Where Do We Draw the Line?: Navigating Conflicts of Interest in the Genetic Counseling Profession

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in
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by
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ABSTRACT

Where Do We Draw the Line?: Navigating Conflicts of Interest in the Genetic Counseling Profession

A thesis presented to the Graduate Program in Genetic Counseling

Graduate School of Arts and Sciences
Brandeis University
Waltham, Massachusetts

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Over the past ten years, the roles of genetic counselors have expanded beyond the clinical realm into new and emerging non-clinical opportunities. Recently, the media began to question whether genetic counselors who counsel patients on genetic testing should be paid by the same companies performing the test, thus presenting the possibility of a conflict of interest (COI). The purpose of this study is to assess genetic counselors’ current opinions on what constitutes a COI, whether they believe it is necessary to disclose a given COI to a patient, whether they experienced a COI in their practice, how they managed the COI, and where they sought out guidance regarding its disclosure. Two hundred forty-two genetic counselors practicing within the U.S. and belonging to NSGC completed our anonymous online survey with a response rate of 9.3%. Regardless of their current role as a genetic counselor, most genetic counselors generally agree whether or not a given hypothetical situation presents a COI and most agree that disclosure of a COI to a patient is necessary. Fewer than 25% of the respondents reported encountering at least one COI throughout their career, whereas 69.2% report that they never had (N=240). Of the 32 genetic counselors that reported experiencing one of seven specific listed COI’s, twenty-
five did not disclose their COI to their patient. The most common resources used by genetic counselors seeking guidance on COI disclosure were their institutional guidelines (N=58) and most genetic counselors found their institution’s guidelines to be the most helpful of all resources used (N=54). In light of the increasing potential for COI’s in the genetic counseling profession, it is important for NSGC to develop clear-cut professional guidelines on what constitutes a COI, and how or when a COI should be disclosed to a patient.

**Keywords:** Conflict of interest; potential conflict of interest; genetic counselor; conflict of interest disclosure; guidelines, National Society of Genetic Counselors (NSGC)
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Introduction

Over the past ten years, the roles of genetic counselors expanded beyond the clinical realm into new and emerging non-clinical opportunities (NSGC, 2006, 2016). In these new roles, genetic counselors no longer provide the same kind of direct patient care as they would by working solely in a traditional clinical setting. Instead, counselors may take on non-clinical roles in industry, research, diagnostic testing laboratories, education, advocacy, health policy, public health, and administration (Warren, Callanan, & Leroy, 2005). Genetic counselors may also have more than one professional responsibility at a given time. For example, a clinical prenatal genetic counselor working for a hospital might also have a part-time job working for a prenatal genetic testing laboratory or a genetic counselor may be employed by a commercial laboratory to counsel patients in a hospital clinic or doctor’s office full time. This shifting landscape has expanded the opportunities available to genetic counselors, but has also raised the possibility for new ethical dilemmas to emerge, especially in regards to the potential for conflicts of interest (COI’s). Some of these ethical concerns include: what practices does the genetic counseling community view as COI’s, how should the genetic counseling community approach potential COI’s that arise, whether COI’s that do present should be disclosed to patients, and if so, how?

Genetic Counseling and COI’s in the News

On March 6, 2016, The Boston Globe published the article, “When baby is due, genetic counselors seen downplaying false alarms,” which raised a number of issues, but ultimately called into question the integrity of the genetic counseling profession (Daley, 2016). Specifically, the article claimed, “…Parents are starting to question the independence of the fast-
growing field of genetic counseling as more and more counselors are paid by the companies that make the tests... (Daly, 2016).” A similar article was published in *The New York Times* in 2012 that also raised questions regarding whether genetic counselors who counsel patients on genetic testing should be paid by the same companies performing the test (Pollack, 2012). Opponents of these arrangements argue that these relationships pose a potential COI, where the company-employed counselors might be influenced to recommend more testing than is appropriate or withhold from offering a test provided by a rival laboratory (Pollack, 2012). These articles sparked a conversation within the genetic counseling community on what constitutes a COI in the profession and how, if at all, to approach conflict of interest disclosure with patients. There are variations in COI disclosure guidelines across various governing professional bodies, making it a challenge for genetic counselors to navigate these ethical quandaries. With the recent rapid expansion of the genetic counseling profession into historically non-traditional roles, it is timely that the National Society of Genetic Counselors (NSGC) is revisiting the existing NSGC guidelines to ensure that they are comprehensive in providing clear ethical and professional guidance on COI’s and COI disclosure (NSGC Code of Ethics, 2016).

*Physicians and COI’s*

While NSGC currently provides limited information or guidance on COIs and COI disclosure to patients within the genetic counseling community (NSGC Code of Ethics, 2016), the medical community is bound by a reporting requirement called *Open Payments* (The Department of Health and Human Services, Centers for Medicare and Medicaid Services, 2016). *Open Payments* is a national program under the Physician Payments Sunshine Act that promotes transparency on all financial relationships between physicians and the healthcare industry (The Department of Health and Human Services, Centers for Medicare and Medicaid Services, 2016).
Physicians that participate in the U.S. federal health programs are required by law to publish data regarding their financial relationships, which then becomes available to the general public. However, this law does not apply to other healthcare providers, including genetic counselors, leaving them without much regulation or guidance on how to manage COI’s and COI disclosure.

While no studies exist that explore patient views on COI’s with respect to genetic testing, there are numerous studies that investigate patient perspectives and opinions on physicians with regard to COI’s (Lockhart et al. in 2013, Camp et al., 2015; Coors et al., 2015; Oakes et al., 2015; Yi et al., 2015; Yi et al., 2016). Camp et al. investigated postoperative patient opinions on the financial relationships between their surgeons and surgical device manufacturers by interviewing 33 patients in a 2015 Canadian study (Camp et al., 2015). Five major themes were identified: 1) the existence of financial relationships between surgeons and surgical device manufacturers is unknown to many patients; 2) patients support financial relationships that foster innovation and research, but oppose relationships involving financial incentives that benefit only the surgeon or the manufacturer; 3) patients believe that disclosure of financial relationships during the consent process distracts the patient from more important risks; 4) patients prefer professional oversight, but reject oversight from the government; 5) patients trust surgeons to make appropriate patient-oriented decisions (Camp et al., 2015). Additionally, patients support these financial relationships with the hopes that someday these interactions will benefit future patients (Camp et al., 2015)

Research Study Goals

There is currently a gap in the literature on identifying conflicts of interest within the genetic counseling profession. In addition, there is limited information on if or how these COI’s should be disclosed to patients. The goals of this study were to: (1) assess genetic counselors’
current opinions on what constitutes a professional COI; (2) determine whether or not genetic counselors experienced a past COI in their practice; (3) investigate whether or not genetic counselors believe it is necessary to disclose a given COI to a patient; (4) determine current practices on how genetic counselors disclose COI’s and how they think COI’s should be disclosed moving forward; and (5) identify which guidelines in the past were most helpful in assisting genetic counselors with the disclosure process. We hope the results of this study provide insight into the potential for COI’s in the future, how genetic counselors are currently approaching COI disclosure with their patients, and also whether or not current guidelines on conflict of interest disclosure should be amended.
Methods

Study Design

This is an exploratory quantitative study supported by qualitative responses by research participants. The Brandeis University Institutional Review Board determined that this study was exempt from full review.

