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## Novel Educational Material for Patients with a Variant of Uncertain Significance (VUS) in a Cancer Risk Gene

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Novel Educational Material for Patients with a Variant of Uncertain Significance (VUS) in a  
Cancer Risk Gene

by

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A thesis submitted in partial fulfillment  
of the requirements for the degree of  
Master of Science in Public Health  
with a concentration in Genetic Counseling  
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## **Abstract**

The number of individuals being tested for hereditary cancer syndromes has greatly increased in the last several years and many people receive Variants of Uncertain Significance (VUS) as a test result. Although VUS results should not guide medical management, patients and even some healthcare providers continue to use a VUS to alter or receive unnecessary medical care.

We conducted a needs assessment via literature review and analyzed VUS patient interviews from a previous study with the goal of identifying various themes that could help determine content, layout, and messaging to incorporate into online educational materials. The needs assessment found few educational materials and identified the following themes: people may take inappropriate medical actions based on VUS results, people report feeling confused regarding their VUS result and how it is not helpful in determining medical management, rates of family sharing regarding genetic test results and family history of cancer remain low, people express concerns about sharing family history information, and advice from patients with a VUS regarding how to share test results and cancer risk information and why it is important.

Using findings from the needs assessment we developed materials to educate patients about their VUS result, provide information about risks associated with a family history of cancer and prompt them to share cancer risk information with family members to promote cancer screening and prevention. Materials were evaluated using the CDC Clear Communication Index Score Sheet. This identified two areas in which to improve, including the number of main messages and numeracy. However, we determined that rather than one single main message we

were comfortable with the materials reinforcing three main messages. Finally, we describe our ongoing process of collecting feedback from patients and healthcare providers that will be used to modify the materials before they are tested as part of a formal research study.

## **Introduction**

Around 2-5% of all colorectal cancers and 5-10% of breast cancers are caused by a hereditary cancer predisposition syndrome, such as Lynch Syndrome or Hereditary Breast and Ovarian Cancer Syndrome (Sehgal et al., 2014; Apostolou & Florentia, 2019). Increases in testing availability and the number of genes tested has led to many people being identified as having a Variant of Uncertain Significance (VUS), where it is uncertain whether the gene change increases cancer risk or not. Based on the American College of Medical Genetics (ACMG) recommendations, a VUS should not change a patient's medical management, and it is pertinent that they understand this so they do not receive unnecessary medical interventions (Richards et al., 2015).

Risk appropriate care is complicated in patients with a VUS because current professional guidelines, such as the National Comprehensive Cancer Network, may call for increased cancer surveillance or medical interventions based on their family history rather than their genetic test results, as VUS results alone are insufficient to warrant medical interventions or increased surveillance. Women with a first-degree family member who has had breast cancer are at double the baseline risk for developing cancer themselves, putting their lifetime risk at around 24% (Brewer et al., 2017). Individuals who have one or more close family members with colorectal cancer are at two to eight times the risk of developing colon cancer themselves (Butterworth, Higgins, & Pharoah, 2006), which can increase these individuals' risk to around 10%.

The National Comprehensive Cancer Network Guidelines [NCCN] for Breast Cancer Screening and Diagnosis (2020a) state that women with a computer-modeled risk of over 20%

(based on family history) may consider receiving a yearly mammogram as early as 30-years-old, and a yearly breast MRI as early as 25-years-old. These ages are significantly younger than the recommendation for women with an average risk, who should begin receiving mammograms yearly at around age 40 (NCCN, 2020a). The NCCN guidelines for Colorectal Cancer Screening (2020b) state that individuals with a first-degree relative with colorectal cancer or high-grade polyp at any age may receive a colonoscopy at 40, or 10 years before the earliest diagnosis in the family. Again, this is significantly younger than the recommendation for people with an average risk, who should begin colonoscopies at around age 50 (NCCN, 2020b).

