The authors would like to acknowledge the National Society of Genetic Counselors outcomes work group because serving on this group revealed the need for and helped in conceptualizing this framework. Deborah Cragun would also like to acknowledge that framework development was inspired and/or influenced by: 1) training she received from her mentors (Dr. Rita DeBate and Dr. Tuya Pal); 2) discussions with Dr. Courtney Scherr and Dr. Anita Kinney; and 3) participation in the Mentored Training in Dissemination and Implementation Research in Cancer (MT-DIRC) program. MT-DIRC is supported through a NCI grant (R25CA171994-02) and by the Veterans Administration.

Dr. Christina Palmer served as Action Editor on the manuscript review process and publication decision.

Compliance with Ethical Standards

Conflict of Interest Heather Zierhut, PhD, MS and Deborah Cragun, PhD, MS declare that they have no conflict of interest.

Human Subjects & Informed Consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

Animal Studies No animal studies were carried out by the authors for this article.

References

- Accreditation Counsel for Genetic Counseling. (2015). Practice-Based Competencies for Genetic Counselors. Retrieved from http://www.gceducation.org/Documents/ACGC%20Core%20Competencies%20Brochure_15_Web.pdf. Accessed 28 Sept 2017
- Agency for Healthcare Research and Quality. National Quality Measures Clearinghouse. (2017). <https://www.qualitymeasures.ahrq.gov/>. Accessed 6 Feb 2017.
- Bernhardt, B. A., Biesecker, B. B., & Mastromarino, C. L. (2000). Goals, benefits, and outcomes of genetic counseling: Client and genetic counselor assessment. *American Journal of Medical Genetics*, *94*(3), 189–197.
- Committee on Quality of Health Care in America. (2001). Crossing the quality chasm: A new health system for the 21st century. National Academies Press. <http://www.ncbi.nlm.nih.gov/pubmed/25057539>.
- DiClemente, R. J., Crosby, R. A., & Kegler, M. (2009). In R. J. DiClemente, R. A. Crosby, & M. Kegler (Eds.), *Emerging theories in health promotion practice and research* (2nd ed.). San Francisco: Jossey-Bass.
- Donabedian, A. (1988). The quality of care - how can it be assessed? *JAMA*, *260*(12), 1743–1748. <https://doi.org/10.1001/jama.1988.03410120089033>.
- Epstein, R.M., Street, R.L., Jr. (2007) Patient-Centered Communication in Cancer Care: Promoting Healing and Reducing Suffering. National Cancer Institute, NIH Publication No. 07-6225. Bethesda. Retrieved from https://healthcaredelivery.cancer.gov/pcc/pcc_monograph.pdf.
- George, R., Kovak, K., & Cox, S. L. (2015). Aligning policy to promote cascade genetic screening for prevention and early diagnosis of heritable diseases. *Journal of Genetic Counseling*, *24*(3), 388–399. doi: <https://doi.org/10.1007/s10897-014-9805-5>.
- Glanz, K., & Bishop, D. B. (2010). The role of behavioral science theory in development and implementation of public health interventions. *Annual Review of Public Health*, *31*, 399–418. <https://doi.org/10.1146/annurev.publhealth.012809.103604>.
- Hallowell, N., Lawton, J., & Gregory, S. (2005). *Reflections on research: The Realities of doing research in the social sciences*. New York: Open University Press.
- Hartmann, J. E., Veach, P. M., MacFarlane, I. M., & LeRoy, B. S. (2015). Genetic counselor perceptions of genetic counseling session goals: A validation study of the reciprocal-engagement model. *Journal of Genetic Counseling*, *24*(2), 225–237. <https://doi.org/10.1007/s10897-013-9647-6>.
- Hoerger, M., Epstein, R. M., Winters, P. C., Fiscella, K., Duberstein, P. R., Gramling, R., et al. (2013). Values and options in cancer care (VOICE): Study design and rationale for a patient-centered communication and decision-making intervention for physicians, patients with advanced cancer, and their caregivers. *BMC Cancer*, *13*, 188. <https://doi.org/10.1186/1471-2407-13-188>.
- House, J. S. (1981). *Work stress and social support*. Boston: Addison-Wesley Pub Co..
- Kenyon, C. C., Palakshappa, D., & Feudtner, C. (2015). Logic models—tools to bridge the theory–research–practice divide. *JAMA Pediatrics*, *169*(9), 801–802. <https://doi.org/10.1001/jamapediatrics.2015.1365>.