Participants

Eligible participants in this study included genetic counselors currently practicing in the United States and genetic counseling students attending training programs in the United States. At the time of this study, individuals who either belonged to a genetic counseling training program or practiced outside of the United States were excluded from this study. We recruited participants (See Appendix A: Recruitment Notification) from NSGC via an e-blast through the organization’s listserv. Approximately two weeks after the initial recruitment email was sent, we sent a follow-up reminder email through the NSGC listserv. Participants had the opportunity to enter a random drawing for one of three $50 Amazon.com gift cards. The participants’ contact information was not directly linked to their survey responses to maintain anonymity.

Data Collection

We used an anonymous online survey created through Qualtrics to collect our data (See Appendix B: Study Instrument). The survey was open from January 11, 2017 through February 8, 2017. The survey consisted of a total of 25 questions. Since participation in this study was voluntary and participants had the opportunity to withdraw at any time, we anticipated variation in the response-rate from question to question. The survey was divided into three main sections
asking questions pertaining to: (1) Demographic Information; (2) Defining Conflicts of Interest; and (3) Guidelines on Disclosing Conflicts of Interest.

In the “Demographic Information” section, we asked questions about their current role(s) as a genetic counselor, the number of years they have worked in this role, and if they previously worked in a different genetic counseling role. We provided a series of definitions for the various roles from which participants could choose. We defined a clinical genetic counselor as “one who counsels patients in a clinical setting and has a role in direct patient care.” Non-clinical genetic counselor was defined as “one who does not counsel patients in a clinical setting and has a role in direct patient care.” We then defined a research genetic counselor as “one who works in research or as a study coordinator. This role may include enrollment of patients into a study, obtaining informed consent, and/or coordinating participant involvement in a study, etc., but does not include counseling patients or having a direct role in patient’s care.” Finally, we defined a non-traditional or “hybrid” genetic counselor as “one who works in either a non-clinical or research setting, but who, as a part of their position, also counsels patients and/or has a role in direct patient care.”

We used the definition as defined by Nussenbaum: “a conflict of interest (COI) occurs when there is a divergence between an individual’s private interests and professional obligations either to a patient or to a society that an independent observer might reasonably question the actions taken by the individual that may have been influenced by consideration of the conflict of interest” (Nussenbaum et al., 2014). We then presented in the remainder of this section a series of hypothetical vignettes where participants were asked whether or not they believed each of the vignettes presented a potential COI and the likelihood they would disclose this circumstance to a patient. We also asked participants whether or not they have experienced a set of specific
scenarios, and if they had, we asked whether or not they believed it presented a potential conflict of interest and whether or not they disclosed this conflict to a patient.

In the final section of the survey, "Guidelines on Disclosing Conflicts of Interest," we asked all participants closed- and open-ended questions regarding if, when and how a COI disclosure should be made to a patient. Additionally, we asked all participants who reported a past COI which guidelines were most helpful in deciding whether or not to disclose a COI (if applicable) and whether they thought amendments should be made to the current NSGC guidelines pertaining to conflicts of interest (NSGC Code of Ethics, 2016).

Data Analysis

We analyzed our quantitative data using SPSS, a statistical application supported by Brandeis University. Frequencies and descriptive statistics were first used to assess the data. In order to define relationships between independent and dependent variables, bivariate and multivariate analyses were performed.

The author manually analyzed all open-ended responses in Microsoft Excel by using an inductive approach to identify themes. She analyzed open-ended survey questions to determine underlying themes that describe participant views on when and how COI disclosure should be made, and also to determine participant suggestions to improve NSGC guidelines.
Results

Demographics and Background Information

We received a total of 359 responses. Thirty-eight responses were excluded from the analysis as they either did not meet inclusion criteria or they did not complete enough of the survey to be useful, leaving a total of 321 responses for data analysis. At the time of data analysis, we also excluded responses from genetic counseling students (N=79) since many of the questions pertained to past experiences of the participant. The remaining 242 participants were practicing genetic counselors in the U.S. belonging to the NSGC listserv, resulting in a response rate of approximately 9.3% (NSGC, 2016).

All 242 participants reported the geographic region in which they practice (Figure 1). The distribution of responses from each region reflects the distribution of U.S. NSGC members within those regions, which suggests that genetic counselors from all NSGC regions are likely represented (NSGC, 2016). In order to further characterize the demographics of our participants, we asked them whether they were “clinical” or “non-clinical” counselors and/or whether they worked in a research setting as well. In addition, we asked about the number of years of experience they had in that role (Figure 2). Out of 242 respondents, the majority identified themselves as “clinical genetic counselors,” that provide direct patient care (68.6%, n=166). The remaining participants were either “non-clinical genetic counselors” (13.6%, n=33), “research genetic counselors” (1.7%, n=4), or “non-traditional or ‘hybrid’ genetic counselors” (16.1%, n=39) that had both clinical and non-clinical responsibilities. The majority of respondents had one to four years experience in their current role and no non-clinical genetic counselors had more
Figure 1: Distribution of U.S. genetic counselors characterized by NSGC region. Genetic counselors (Survey Respondents), N=242; Genetic counselors (2016 NSGC Professional Status Survey), N=2594.

Figure 2: Number of years spent practicing in current role as a genetic counselor. Total number of respondents, N=242; GC, Genetic counselor
than nine years of experience in this role (Figure 2).

Counselors’ Opinions on Potential COI’s and Their Disclosure in Hypothetical Scenarios

We gave respondents a series of hypothetical scenarios and asked them to imagine themselves as a clinical genetic counselor offering genetic testing from Laboratory A to all of their patients who pursue testing. When asked to state whether they believed a given scenario would present a potential COI, the majority of respondents stated “Yes” for all seven scenarios (Table 1).