Family sharing of familial cancer risk information is low, limiting the ability to reduce cancer related morbidity and mortality among relatives who are at higher risk than the general population (Bowen et al., 2017; Kinney et al., 2014; Eizjenga et al., 2018; Wiseman et al., 2010; Chivers, et al., 2010). Communication about both VUS results and family cancer history appear to be subpar and there is little patient-friendly educational material that addresses both of these topics (Bowen et al., 2017; Kinney et al., 2014; Eizjenga et al., 2018; Wiseman et al., 2010; Chivers, et al., 2010). Our study aims to create and evaluate material that will directly address the needs of this patient population.



## **Overview of Process**

Prior to developing an educational tool, we conducted a needs assessment that included a literature review and analysis of VUS patient interview transcripts. Findings from this review and analysis were organized into a table by themes and used by the evaluation team to create educational materials. The first author, MK, evaluated materials using the CDC Clear communications index score sheet to assess the clarity and understandability of the educational materials. The evaluation plan was reviewed by the University of South Florida's Institutional Review Board (IRB) and determined to be exempt from IRB oversight as it consisted of an iterative evaluation designed to gain feedback about the educational materials from both patients who had received a VUS result and genetic healthcare providers.

### Needs Assessment

The needs assessment began with a literature review using the search terms, "Variant of Uncertain Significance," and, "Variant of Uncertain Significance education." in the University of South Florida's online, "FindIt!" service that includes hundreds of databases such as Pubmed and CINAHL. Abstracts were scanned by MK to determine relevancy to the study. Studies that discussed patient and provider perception and understanding of VUS test results, how they communicate (or do not communicate) such results to family members, and how patients feel about such test results were included. Excluded were articles that did not involve genetic testing, discussed VUSs in non-cancer genetics specialties or different testing modalities (e.g.: microarray), and articles discussing reclassification of specific VUS test results. Ten studies directly related to the project were identified. The major and minor findings of the studies were

synthesized into a table by MK. When deemed useful, direct quotes were also organized into the table. After the first few notable findings, themes from the data began to emerge and key findings were then organized into thematic categories by MK. For example, a handful of studies discussed how a VUS may lead individuals to undergo medical management that may not be risk-appropriate. These findings were grouped together under the theme “Taking inappropriate action based on a VUS result.”

Interview transcripts from a previous study involving six women with VUSs in a cancer risk gene were each reviewed by the first author, MK. This was done to increase familiarity with the content of the interviews and provide a general understanding of the topics addressed in the interviews, which included feelings regarding VUS results and family sharing of results. MK then completed a second review to systematically extract any information that supported or added new content to the themes from literature review, and to identify additional themes and content that might help inform the development of educational materials.

To complete this process, interviews were read segment by segment with each segment being compared to the literature review data table to determine if it added detail to an existing theme or belonged to a novel theme. For example, quotes from transcripts were added to illustrate the theme from the literature review regarding confusion over what a VUS is.

A few new themes were added to the table to represent other findings extracted from transcript sections. These included descriptions of various feelings about the uncertainty surrounding their VUS results, attitudes surrounding the importance of sharing information, and advice to other VUS patients. For each of these unique themes, exemplary quotes were extracted and added to the table to represent the range of responses from the six patient interviews.

Upon completion, the table was shared and reviewed by DC, a member of the evaluation team who has experience in qualitative data analysis and thematic categorization. The themes and supporting examples were discussed, revised, and recategorized until agreement was reached and thematic categories were finalized.

### Needs Assessment Findings

The initial literature review found evidence that many patients struggle to understand their VUS result and have a hard time accepting the lack of medical management that comes with it (Bowen et al., 2017; Kinney et al., 2014; Eizjenga et al., 2018; Wiseman et al., 2010; Chivers, et al., 2010). Further, there is evidence that non-genetics providers are often tasked with interpreting these results, which increases the rate of inappropriate medical management, such as prophylactic mastectomy when it is not indicated (Murray et al., 2011; Macklin et al., 2019). Patients tend to misinterpret their own results, and subsequently may communicate inappropriate or less reassuring messages to family members (Reuter et al., 2019; Medendorp et al., 2020). The less reassuring and clear the patient was in explaining the result to family members, the more likely the family member was to perceive cancer as hereditary as well as higher cancer risks (Vos et al., 2011). Table 1 summarizes key findings of the literature review and analysis of interview data. No research studies were identified that detailed the development of educational tools for VUS patients. One study mentioned an online tool developed to help family members of a VUS patient understand the result in the context of family variant interpretation research studies (Garrett et al., 2016). While some elements of this website are similar to ours, including a description of VUS results and how to contact family members to explain such results, overall, it