- Kinney, A. Y., Boonyasriwat, W., Walters, S. T., Pappas, L. M., Stroup, A. M., Schwartz, M. D., et al. (2014). Telehealth personalized cancer risk communication to motivate colonoscopy in relatives of patients with colorectal cancer: The family CARE randomized controlled trial. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*, *32*(7), 654–662. <https://doi.org/10.1200/JCO.2013.51.6765>.
- Légaré, F., O'Connor, A. C., Graham, I., Saucier, D., Côté, L., Cauchon, M., & Paré, L. (2006). Supporting patients facing difficult health care decisions: Use of the Ottawa decision support framework. *Canadian Family Physician Medecin de Famille Canadien*, *52*, 476–477 <http://www.ncbi.nlm.nih.gov/pubmed/17327891>.
- Lerner, J. S., Li, Y., Valdesolo, P., & Kassam, K. S. (2015). Emotion and decision making. *Annual Review of Psychology*, *66*(1), 799–823. <https://doi.org/10.1146/annurev-psych-010213-115043>.
- Lundahl, B., Moleni, T., Burke, B. L., Butters, R., Tollefson, D., Butler, C., & Rollnick, S. (2013). Motivational interviewing in medical care settings: A systematic review and meta-analysis of randomized controlled trials. *Patient Education and Counseling*, *93*(2), 157–168. <https://doi.org/10.1016/j.pec.2013.07.012>.
- Makoul, G., & Clayman, M. L. (2006). An integrative model of shared decision making in medical encounters. *Patient Education and Counseling*, *60*(3), 301–312. <https://doi.org/10.1016/j.pec.2005.06.010>.
- McAllister, M., & Dearing, A. (2015). Patient reported outcomes and patient empowerment in clinical genetics services. *Clinical Genetics*, *88*(2), 114–121. <https://doi.org/10.1111/cge.12520>.
- McAllister, M., Payne, K., Nicholls, S., MacLeod, R., Donnai, D., & Davies, L. M. (2007). Improving service evaluation in clinical genetics: Identifying effects of genetic diseases on individuals and families. *Journal of Genetic Counseling*, *16*(1), 71–83. <https://doi.org/10.1007/s10897-006-9046-3>.
- McAllister, M., Payne, K., Macleod, R., Nicholls, S., Donnai, D., & Davies, L. (2008). Patient empowerment in clinical genetics services. *Journal of Health Psychology*, *13*(7), 895–905. <https://doi.org/10.1177/1359105308095063>.
- McAllister, M., Wood, A., Dunn, G., Shiloh, S., & Todd, C. (2011). The genetic counseling outcome scale: A new patient-reported outcome measure for clinical genetics services. *Clinical Genetics*, *79*, 413–424. <https://doi.org/10.1111/j.1399-0004.2011.01636.x>.
- McAllister, M., Moldovan, R., Paneque, M., & Skirton, H. (2016). The need to develop an evidence base for genetic counselling in Europe. *European Journal of Human Genetics: EJHG*, *24*(4), 504–505. <https://doi.org/10.1038/ejhg.2015.134>.
- Meiser, B., Butow, P. N., Barratt, A. L., Schnieden, V., Gattas, M., Kirk, J., & Psychological Impact Collaborative Group. (2001). Long-term outcomes of genetic counseling in women at increased risk of developing hereditary breast cancer. *Patient Education and Counseling*, *44*(3), 215–225.
- Meiser, B., Irle, J., Lobb, E., & Barlow-Stewart, K. (2008). Assessment of the content and process of genetic counseling: A critical review of empirical studies. *Journal of Genetic Counseling*, *17*(5), 434–451. <https://doi.org/10.1007/s10897-008-9173-0>.
- Miller, W. R., & Rollnick, S. (2013). *Motivational interviewing: Helping people change* (3rd ed.). New York: The Guilford Press.
- Nilsen, P., Eccles, M., Grimshaw, J., Walker, A., Johnston, M., Pitts, N., et al. (2015). Making sense of implementation theories, models and frameworks. *Implementation Science*, *10*(1), 53. <https://doi.org/10.1186/s13012-015-0242-0>.
- Paul, J., Metcalfe, S., Stirling, L., Wilson, B., & Hodgson, J. (2015). Analyzing communication in genetic consultations—a systematic review. *Patient Education and Counseling*, *98*(1), 15–33. <https://doi.org/10.1016/j.pec.2014.09.017>.
- Payne, K., Nicholls, S., McAllister, M., Macleod, R., Donnai, D., & Davies, L. M. (2007a). Outcome measurement in clinical genetics services: A systematic review of validated measures. *Value in Health: The Journal of the International Society for Pharmacoeconomics and Outcomes Research*, *11*(3), 497–508. <https://doi.org/10.1111/j.1524-4733.2007.00259.x>.
- Payne, K., Nicholls, S. G., McAllister, M., MacLeod, R., Ellis, I., Donnai, D., & Davies, L. M. (2007b). Outcome measures for clinical genetics services: A comparison of genetics healthcare professionals and patients' views. *Health Policy (Amsterdam, Netherlands)*, *84*(1), 112–122. <https://doi.org/10.1016/j.healthpol.2007.03.005>.