We compared the responses from all genetic counselors that provide direct patient care (i.e. the “clinical” and “non-traditional or ‘hybrid” genetic counselors) with those who do not provide direct patient care (i.e. “non-clinical” and “research” genetic counselors). We found a statistically significant difference (p<0.05) in their responses to the two scenarios relating to ownership of equity interests by the genetic counselor or their spouse/partner in Laboratory A (a non-publicly-traded company) while routinely offering genetic testing from Laboratory A to patients (Table 2). “Equity interests” was defined as stock, stock options, partnership, ownership interests in the company, etc. Genetic counselors involved in direct patient care were more likely to view these two scenarios as potential COI’s than those who are not involved in direct patient care. We found no other significant differences between the two groups’ views regarding COI’s for the remaining scenarios.

When asked the likelihood of disclosing the circumstances described in each of these seven hypothetical scenarios to a patient, most genetic counselors’ said that it was either “Completely Likely” or “Likely” that they would disclose the given circumstance to a patient (Table 1). Approximately 155 (70.1%, N=221) of the genetic counselors reported that if they were employed by Laboratory A to counsel patients at a local hospital with the physician
<table>
<thead>
<tr>
<th>Scenario</th>
<th>&quot;Yes&quot; Presents a Potential COI</th>
<th>&quot;Completely Likely&quot; or &quot;Likely&quot; to Disclose to a Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>You are paid by Laboratory A to speak at educational programs offered to other health care providers.</td>
<td>165 (68.2%)</td>
<td>60 (36.4%)</td>
</tr>
<tr>
<td>You are employed by Laboratory A, and as part of your job, counsel patients at a local hospital. You recommend to the physician that you work with that all of your patient samples be sent to Laboratory A. He/she then signs off and orders the testing at Laboratory A as per your recommendation.</td>
<td>221 (91.3%)</td>
<td>155 (70.1%)</td>
</tr>
<tr>
<td>You serve as a paid case consultant to assist with product development and quality improvement for Laboratory A.</td>
<td>150 (62.0%)</td>
<td>88 (58.7%)</td>
</tr>
<tr>
<td>Your spouse/partner works at Laboratory A in their genetic testing department.</td>
<td>143 (59.1%)</td>
<td>29 (20.4%)</td>
</tr>
<tr>
<td>You have equity interests in Laboratory A, which is a non-publicly-traded company.</td>
<td>209 (86.4%)</td>
<td>49 (23.4%)</td>
</tr>
<tr>
<td>Your spouse/partner has equity interests in Laboratory A, which is a non-publicly traded company.</td>
<td>184 (76.0%)</td>
<td>28 (15.2%)</td>
</tr>
<tr>
<td>You are employed by Laboratory A and receive a fixed salary that is not adjusted by the number of tests that you refer to this lab.</td>
<td>131 (54.1%)</td>
<td>101 (77.1%)</td>
</tr>
</tbody>
</table>

Table 1: Genetic counselors that agree the given scenarios present a potential for a COI. Total number of respondents, N=242 for each of the seven scenarios. Genetic counselors that are “Completely Likely” or “Likely” to disclose the given circumstance to a patient.

ordering testing from their lab, they were “Completely Likely” or “Likely” to disclose this circumstance to the patient. Additionally, 101 (77.1%, N=131) genetic counselors stated that if
they were employed by Laboratory A to counsel patients at a local hospital, but their salary was fixed and not adjusted by the number of tests referred to their lab, they were “Completely Likely” or “Likely” to disclose this circumstance to the patient (Table 1).

**Genetic Counselors’ Experience with COI’s**

We then asked genetic counselors if they had any knowledge of ever encountering a conflict of interest in their professional genetic counseling career. An overwhelming majority (69.2%) stated that they had never had a COI. Approximately 10.4% of respondents reported having non-financial COI’s only, 7.5% reported having financial COI’s only, 6.7% stated having

<table>
<thead>
<tr>
<th>Scenario Presents a Potential COI?</th>
<th>Those Involved in Direct Patient Care vs. Those Not Involved in Direct Patient Care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Direct Patient Care</td>
</tr>
<tr>
<td>1 You have equity interests in Laboratory A, which is a non-publicly traded company.</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>2 Your spouse/partner has equity interests in Laboratory A, which is a non-publicly traded company.</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

**Table 2:** Responses of counselors involved in direct patient care (n=205) vs. those that are not (n=37) regarding whether a given hypothetical situation presents a potential COI. A comparison between these two groups for whether Scenarios 1 and 2 present a potential COI shows: Scenario 1: $\chi^2=7.20$, p<0.05 (N=242); Scenario 2: $\chi^2=8.91$, p<0.05 (N=242).

both non-financial and financial COI’s, and 6.3% of respondents did not know if they had ever encountered a conflict of interest (N=240) (Figure 3). Of the 59 respondents who reported having some form of a COI (24.6% in total), 81.4% (n=48) stated that their employer was aware
of this COI at the time, whereas 8.5% (n=5) said they thought their employer *might* have known about the conflict.

**Figure 3:** Genetic counselors' experience with having a COI in their professional genetic counseling career. Approximately 24.6% of respondents reported having some form of a past COI. Total number of respondents, N=240.

We then asked respondents if they ever personally experienced any of ten specific scenarios that might present a potential COI and whether they believed the scenario actually presented a COI. The majority (189/240, 78.8%) stated that they never experienced any of the scenarios listed, whereas 51 of the 240 respondents (21.3%) reported experiencing at least one (Table 3). The majority of these respondents believed that the given scenario either presented potential for a COI or maybe presented potential for a COI (Table 3). For four of the ten scenarios, none of the participants reported encountering the given situation in the past.

We then followed up with the same respondents that previously reported that the scenario presented or maybe presented potential for a COI, whether they disclosed the given circumstance to a patient. Twenty-five genetic counselors that answered this question stated that they did not disclose their potential COI to a patient, whereas ten genetic counselors reported that they did
Table 3: Genetic counselors’ past experience of select COI’s. *Note: Respondents had the option to select more than one response based on having personal experience with more than one of the scenarios provided (N=240). Counselors then reported whether they felt this situation presented or might have presented a COI. Finally, they stated whether or not they disclosed the given circumstance to a patient (N=32).

disclose (Table 3). Three genetic counselors could not recall whether or not they disclosed their potential COI to a patient (N=32).