is not an interactive tool designed to increase family sharing of cancer risk information for personal cancer risk reduction (Garrett et al., 2016).

A review of VUS patient interview transcripts further supported the literature review findings. Some patients expressed initial confusion over their results, which then turned into frustration due to the lack of meaning these results have for medical management. Other patients seemed to understand that although the results won't change anything now, it might be important for family members to know about a VUS in case more information is found in the future.

When prompted to offer advice to other individuals who might receive a VUS result on genetic testing, all of the participants readily offered their insight. Advice included disseminating risk information throughout the family in steps, starting with the family members perceived to be the most supportive. One patient expressed that sharing VUS results should be considered a necessity, while another patient and her husband described how they will only reveal their VUS to their family members should it be reclassified as pathogenic. They explained that for the time being, they shared familial risk information and should they pass away before the VUS is reclassified, their test result is included in their will.

**Table 1*****Findings from the Needs Assessment***

<b>Theme</b>	<b>Quotes/other Evidence</b>	<b>Incorporation into Educational Tool</b>
Taking inappropriate medical action based on a VUS result	<p>Of 22 women who had a <i>BRCA</i> VUS (including three likely pathogenic) and received a Risk Reducing Oophorectomy, 20 had a personal history of breast cancer and 2 had a family history of breast or ovarian cancer subsequently two of these women had their result reclassified as benign and one woman had her VUS upgraded to deleterious. (Murray et al., 2011).</p> <p>Almost 60% of surveyed physicians reported they would not feel comfortable explaining VUSs to patients (Macklin et al., 2018) 76% of providers surveyed recommended familial genetic testing for a VUS (Macklin et al., 2018). “Previous studies have shown that patients struggle with the ambiguity of a VUS result and confusion over its clinical implications.” (Reuter et al., 2019. p. 883).</p>	<p>Messages include: 1) VUS results should not usually change medical management; 2) Genetic testing for the VUS is not usually helpful for family members because it is not used to change their medical care; 3) Medical care is usually based on personal and family history of cancer.</p>
Confusion over what a VUS is and frustration about how it is not helpful	<p>“... VUS reports discussed with counselees are too frequently inaccurately perceived typically leading to overestimation of cancer risks, adverse psychological outcomes and more radical medical decisions” (Eccles et al., 2015, p. 2062).</p> <p>“Like I said, I was hoping more for a yes or a no because I was going to use these results to determine if I felt like I needed to do any further precaution. Prophylactic treatment. That's why I was [wanting] more of a yes or no because that was going to help me weigh my decision of what to do next.” [Participant 1, Female, BRCA2 VUS] [regarding initial feelings of receiving VUS result] “Really what does "variance of unknown significance" mean? That was my biggest question that I had, that I wanted answers to ...” [Participant 1, Female, BRCA2 VUS]</p> <p>Two studies showed that between 6.6% and 15% of those with a VUS result perceived their risk of carrying a predisposition to cancer as nonexistent. Still, other studies show that individuals with a VUS result still perceive their risk of having a pathogenic mutation as high. Other reports show that perceived cancer risk after a VUS result decreases with time (Medendorp et al., 2020).</p>	<p>Messages explain how a VUS doesn't change anything at this point in time and most VUS results are later found to be normal variation – not disease causing.</p> <p>Patient stories or quotes that offer a relatable perspective and explanation of how others who received a VUS result expressed some confusion and frustration.</p>