- Pengchit, W., Walters, S. T., Simmons, R. G., Kohlmann, W., Burt, R. W., Schwartz, M. D., & Kinney, A. Y. (2011). Motivation-based intervention to promote colonoscopy screening: An integration of a fear management model and motivational interviewing. *Journal of Health Psychology, 16*(8), 1187–1197. <https://doi.org/10.1177/1359105311402408>.
- Peters, K. F., & Petrill, S. A. (2011). A comparison of the background, needs, and expectations of patients seeking genetic counseling services. *American Journal of Medical Genetics. Part A, 155A*(4), 697–705. <https://doi.org/10.1002/ajmg.a.33979>.
- Pithara, C. (2014). Identifying outcomes of clinical genetic services: Qualitative evidence and methodological considerations. *Journal of Genetic Counseling, 23*(2), 229–238. <https://doi.org/10.1007/s10897-013-9654-7>.
- Redlinger-Grosse, K., Veach, P. M., Cohen, S., LeRoy, B. S., MacFarlane, I. M., & Zierhut, H. (2015). Defining our clinical practice: The identification of genetic counseling outcomes utilizing the reciprocal engagement model. *Journal of Genetic Counseling, 16*, 713–728. <https://doi.org/10.1007/s10897-015-9864-2>.
- Roter, D., Ellington, L., Erby, L. H., Larson, S., & Dudley, W. (2006). The genetic counseling video project (GCVF): Models of practice. *American Journal of Medical Genetics. Part C, Seminars in Medical Genetics, 142C*(4), 209–220. <https://doi.org/10.1002/ajmg.c.30094>.
- Ruiter, R. A. C., Kessels, L. T. E., Peters, G.-J. Y., & Kok, G. (2014). Sixty years of fear appeal research: Current state of the evidence. *International Journal of Psychology : Journal International de Psychologie, 49*(2), 63–70. <https://doi.org/10.1002/ijop.12042>.
- Silvey, K., Stock, J., Hasegawa, L. E., & Au, S. M. (2009). Outcomes of genetics services: Creating an inclusive definition and outcomes menu for public health and clinical genetics services. *American Journal of Medical Genetics. Part C, Seminars in Medical Genetics, 151C*(3), 207–213. <https://doi.org/10.1002/ajmg.c.30218>.
- Street, R. L. (2013). How clinician-patient communication contributes to health improvement: Modeling pathways from talk to outcome. *Patient Education and Counseling, 92*(3), 286–291. <https://doi.org/10.1016/j.pec.2013.05.004>.
- Street, R. L., & Epstein, R. M. (2007). *Patient-Centered Communication in Cancer Care: Promoting Healing & Reducing Suffering*. Bethesda: NIH publication.
- Street, R. L., Makoul, G., Arora, N. K., & Epstein, R. M. (2009). How does communication heal? Pathways linking clinician-patient communication to health outcomes. *Patient Education and Counseling, 74*(3), 295–301. <https://doi.org/10.1016/j.pec.2008.11.015>.
- Uhlmann, W. R., Schuette, J. L., & Yashar, B. M. (2009). In W. R. Uhlmann, J. L. Schuette, & B. M. Yashar (Eds.), *A guide to genetic counseling* (2nd ed.). Hoboken: Wiley-Blackwell.
- Veach, P. M., LeRoy, B. S., & Bartels, D. M. (2003). *Facilitating the genetic counseling process: A practice manual*. New York: Springer-Verlag.
- Veach, P. M., Bartels, D. M., & LeRoy, B. S. (2007). Coming full circle: A reciprocal-engagement model of genetic counseling practice. *Journal of Genetic Counseling, 16*, 713–728. <https://doi.org/10.1007/s10897-007-9113-4>.
- Veach, P. M., LeRoy, B., & Bartels, D. M. (2010). *Genetic counseling practice : Advanced concepts and skills*. Hoboken: Wiley-Blackwell.
- Wang, C., Gonzalez, R., & Merajver, S. D. S. D. (2004). Assessment of genetic testing and related counseling services: Current research and future directions. *Social Science & Medicine, 58*, 1427–1442. [https://doi.org/10.1016/S0277-9536\(03\)00337-X](https://doi.org/10.1016/S0277-9536(03)00337-X).
- Witte, K. (1992). Putting the fear back into fear appeals: The extended parallel process model. *Communication Monographs, 59*(4), 329–349. <https://doi.org/10.1080/03637759209376276>.
- Zellerino, B. C., Milligan, S. A., Gray, J. R., Williams, M. S., & Brooks, R. (2009). Identification and prioritization of quality indicators in clinical genetics: An international survey. *American Journal of Medical Genetics. Part C, Seminars in Medical Genetics, 151C*(3), 179–190. <https://doi.org/10.1002/ajmg.c.30220>.
- Zierhut, H. A., Shannon, K. M., Cragun, D. L., & Cohen, S. A. (2016). Elucidating genetic counseling outcomes from the perspective of genetic counselors. *Journal of Genetic Counseling, 25*(5), 993–1001. <https://doi.org/10.1007/s10897-015-9930-9>.