Genetic Counselors’ Views on Disclosing COI’s to Patients

We then asked all participants whether or not they believed disclosing a potential COI to a patient would negatively impact the patients’ trust. Forty-three percent of the genetic
counselors (N=240) thought that disclosure would not have a negative influence (Figure 4). Reasons given included that “Patients appreciate transparency” and that disclosure helps build rapport between the patient and the genetic counselor. One participant shared “…I believe that building rapport and honesty usually go far in a patient’s eyes.” Several felt that disclosure of COI’s empowers patients and preserves patient autonomy. Conversely, approximately 32.1% believed that disclosure would negatively impact the patients’ trust (Figure 4). Some reasons given were that “Disclosing them may call attention to them” and makes patients question why the information is being shared in the first place. Finally, 24.6% reported “Other” when asked if disclosure negatively impacts patients’ trust (Figure 4). Respondents could choose “Other” if they felt there was no clear-cut “Yes” or “No” answer to this question.

**Genetic Counselors’ Opinions on How and When to Disclose a Potential COI**

As an open-ended question, we asked the genetic counselors to give their opinions on when and how disclosure of a potential COI should be made to a patient. Qualitative analysis of 212 responses showed that approximately 50% of respondents stated that disclosure should be made during the time the counselor reviews all of the testing options with the patient. About 25% thought disclosure should be made at the beginning of the session when introductions are being made and approximately 15% believed it was best to make disclosure prior to the appointment. There was a split opinion on how disclosure should be made. Twenty percent of respondents thought that disclosure should be made verbally while twenty percent thought it should be made in writing.

**Where Genetic Counselors Sought Out Guidance on Whether or Not to Disclose a Potential COI**

We asked the 59 genetic counselors that reported having some form of COI in the past (Figure 3) where they sought out guidance when deciding whether or not to disclose their
Figure 4: Genetic counselors' views on whether or not disclosing a potential COI negatively impacts the patients' trust in the care that they receive. Yes (; No (n=104); Other (n=59); Total number of respondents, N=240.

potential COI to a patient. The two most common resources listed were their institutional guidelines and the NSGC Code of Ethics (NSGC Code of Ethics, 2016), but 12 participants referred to other resources not on the list of those offered (N=58) (Figure 5). Twenty-six respondents reported that they did not seek out any guidance in the past to help assist in navigating COI disclosure (Figure 5).

When asked which resources were most helpful in guiding the genetic counselors on whether or not to disclose, the most reported resource (n=15, N=54) was their institution's guidelines (Figure 5). Additionally, many other respondents reported that other sources not listed were the most helpful (n=14). Finally, ten genetic counselors reported that they did not find any available resources helpful when trying to navigate COI disclosure with a patient (Figure 5).
Where Genetic Counselors Sought Out Guidance on COI Disclosure in the Past*

![Graph showing the number of genetic counselors who sought out guidance from different sources.]

**Figure 5:** Resources genetic counselors used when they sought out guidance regarding COI's encountered in their practice (N=58) and resources that they found most helpful in guiding COI disclosure (N=54). *Note: Respondents had the ability to select more than one option.*
Discussion

This is the first study to our knowledge that explores genetic counselors' opinions on what constitutes a COI and how disclosure of the COI should be made to a patient. This study also investigated genetic counselors' personal experiences with COI's and COI disclosure and the resources they found helpful in guiding them with the disclosure process. Based on the large number of responses received and thoughtful comments from participants, it appears that this topic is both relevant and important to genetic counselors at this time. The demographics we collected in our study (location based on NSGC region, current role as a genetic counselor, etc.) is comparable to the demographics found in the 2016 Professional Status Survey reports (NSGC, 2016), suggesting that our results may be generalizable to the genetic counseling population as a whole.

Counselors' Opinions on Potential COI's and Their Disclosure in Hypothetical Scenarios

After reviewing each of the seven hypothetical scenarios provided, the majority of genetic counselors believed all seven presented a potential for a COI. These results are not unexpected since six of the seven hypothetical scenarios were clear COI’s. However, when asked whether being employed by Laboratory A and receiving a fixed salary that is not adjusted by the number of tests you refer to Lab A is a COI, there was more variation in the responses (approximately 54.1% said “Yes”, 31.0% said “No”, and 14.9% said “I am unsure,” N=242) compared to the remaining vignettes (Table 1). This scenario was intended to serve as a control describing more of a bias than a COI.

We then compared the responses of genetic counselors involved in direct patient care
("clinical" and "non-traditional or 'hybrid'" genetic counselors) to those who are not ("non-clinical" and "research" genetic counselors) with respect to whether or not they thought a given hypothetical scenario presented a COI. The only statistically significant difference we found is that genetic counselors who are not directly involved in patient care were more likely to believe that having ($\chi^2 = 7.20, p < 0.05, N=242$) or their spouse/partner having ($\chi^2 = 8.91, p < 0.05, N=242$) equity interests in Laboratory A while counseling patients on Laboratory A’s testing, does not present a potential COI (Table 2). Aside from these findings, it seems that most genetic counselors, regardless of their current professional role, are in accord as to what constitutes a potential for a COI and what does not.

When asked the likelihood of disclosing each of the seven hypothetical circumstances to a patient, the results show that genetic counselors generally believe that COI disclosure to a patient is necessary. However, more genetic counselors stated they were “Completely Likely” or “Likely” to disclose that they were employed by Laboratory A when the physician is the one who orders all testing from that lab rather than themselves (Table 1). Conversely, genetic counselors were least likely to disclose to a patient any COI’s that involve their spouse/partner (Table 1). Based on these results, it appears that the likelihood of disclosing a COI to a patient largely depends on the specific type of COI.

Genetic Counselors’ Experience with COI’s

Nearly 70% of respondents (N=240) reported that they never encountered a COI in their professional genetic counseling career (Figure 3), which is a stark contrast to Stoll et al., who authors affirm that "Every one of us navigates COI in our every day life – professional priorities often conflict with personal ones, clinicians’ with those of patients, and employees’ with those of employers (Stoll, Mackison, & Allyse, 2017).” To see such a high percentage of respondents...
report that they have never had a COI makes us question the possibility that participants potentially underreported their past experience with COI’s. According to Chugh et al., an individual may be completely unaware of a conflict they might have, allowing unconscious acts of ethically questionable behavior to be more prevalent than reported (Chugh, Bazerman, Banaji, 2005). It is possible that counselors may be psychologically incapable of knowing if a given situation presents a potential COI or they may have difficulty in recognizing the impact that their COI might have. It is also possible that the respondents encountered a past COI, but did not consider it to be a conflict if it did not influence their behavior. A comment made by one participant clarified that they had a perceived COI, but not an actual COI. “Although comforting, this language is misleading. It is important to recognize that COI are not simply a matter of perception. We may legitimately debate the influence the COI have [sic] in particular situations, but they are an objective reality that can be defined and assessed (Stoll, Mackison, & Allyse, 2017).”