**Table 1 (Continued)**

Theme	Quotes/other Evidence	Incorporation into Educational Tool
<p>Family members are often not aware of the test result. They also are unaware how cancer family history can increase risk for cancer (even when no genetic cause is found).</p>	<p>Of 85 women who had a mother/sister with breast cancer and a VUS in BRCA1/2: 42% said they felt very little info was shared with them 52/81 said they believed the result was negative 22/81 were unaware of the test result 69/81 were not aware their family member had been provided a summary letter (Himes et al., 2019).</p> <p>Family members reported that general print materials would be most helpful (in the context of Lynch syndrome) (Petersen et al., 2019).</p> <p>How a VUS result is communicated to other at-risk family members influences how those individuals perceive the result as well (Vos et al., 2011). Many patients attributed their cancer risk to environmental or behavioral factors upon receipt of a VUS result, completely ruling out the possibility of any genetic etiology (Reuter et al., 2019). Those without a strong family history of cancer were more likely to view a VUS as being insignificant in their own cancer diagnosis (Reuter et al., 2019)</p> <p>“However, patients struggled to understand that the absence of a pathogenic variant did not rule out a genetic etiology for the cancers in their family, a theme which has been previously documented in the context of <i>BRCA1</i> and <i>BRCA2</i> testing,” (Reuter et al., 2019, p. 881).</p>	<p>Handouts &amp; videos for family members that 1) Describe a VUS result simply and accurately 2) Address that having a closely related family member with cancer can increase one’s lifetime risk for cancer and may change recommendations for medical care.</p>
<p>Concerns about sharing with family members</p>	<p>People face difficulties when deciding whether to communicate personal health information (Greene et al., 2012). There are very few reports of clinicians disclosing shared cancer risk information with their patients’ family against the patient’s wishes (Mendes et al., 2016). “Successful family communication about important genetic information is dependent on a number of factors including pre-existing family dynamics and an individual’s ability to give and receive complex genetic information.” (Hodgson et al., 2014, p. 4). One of the most powerful predictors of whether a woman will share her genetic information is based on her perceived reaction of the family member (Montgomery et al., 2013).</p>	<p>Experiences and quotes from VUS patients discussing their concerns about family member reactions and outcomes of disclosing information.</p> <p>Handouts for family members of VUS patients.</p>

**Table 1 (Continued)**

Theme	Quotes/other Evidence	Incorporation into Educational Tool
Advice from people with VUS results about sharing VUS result with family members	<p>“I definitely think that it's a positive thing. I don't see any negatives to doing it, so why wouldn't you? At least from my perspective anyways, I don't see a negative to it, but then again, I have a family that has always been supportive and so I knew that they would be supportive still with this. Somebody who doesn't have that type of family, I guess, maybe my suggestion would be to share first with somebody who you know is going to be supportive so that you can get that reinforcement or that courage that you need to continue to share with others.” [Participant 1, Female, <i>BRCA2</i> VUS]</p>	<p>Experiences and quotes from VUS patients discussing their concerns about family member reactions and outcomes of disclosing information.</p> <p>Handouts for family members of VUS patients.</p>
	<p>“I would tell them that if you really love the people in your life, this is information that they need to have. There's no decision or question in my mind about the necessity of sharing this information.” [Participant 2, Female, <i>BRCA2</i> VUS]</p> <p>“We actually have a copy of the genetic testing in with our will and trust. And if we both pass at the same time then that information will become available. We have four children, we have 12 grandchildren. But we chose to not share it [VUS] with them unless we get an update in the future from [Cancer Center] that says, yeah this is an important thing to share. You know?” [Participant 3, Female, <i>BRCA2</i> VUS]</p>	
Importance of sharing cancer risk and cancer screening information with family members	<p>“Or if it's something that they would be of concern, you know, at passing on to their children or so on, then ... You know what we've shared with them so far is, mom had severe colon cancer and therefore you should have early testing [screening for colorectal cancer] and that your kids should know about it so that they should probably be tested [screened for cancer]. That's just an example.” [Participant 3, Female, <i>BRCA2</i> VUS]</p>	<p>Language emphasizing the importance of sharing cancer risk information so family members can get the medical care that is right for them – care that may even save their life.</p>
Desiring more information	<p>[Regarding having take-home educational info about her result] “My husband and I looked at it on numerous occasions too, so I do feel like having something more than just the results to go home with, something else that talks about genetics, et cetera, was helpful.” [Participant 1, Female, <i>BRCA2</i> VUS]</p>	<p>Website providing them more information including VUS handouts and a video.</p>