The two most commonly reported COI’s by genetic counselors include receiving unsolicited personal gifts from laboratories and serving as a paid case consultant to assist with product development and quality improvement for a major laboratory (Table 3). These results might reflect some of the most common COI’s that genetic counselors may possibly encounter in their profession. Remarkably, of those who reported experiencing one of the select COI’s given, only a fraction actually disclosed their potential COI to their patient (Table 3). These results are interesting when compared to the results in Table 1, where a number of genetic counselors reported that it was “Completely Likely” or “Likely” that they would disclose a specific COI to a patient in the hypothetical scenario. For example, eighty-eight out of one hundred fifty-four people reported that it was “Completely Likely” or “Likely” that they would disclose to a patient
that they’ve served as a paid case consultant for a laboratory to assist in product development and quality improvement. Out of the eight genetic counselors that reported personal experience with this scenario and agreed it presented a potential COI, seven reported that they did not disclose this potential COI to their patients (Table 3). The discrepancy between whether genetic counselors disclose in a hypothetical scenario and whether they disclose in real life might reflect an internal conflict they face. They strive to act morally and ethically in an ideal situation, but might have difficulty in real life. Extenuating circumstances could also make the act of disclosure more challenging. For example, a genetic counselor may have every intention of disclosing their potential COI to a patient, but might refrain from doing so if the patient is easily confused and already has difficulty understanding the testing that is being offered. The hypothetical scenario is with an ideal patient, while most circumstances surrounding a particular counseling session are far from ideal.

Of the genetic counselors that reported having a past COI, nearly all stated that their employer was aware of the conflict at the time. This actually raises two important questions: (1) who are all the parties that must be made aware of the COI?; and (2) is disclosure to only your employer sufficient?

*Genetic Counselors’ Views on Disclosing COI’s to Patients*

Though the majority of genetic counselors thought that disclosure would not negatively influence the patient-counselor relationship (Figure 4), qualitative data shows that some respondents felt that whether or not disclosure negatively impacts a patients’ trust in their counselor largely depends on the patient, patient-counselor relationship, and/or type of COI. They also had generally mixed opinions on when to disclose and how. There was no general consensus on these issues (i.e. what to disclose, whether to disclose or not, how the patient will
perceive the COI, etc.). In Yi et al.’s 2015 study of surgical patients, the authors concluded that most patients are favorable toward financial relationships between physicians and industry as long as this information is shared with the patient in advance (Yi et al., 2015). In their follow-up study, Yi et al. showed that many patients believe that their trust in their healthcare provider would not be negatively impacted, so long as the COI is disclosed to them (Yi et al., 2016). It would be interesting to know when genetic counselors responded to this question, if they were commenting on how the potential COI impacts the patients’ trust or if they were referring to the act of disclosure itself having an impact.

*Genetic Counselors’ Opinions on How and When to Disclose Potential a COI*

Qualitative data analysis showed that genetic counselors also had differing opinions on how and when disclosure to a patient should be made. The majority of respondents thought disclosure should occur when discussing testing options in a session. Others felt that it should be done either at the beginning or prior to the session. Ideally, disclosure should be made prior to the appointment giving the patient complete autonomy to decide if they even want to schedule an appointment with that specific genetic counselor. Additionally, studies investigating physicians and COI disclosure demonstrate that “patients believe that disclosure of financial relationships during the consent process distracts the patient from more important risks (Camp et al., 2015).” Some counselors felt that disclosing COI’s too early in the session might ruin their rapport and some even felt that disclosure prior to the session would be a barrier to care for the patient. It is possible that genetic counselors working in the trenches with a role in direct patient care might find it more practical to disclose their COI’s when reviewing the test options with a patient.

Out of 212 respondents, twenty percent felt that disclosure should be made verbally, while twenty percent thought disclosure would be best in writing or on the consent form for the
test. Studies on medical patients show that they generally prefer for COI’s to be disclosed in written form as opposed to verbal disclosure (Lockhart et al., 2013; Coors et al., 2015).

Genetic counselors that were unsure when and how disclosure should be made shared that their goal was to actively avoid any COI’s that might arise. Though this strategy is helpful in reducing the number of COI’s one might need to manage, it is nearly impossible to avoid all COI’s throughout one’s lifetime. Others felt that if a COI was inevitable, it is crucial to always offer the patient alternatives, such as offering other tests from different laboratories or having the patient meet with another genetic counselor.

Where Genetic Counselors Sought Out Guidance on Whether or Not to Disclose a Potential COI

It appears that most genetic counselors relied on their institution’s guidelines to help aid in COI disclosure and most found these guidelines to be the most helpful (Figure 5). This is not unexpected since many institutions have policies on COI’s and COI disclosure, and as employees, genetic counselors must abide by these rules. What perhaps not anticipated was the fact that many genetic counselors did not rely on any guidelines to help aid in COI disclosure and a number of genetic counselors were not bale to find any helpful resources (Figure 5).

Some genetic counselors sought out guidance from the NSGC Code of Ethics, but not all found these guidelines to be helpful in terms of COI disclosure. When asked to make suggestions for amending the NSGC Code of Ethics to better guide on COI’s and their disclosure, many respondents suggested that examples be provided on what constitutes a COI. Others stated that there was a need for stronger recommendations for when and how COI disclosures should be made. Some suggested that perhaps the Code of Ethics have a separate section that addresses genetic counselors working in non-traditional settings, such as a genetic testing company. The NSGC Code of Ethics is currently being revised; however, the initial
circulated draft did not address all of these concerns (NSGC Code of Ethics Final Revisions, 2017). Since the NSGC Code of Ethics is a fairly broad document, perhaps NSGC could create detailed Practice Guidelines that can address these specific issues in more detail. These proposed Practice Guidelines could provide examples of COI’s that should be disclosed to patients and recommendations for when or how disclosure should be made.

*Study Limitations*

Many individuals within the field of genetic counseling may have differing definitions of what a clinical or non-clinical role is. As such, we attempted to further define these roles for our participants; however, they still may have interpreted these roles differently. Additionally, involvement in this survey was voluntary, which may have resulted in a selection bias based on interest in and/or experience with COI’s that may affect the validity of our findings. With only a few participants reporting a past encounter with a COI, it is possible that genetic counselors that actually had COI’s did not take this survey. Socially, there is a stigma surrounding the topic of COI’s and it is possible that genetic counselors who feel negatively toward their past COI’s preferred not to participate. In addition, there may be a recall bias when genetic counselors were asked if they ever encountered a potential COI and whether or not they disclosed that potential COI to a patient.

*Practice Recommendations*

The reality is that conflicts of interest are inevitable across all professions. There is no harm in having a potential conflict of interest, so long as the conflict is appropriately managed. One way to appropriately manage a conflict of interest is by disclosure. Not all conflicts of interest are equal and not all conflicts of interest need to be disclosed. However, disclosure not only protects the patient, but it also protects the genetic counselor and the genetic counselors’
employer or institution. Disclosure can be made in a number of ways, but it may be best to disclose in writing or to document that disclosure was made in a clinic note. It may also be best to disclose to a patient before the appointment is made since it preserves the patients’ autonomy. At the very least, genetic counselors should consider making the disclosure before a decision to do the testing is made. One possible solution could be to implement a tool similar to the Open Payments reporting requirement that physicians currently adhere to (The Department of Health and Human Services, Centers for Medicare and Medicaid Services, 2016). At the moment, it may be good practice for the genetic counselor to offer the patient alternatives by offering other testing options or offering that the patient with another counselor. By providing these alternatives, the genetic counselor is able to facilitate the patients’ decision-making process and help ensure that the patient is providing informed consent for any testing they pursue.

Research Recommendations

This study raised a number of questions that may be explored in future studies. For those that believe disclosure negatively impacts the patient’s trust, what do they believe is the specific cause that is damaging this relationship? Do they believe that it is the COI that negatively influences the patient’s trust or do they believe it is the act of disclosure itself? Moreover, it would be interesting to investigate the opinions of genetic counselors on who they believe should provide disclosure. Should the genetic counselor provide disclosure or should it be their institution? Or is it sufficient for the scheduler to disclose all COI’s relevant to the session to the patient when scheduling the appointment? Since this initial study is exploratory by nature, future research is warranted.
Conclusion

This study demonstrates that most genetic counselors believe they have the ability to identify a potential COI and that the type of COI would strongly influence whether or not they would disclose to a patient. More than two thirds of the genetic counselors in this study report that they never experienced a potential COI in their professional career as a genetic counselor. Forty-three percent of genetic counselors do not believe that disclosing a potential COI to a patient would negatively impact the patient’s trust in the care that they are receiving. About half of genetic counselors in this study believe disclosure should be made when discussing the testing options, and there is no consensus as to whether disclosure should be made verbally or in writing. By contrast, those that experienced a past COI the majority did not disclose their COI to their patient. The most relied upon and most helpful resources for guiding whether or not to disclose with a patient were the genetic counselors’ institutional guidelines. As we continue to openly discuss COI’s and COI disclosure, it is likely that there will be a better consensus on when and how to approach these COI’s with patients in the future.
REFERENCES


APPENDIX A: RECRUITMENT NOTICES

Subject: Where Do We Draw the Line?: Navigating Conflicts of Interest in the Genetic Counseling Profession

Seeking Practicing Genetic Counselors and Genetic Counseling Students to Participate in a Research Study

You are invited to participate in an online research survey to investigate genetic counselors’ and genetic counseling students’ practices and perspectives in regards to conflicts of interest (COIs) and their disclosure to patients. This research is being carried out as part of my Master’s thesis at Brandeis University and has been approved by the Brandeis Institutional Review Board.

This study is open to all genetic counselors and genetic counseling students who currently practice or attend a graduate training program in the United States.

The specific goals of this research study are to:
  - Assess the perspectives of genetic counselors/genetic counseling students on what constitutes a COI and whether a specific COI should be disclosed;
  - Learn about genetic counselors’ personal experiences with COIs and how they addressed any COIs;
  - Identify specific recommendations genetic counselors and genetic counseling students have for strengthening existing professional guidelines on COIs.

This anonymous survey should take on average 15 minutes to complete. All participants who complete the survey will have the opportunity to enter a drawing for one of three $50 Amazon.com gift cards. The email address you provide for the drawing will not be linked to your survey responses.

If you wish to be a part of this study, please click the link provided below.

If you have any questions, concerns, or comments, please do not hesitate to contact me by email at slaudisi@brandeis.edu, or my Brandeis University faculty sponsor, Judith Tsipis, at tsipis@brandeis.edu.

Thank you in advance for your time and participation.

Click here to take the survey!

Sincerely,

Stephanie M. Laudisi, MS
Master’s Degree Candidate, Class of 2016
Genetic Counseling Program
Brandeis University

Judith E. Tsipis, PhD
Director, Genetic Counseling Program
Professor of Biology
Brandeis University
Reminder e-blast

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Please complete this survey by February 8, 2017.

If you have any questions, concerns, or comments, please do not hesitate to contact me by email at slaudisi@brandeis.edu, or my Brandeis University faculty sponsor, Judith Tsipis, at tsipis@brandeis.edu.

Thank you in advance for your time and participation.

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Stephanie M. Laudisi, MS
Master’s Degree Candidate, Class of 2016
Genetic Counseling Program
Brandeis University

Judith E. Tsipis, PhD
Director, Genetic Counseling Program
Professor of Biology
Brandeis University
APPENDIX B: STUDY INSTRUMENT

Where Do We Draw the Line?: Navigating Conflicts of Interest in the Genetic Counseling Profession

You are being asked to participate in this anonymous study because you are either a genetic counselor or genetic counseling student practicing or attending school in the United States. The purpose of this study is to investigate genetic counselors' and genetic counseling students' practices and perspectives in regards to conflicts of interest (COIs) and their disclosure to patients.

Your responses to this online survey will be anonymous. The survey is estimated to take approximately 15 minutes to complete. Participation in the survey is voluntary and you may exit the survey at any time.

Participants who complete this survey may enter a drawing for one of three $50 Amazon.com gift cards by providing their email address on a form that is not linked to their surgery responses.

By clicking 'Next', you acknowledge that you have read the information above and you consent to participate in this survey.

☐ Next
☐ I do not wish to participate

If “I do not wish to participate” Is Selected, Then Skip To End of Survey
A *Boston Globe* Article and the Issues It Raised Regarding Conflicts of Interest for Genetic Counselors

On March 6, 2016, The *Boston Globe* published the article, "When baby is due, genetic counselors seen downplaying false alarms," by Beth Daly. In the article, Ms. Daly writes:

"...Parents are starting to question the independence of the fast-growing field of genetic counseling as more and more counselors are paid by the companies that make the tests..."

"...About 14 percent of the nation's 4,000 genetic counselors worked directly for testing labs in 2014, up from 9 percent just two years earlier, according to their professional society. The balance tend to work for hospitals or doctor's practices..."

"... Concerns are also growing that counselors are working in close proximity to patients in doctors' offices may be overpromoting [*sic*] tests..."