## Educational Materials Development

Educational materials were primarily developed by MK and DC with input from a PhD researcher in Health Communication (MDK) and several other evaluation team members. We began by building on and modifying existing educational material about VUS results that had been created previously by several evaluation team members as part of an audio/visual tool describing possible genetic test results. The team decided that including audio as well as visual animations might make the content was more interactive as part of several brief videos.

When developing the materials, the team felt it was important to help patients differentiate between sharing cancer family history information and VUS test results because a family history of cancer has the potential to change management for family members (Richards et al., 2015, NCCN 2020a, NCCN 2020b), and thus was deemed more important to be shared than a VUS result that should not change medical management based on ACMG guidelines (Richards et al., 2015). Nevertheless, we acknowledge other reasons why family members may benefit from knowing that someone in the family had genetic testing.

Addressing family communication was also an important part of the tool. We found from patient interviews that hearing the experiences of others who have gone through a similar situation may be helpful. As such, advice about sharing VUS or cancer risk information was used to develop handouts with quotes inspired by the interviewees that address concerns about sharing family information. Further, the concern with sharing accurate information with family led to the development of the single-page handouts that participants could easily email or print to share accurate and simple information with their family members.

Once the overall format was established and draft materials created, many rounds of editing by evaluation team members involved working on the level of vocabulary used and how



information was presented in each of the different aspects of the tool with the goal of making the materials as succinct and clear as possible. After several rounds of review and edits by the evaluation team, one interactive video about VUS results, two videos explaining breast and colon cancer risks and screenings, three single-page handouts, and two handouts with advice or ideas of what one could say to family members were developed. These multiple components were ultimately integrated into a single website. The main components are described in more detail below.

The main resource is a three-minute, interactive video designed to explain VUS results to patients as well as introduce the idea of familial cancer risks and that cancer could be prevented or found early when it is easier to treat. To keep the length of the video short we included two “learn more,” options to explain genetic testing and the reclassification process for VUS results in more detail.

The website included frequently asked questions (FAQs), which succinctly answer several questions people with a VUS might have such as, “What is a VUS?”, “Should my family members be tested for the VUS?”, and “What information should I share with my family members?” Together the VUS educational video, FAQs, and single page VUS handout describe VUS results, explain that VUS results should not be used to change medical management, discuss familial risks associated with cancers regardless of genetic testing, and link to support materials that can be printed and aid in discussing risks with family members.

Two additional videos (about two minutes each) were produced to explain how a family history of colorectal cancer or breast cancer affect lifetime risks for developing those cancers and the efficacy of cancer screening. Two single-page handouts reinforced the content in the educational videos, explaining how a family history of colorectal or breast cancer can affect

lifetime risks for cancer and prompting individuals with a family history to talk to their healthcare providers about cancer screening.

#### Evaluation Methods using the Clear Communication Index

The Centers for Disease Control (CDC) Clear Communication Index Score Sheet (2020) was used to evaluate the educational materials after incorporating feedback or improvements provided by several research team members. This Index Score was designed to assess educational or other communication materials' main messages, language levels, information design, and behavioral recommendations, among other measures (CDC, 2020). The index score is created based on multiple criteria such as, "Does this material contain one main message statement?", and "Is the main message at the top, beginning, or front of the material?" For questions in which the education materials meet the outlined criteria, a score of 1 is given. A score of 0 is given if it does not meet the criteria. Scores of 90 and above are considered passing, while those that fall below do not pass.

#### Evaluation Findings using the Clear Communication Index

Using the CDC Clear communications Index Score Sheet, the educational materials as a whole scored 60 out of 100. Reasons for point deductions include the materials having three main messages as opposed to a single main message, as well as the use of passive voice in the call to action portion of the educational materials. Further, while the materials did define and explain a number of terms, points were lost because not all unfamiliar terms are explained or described, instead being simply defined. In the breast and colon cancer risk videos, the words such as mammogram and colonoscopy are defined but not explained in detail.

In terms of numeracy, the materials also lost points as they do not always explain what numbers mean. For example, lifetime risks for cancer in various scenarios are presented to patients as a percentage (e.g. women in general have a 12% lifetime risk of developing cancer) but these risk figures are not defined or explained in another way.

Areas in which the materials excelled include having at least one call to action (in this case sharing cancer risk and screening information with family), using numbers that are familiar to the audience such as whole numbers when describing the efficacy of mammograms and colonoscopy (rather than percentages or fractions), and explaining how having a family history of cancer can increase cancer risks to the audience. The materials earned additional points because the benefits and risk associated with the recommended behavior (e.g. family cancer risk information sharing) were acknowledged.

### Evaluation of Materials by Patients and Providers

To further improve the educational materials, we planned to elicit feedback from cancer genetic healthcare providers as well as patients with a VUS in an iterative manner until saturation of feedback is reached. This plan involves offering participants a short pre-survey after which they review the materials and then complete the post-survey. A subset of individuals will be asked to participate in interviews designed to gather additional feedback on the materials.

### Survey Measures

The Disclosure Decision Making model and the COM-B behavior change model were used to develop patient and provider surveys (Greene et al., 2012; Michie et al., 2011). The Disclosure-Decision Making Model states that constructs such as anticipated response of family

members and disclosure efficacy (e.g.: a person's perceived ability to accurately relay such information to others), and the relationship quality between two individuals determine whether a person will disclose health information to family members (Greene et al., 2012; Michie et al., 2011). To assess the first two constructs, VUS participants were asked if they agreed or disagreed with statements such as, "I believe sharing cancer risk information will upset some of my family members," and, "If I wanted to share this information, I am confident I would be able to explain the information." These questions were assessed in the patient pre- and post-surveys to see if the material influenced these constructs. Questions assessing relationship quality between them and their first-degree family members were included in the initial draft of the survey but were subsequently removed for the sake of brevity.

The COM-B model states that behavior change (i.e., familial cancer risk disclosure) is related to an individual's perceived capability, opportunity, and motivation (Michie et al., 2011). Motivation was assessed using twenty-five 5-point Likert-type questions asking the extent to which they agree or disagree with statements such as, "Sharing information with all my adult family members is something I want to do." Opportunity was assessed with eighteen 5-point Likert-type statements such as, "If I decided to share this information with all my adult family members, I would have the chance to do it." Capability was assessed with eight 5-point Likert-type statements such as, "I am confident I would know what to tell my family members.", and, "I am confident I would be able to deal with their reactions."

While this study lacked the statistical power to evaluate the efficacy of the material, knowledge questions were included in the pre- and post-surveys for VUS participants to assess changes in knowledge. Examples of knowledge questions included, "Finding a VUS usually

means someone should get cancer screening more often than those without a VUS,” and, “When a person has cancer, their family members may be at higher risk for cancer.”

Participants were asked for basic demographics including their age group, if they had ever been diagnosed with cancer (which cancers and at what age) as well if any of their family members had been diagnosed with cancer (which cancers).

Both provider and patient participants were asked questions regarding their perceived acceptability and appropriateness of the materials. These questions were based on existing four-item measures known as Acceptability of Intervention Measure (AIM) and Intervention Appropriateness Measure (IAM) (Weiner et al., 2017). These measures include Likert-type statements such as, “I like the educational materials,” and, “the educational tools meet my approval.” All participants were also provided free response questions in the post-survey requesting their feedback regarding the materials.