"...Most medical companies must report how much they pay doctors for research, royalties, travel, and speaking fees, but the federal law doesn't cover payments to genetic counselors. As a result, patients have no easy way to know whether their counselor has a possible conflict of interest..."

This article has generated a great deal of discussion throughout our community. As a result, I became interested in exploring the potential for conflicts of interest in the field of genetic counseling and assessing genetic counselors' opinions on what constitutes a conflict of interest.

I. Demographics

1. Are you currently a student in a genetic counseling graduate program?
   - □ Yes
   - □ No

   If “No” is Selected, Then Skip to Question 3
   If “Yes” is Selected, Then Skip to Question 2

2. Is your genetic counseling graduate program located in the United States?
   - □ Yes
   - □ No

   If “No” is Selected, Then Skip to End of Survey
   If “Yes” is Selected, Then Skip to Question 4
3. As a genetic counselor, do you currently practice within the United States?
   □ Yes
   □ No

If “No” is Selected, Then Skip to End of Survey
If “Yes” is Selected, Then Skip to Question 5

4. Within which NSGC region is your genetic counseling program located?
   □ Region I: (CT, MA, ME, NH, RI, VT, Canadian Maritime Provinces)
   □ Region II: (DC, DE, MD, NJ, NY, PA, VA, WV, Quebec, Puerto Rico, Virgin Islands)
   □ Region III: (AL, FL, GA, KY, MS, NC, SC, TN)
   □ Region IV: (AR, IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, OK, SD, WI, Ontario)
   □ Region V: (AZ, CO, MT, NM, TX, UT, WY, Alberta, Manitoba, Saskatchewan)
   □ Region VI: (AK, CA, HI, NV, OR, WA, British Columbia)

If Any of the Above Options Are Selected, Then Skip to Question 12

5. Within which NSGC region do you currently practice?
   □ Region I: (CT, MA, ME, NH, RI, VT, Canadian Maritime Provinces)
   □ Region II: (DC, DE, MD, NJ, NY, PA, VA, WV, Quebec, Puerto Rico, Virgin Islands)
   □ Region III: (AL, FL, GA, KY, MS, NC, SC, TN)
   □ Region IV: (AR, IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, OK, SD, WI, Ontario)
   □ Region V: (AZ, CO, MT, NM, TX, UT, WY, Alberta, Manitoba, Saskatchewan)
   □ Region VI: (AK, CA, HI, NV, OR, WA, British Columbia)

6. Do you currently practice in a state that requires licensure?
   □ Yes
   □ No

7. Does your state have regulations concerning conflicts of interest that apply to genetic counselors?
   □ Yes
   □ No
   □ I am unsure
8. How would you best describe your **current** role as a genetic counselor?

- **Clinical genetic counselor:** one who counsels patients in a clinical setting and has a role in direct patient care.
- **Non-clinical genetic counselor:** one who does not counsel patients in a clinical setting and has a role in direct patient care.
- **Research genetic counselor:** one who works in research or as a study coordinator. This role may include enrollment of patients into a study, obtaining informed consent, and/or coordinating participant involvement in a study, etc., but does not include counseling patients or having a direct role in patient's care.
- **Non-traditional or "hybrid" genetic counselor:** one who works in either a non-clinical or research setting, but who, as a part of their position, also counsels patients and/or has a role in direct patient care.

**Carry Forward Selected Choice from Question 8 to Question 9**

9. How long have you worked in this role?

<table>
<thead>
<tr>
<th>Role</th>
<th>Under 1 year</th>
<th>Between 1 and 4 years</th>
<th>Between 5 and 9 years</th>
<th>Between 10 and 14 years</th>
<th>Over 15 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical genetic counselor</td>
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<td>Non-clinical genetic counselor</td>
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<tr>
<td>Research genetic counselor</td>
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<tr>
<td>Non-traditional or &quot;hybrid&quot; genetic counselor</td>
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</table>

10. If you have previously worked in a different role as a genetic counselor, please select all that apply.

- Clinical genetic counselor
- Non-clinical genetic counselor
- Research genetic counselor
- Non-traditional or "hybrid" genetic counselor
- I have not worked in any other role as a genetic counselor

**Carry Forward Selected Choices From Question 10 to Question 11**
11. How long have you worked in this role?

<table>
<thead>
<tr>
<th>Role</th>
<th>Under 1 year</th>
<th>Between 1 and 4 years</th>
<th>Between 5 and 9 years</th>
<th>Between 10 and 14 years</th>
<th>Over 15 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical genetic counselor</td>
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</tr>
<tr>
<td>Non-clinical genetic counselor</td>
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<tr>
<td>Research genetic counselor</td>
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</table>

II. What is a Conflict of Interest?

"A conflict of interest (COI) occurs when there is a divergence between an individual's private interests and professional obligations either to a patient or to a society that an independent observer might reasonably question the actions taken by the individual that may have been influenced by consideration of the conflict of interest" (Nussenbaum et al., 2014). There are two major types of conflict of interest: non-financial and financial conflicts of interest. For the purposes of this study, we will be focusing on financial conflicts of interest.
12. Imagine that you are a clinical genetic counselor who recommends genetic testing from Laboratory A to all of your patients who decide to have genetic testing. Please state whether you think that each of the following scenarios would present you with a potential conflict of interest.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Yes</th>
<th>No</th>
<th>I Am Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>You are paid by Laboratory A to speak at educational programs offered to other health care providers</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>You are employed by Laboratory A and as part of your job counsel patients at a local hospital. You recommend to the physician that you work with that all of your patient samples be sent to Laboratory A. He/she then signs off and orders the testing at Laboratory A as per your recommendation.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>You serve as a paid case consultant to assist with product development and quality improvement for Laboratory A.</td>
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<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Your spouse/partner works at Laboratory A in their genetic testing department.</td>
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<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>You have equity interests (stock, stock options, partnership, ownership interests in the company, etc.) in Laboratory A, which is a non-publicly-traded company.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Your spouse/partner has equity interests (stock, stock options, partnership, ownership interests in the company, etc.) in Laboratory A, which is a non-publicly-traded company.</td>
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<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>You are employed by Laboratory A and receive a fixed salary that is not adjusted by the number of tests that you refer to this lab.</td>
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Please use the space provided to leave any comments regarding any of the above questions.

Carry Forward Selected Choices From Question 12 to Question 13 When “Yes” Was Chosen
13. What is the likelihood that you would disclose this circumstance to a patient?