As part of the pre-survey, providers were asked basic demographics questions such as their gender, how long they have been involved in Cancer Genetic Counseling, and how much time they spend counseling patients about VUS results. They were also asked six 5-point Likert-type questions asking the extent to which they agree with statements such as, “I encourage patients with a VUS to disclose their test results to family members.”, and, “ For patients with breast or colorectal cancer who don’t have a pathogenic variant, I usually talk to them about increased cancer risks for their first degree relatives.”

#### Semi-structured interview guide

Semi-structured interviews were planned for those participants who expressed willingness to be interviewed on the survey. These interview questions aimed to expand on the

participants' specific answers to survey questions and gather more detailed feedback about the educational materials.

### Sample Recruitment and Procedures

Patients 18 years and older with a personal or family history of breast or colorectal cancer and a VUS result on genetic testing were recruited from the Inherited Cancer Registry (ICARE) via email invitations. Healthcare providers were recruited by the National Society of Genetic Counselors (NSGC) website directory. Providers who indicated they practiced in Cancer Genetics and were open to student contact were emailed. Emails were sent out in multiple rounds, with ten emails sent per batch. If an insufficient number of participants responded after five days, the next batch of ten emails was sent.

Participants were able to access an informational document that described the evaluation procedures including the voluntary nature of the evaluation, time involved, and how they would be compensated \$15 for completing the pre-survey, reviewing the materials, and completing the post-survey. They were instructed to proceed to the pre-survey if they chose. After completing the pre-survey they were linked to the online, educational material and were instructed to follow a link to the post-survey after reviewing the materials. Once participants finished the post-survey they were invited to sign up for a semi-structured interview.

For future data collection, participants who agreed to an interview as part of the initial survey will be contacted for interview via online video chat such as Microsoft Teams or Zoom. Each interview should last about 30-45 minutes where participants will be asked follow-up questions about the acceptability and understandability of the material as well as ways to improve it. Individuals who complete interviews will be given another fifteen dollar gift card.

### Findings from Patient and Provider Surveys and Interviews

At the time of write up, recruitment of provider and patient participants had begun, but no complete responses had been collected from the surveys and thus no interviews had been conducted.

## **Discussion**

After conducting a needs assessment, we developed educational materials designed to address patient understanding of VUS results as well as risks of family cancer history and benefits of cancer screening to fill a gap we identified. Although one website, FindMyVariant.org, was identified through literature review its purpose was to find family members of those with a VUS for familial segregation analysis in hopes of resolving VUS results more quickly (Garret et al., 2016). While FindMyVariant addresses family communication, its main purpose is related to collecting data for VUS reanalysis rather than for the purpose of cancer screening and management in other at-risk family members based on cancer family history (Garrett et al., 2016).

FindMyVariant does not address that it is important for family members to know cancer family history information because it may alter their own cancer screening and risk management options (Garrett et al., 2016). Further, the FindMyVariant website actively promotes the sharing of VUS results, while our materials attempt to let the patients decide whether to share their VUS result, while emphasizing the importance of sharing family cancer history. FindMyVariant describes how they can use various tools such as social media and other mutual contacts to reach out to more distant family members rather than addressing concerns patients might have about family communication (Garret et al., 2016). Finally, the FindMyVariant website consists of online text, but does not have videos or printable/downloadable handouts.

For many individuals, the idea of obtaining a VUS result on genetic testing, or a familial risk for cancer can seem nebulous. Around half of adults in the US have intermediate health



literacy, meaning they possess some skills that are deemed necessary to perform moderately challenging literacy activities, but this does not include the ability to find the definitions of medical terms they may come across on their own (Kutner et al., 2006). This was considered heavily when developing the tool. However, the materials lost points in the numeracy section of the Clear Communication Index Score Sheet. The example in the CDC index says, “The amount of meat recommended as part of a healthy meal is 3 to 4 ounces – it will look about the same as a deck of cards” (2020). There is difficulty in further quantifying lifetime risks for cancer, other than percentages. They could be expressed in two different ways by saying, “Having one first-degree family member with colorectal cancer doubles the risk for cancer.” However, this may be misleading because a doubled risk could be as low as 10% given general population risks for colorectal cancer. An alternative we will consider is to say 1 in 10 individuals who have a close family member with colorectal cancer will also get colorectal cancer in their lifetime. We will assess the presentation of cancer risks and alternative presentations when receiving feedback from patients in order to gain a better understanding of how they perceive those numbers.

Based on criteria from the Clear Communication Index Score Sheet, educational materials should have a single main message (2020). Given the complex nature of VUS genetic test results and familial cancer risks, distilling the message down to one point is nearly impossible. Notably, if the Clear Communication Index Score Sheet were modified to allow up to three main messages, scoring of the educational materials improves from 60% to 80%, where each point is worth 5% of the total score. The first question, worth one point, is if the material has one main message. If the answer to this is, “no,” then points are lost for this question and automatically lost for the next three questions which assess if the main message is at the top of the materials, if the main message is emphasized with visual cues, and if there is at least one

visual that conveys the main message. If three main messages were allowed, the material gains points for all of these items. The main messages are emphasized with visual cues, (they are animated to appear with the narration and are encapsulated in boxes that match the theme of the materials) as well as portrayed with a visual. In addition, there are many visuals in the each component of the material that support the main messages. For example, a visual representation of the proportion of people who will survive if cancer is found at an early stage compared to a later stage is included in both the breast and colon cancer videos.

In order to get the materials an additional ten points for a passing grade of 90, it would require two more items be changed to fit the criteria in the score sheet (2020). Two items that could be changed relate back to literacy and numeracy. For example, if every unfamiliar term were explained rather than simply defined, the materials would gain a point, or five percentage points. As stated previously, if every number used were explained in simple language, it would gain another point, or five percentage points. Still, these changes would only promote the materials to a passing grade if three main messages were allowed.

### Practical Implications

In general, doing a need assessments via literature review is a helpful way to guide development of educational materials in hopes they better meet the needs of the target population. For this particular study, the, “corporate approach,” was taken (Stevens & Gillam, 1998). This approach is described as a method in which informants (which include physicians, public health officials, patients, and other allied health professionals), provide knowledge and guidance as to what patient needs are (Stevens and Gillam, 1998). Thus, a needs assessment is

the first step to developing educational materials that will be deemed acceptable and efficacious by patients.

Another important step in developing educational materials includes review by experts in the field (Arora, Sinha, Malhotra, & Ranjan, 2017). In fact, it is recommend this step is completed before patients are provided with the material (Arora et al., 2017). A focus group has been planned with various cancer genetics experts involved with the research team in order to further edit the materials before patients are asked to review the materials.

Once feedback from providers and patients is received and the materials completed, testing the materials in a clinical setting with genetic counselors or other genetics providers may also help assess its acceptability. This is particularly important because acceptability as assessed by providers can determine whether or not providers will implement the tool in their own practice and whether patients will follow the recommended behavioral change (Sekhon, Cartwright, & Francis, 2017).

### Limitations

Limitations of this needs assessment and evaluation include a low level of patient and provider participant recruitment at the time of write-up. To address this, it was decided that participants be directly invited to review the tool via interview, rather than complete a two-part survey.

Only one member of the research team conducted the literature review and systematically analyzed the interviews. However, a second evaluation team member had reviewed the transcripts previously and helped with thematic categorization of findings. Additionally,

reliability of the CDC Clear Communication Index Score could be determined if the materials are independently scored by multiple individuals.

### Conclusion

To our knowledge, this is the first time VUS educational materials have been developed in a systematic way, focusing on previous research to address the concerns and unique needs of VUS patients. The novel educational materials were designed to aid VUS patients in understanding their genetic test result, the importance of sharing familial cancer risks, and assist in family communication of cancer risk (and VUS results if they choose). While the iterative feedback process from patient and provider participants is not yet complete, future aims include receiving such feedback and adjusting the materials accordingly. After this evaluation process is complete, studies on the efficacy of the material may commence.

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