<table>
<thead>
<tr>
<th></th>
<th>Completely Likely</th>
<th>Likely</th>
<th>Unlikely</th>
<th>Not Likely At All Likely</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
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<td>☐</td>
<td>☐</td>
<td>☐</td>
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<td>☐</td>
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<td>☐</td>
</tr>
</tbody>
</table>
14. Please select the first response that comes to mind for each of the following questions:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>I Am Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Should clinical genetic counselors be prohibited from receiving speaking fees from diagnostic testing laboratories that they sometimes refer patient samples to?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Should a (clinical) prenatal genetic counselor also hold a part-time job in a non-invasive prenatal testing (NIPT) company?</td>
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</tr>
<tr>
<td>Do you believe that a perceived conflict of interest is as likely to undermine the genetic counselor-patient relationship as an actual conflict of interest?</td>
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</tr>
</tbody>
</table>

15. To your knowledge, have you ever had a conflict of interest in your professional genetic counseling career?
   - Yes. Only non-financial conflicts of interest.
   - Yes. Only financial conflicts of interest.
   - Yes. I have had both non-financial and financial conflicts of interest.
   - No. I have never had a conflict of interest.
   - I do not know if I ever had a conflict of interest.

If “Yes. Only non-financial conflicts of interest.” is Selected, Then Skip to Question 16
If “Yes. Only financial conflicts of interest.” is Selected, Then Skip to Question 16
If “Yes. I have had both non-financial and financial conflicts of interest.” is Selected, Then Skip to Question 16
If “No. I have never had a conflict of interest.” is Selected, Then Skip to Question 17
If “I do not know if I ever had a conflict of interest.” is Selected, Then Skip to Question 17

16. Do you believe that at the time your employer was aware of this conflict?
   - Yes
   - Maybe
   - No
   - I am unsure

Please use this space provided to leave any comments regarding the question from above.
17. Have you ever experienced any of the following scenarios? Please select all that apply.
   □ You served as an expert witness on behalf of a genetic testing company/laboratory whose products you also recommended to patients.
   □ You received unsolicited personal gifts (worth more than $25) from laboratories or medical/pharmaceutical companies whose tests or products you also recommended to patients.
   □ You served as a paid case consultant to assist with product development and quality improvement for a major laboratory company whose tests or products you also recommended to patients.
   □ You received royalties for inventions and intellectual property that is related to genetic testing, pharmaceuticals, and/or medical technology that you also recommended to patients.
   □ You had equity interests (stock, stock options, partnership, ownership interests in the company, etc.) with a non-publicly-traded laboratory or medical/pharmaceutical company, whose products you recommended to patients.
   □ You routinely recommended patients to a laboratory that also paid you to speak at an educational program for healthcare providers.
   □ You received product evaluation payments for new genetic tests, which you happened to also recommend to patients.
   □ Your spouse/partner had equity interests (stock, stock options, partnership, ownership interests in the company, etc.) with a non-publicly-traded company whose products you also recommended to patients.
   □ You routinely recommended patients to a laboratory that paid your spouse/partner to speak at an educational program for healthcare providers.
   □ Other
   □ I have not experienced any of the above scenarios.

If "I have not experienced any of the above scenarios." is Selected, Then Skip to Question 21
Carry Forward Selected Choices from Question 17 to Question 18
18. Do you believe this presented a potential conflict of interest?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Maybe</th>
<th>I Am Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>You served as an expert witness on behalf of a genetic testing company/laboratory whose products you also recommended to patients.</td>
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<tr>
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<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have not experienced any of the above scenarios.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If “Yes” is Selected, Then Carry Forward Selected Choices to Question 19
If “Maybe” is Selected, Then Carry Forward Selected Choices to Question 20
If “No” or “I am unsure” is Selected, Then Skip to Question 21
19. Of the scenarios you experienced that present a potential conflict of interest, did you disclose this potential conflict to a patient?

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Yes</th>
<th>No</th>
<th>I Do Not Recall</th>
</tr>
</thead>
<tbody>
<tr>
<td>You served as an expert witness on behalf of a genetic testing company/laboratory whose products you also recommended to patients.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>You received unsolicited personal gifts (worth more than $25) from laboratories or medical/pharmaceutical companies whose tests or products you also recommended to patients.</td>
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<td>You served as a paid case consultant to assist with product development and quality improvement for a major laboratory company whose tests or products you also recommended to patients.</td>
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<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>You had equity interests (stock, stock options, partnership, ownership interests in the company, etc.) with a non-publicly-traded laboratory or medical/pharmaceutical company, whose products you recommended to patients.</td>
<td>☐️</td>
<td>☐️</td>
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<td>You routinely recommended patients to a laboratory that also paid you to speak at an educational program for health care providers.</td>
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<tr>
<td>You received product evaluation payments for new genetic tests, which you happened to also recommend to patients.</td>
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<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>Other</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>I have not experienced any of the above scenarios.</td>
<td>☐️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
</tbody>
</table>
20. Of the scenarios you experienced that **might** present a potential conflict of interest, did you disclose this potential conflict to a patient?

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Yes</th>
<th>No</th>
<th>I Do Not Recall</th>
</tr>
</thead>
<tbody>
<tr>
<td>You served as an expert witness on behalf of a genetic testing company/laboratory whose products you also recommended to patients.</td>
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<td>☐</td>
<td>☐</td>
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<tr>
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<td>You had equity interests (stock, stock options, partnership, ownership interests in the company, etc.) with a non-publicly-traded laboratory or medical/pharmaceutical company, whose products you recommended to patients.</td>
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<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>I have not experienced any of the above scenarios.</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
III. Guidelines on Disclosing Conflicts of Interest

21. Do you believe that disclosing a potential conflict of interest to a patient will negatively impact the patients’ trust in the care you are providing?
   □ Yes
   □ No
   □ Other

Please use the space provided to leave any comments regarding the question from above.

22. If you were to disclose a potential conflict of interest to a patient, when and how would you disclose this information? (Prior to meeting with a patient? At the start of a session with a patient, either verbally or in writing? When discussing possible test options? Etc.)

23. When you experienced your past conflict of interest, did you seek guidance from any of the following to help decide whether or not to disclose to a patient? Please check all that apply.
   □ NSGC Code of Ethics
   □ State Licensure Laws
   □ Guidelines from other Professional Organizations (ACMG, ACOG, etc.)
   □ Institutional Guidelines
   □ Hospital Ethics Boards
   □ Genetic Counseling Training Programs
   □ Other
   □ None of the above

Answer Question 23 If Selected “Yes. Only non-financial conflicts of interest.” in Question 15
Answer Question 23 If Selected “Yes. Only financial conflicts of interest.” in Question 15
Answer Question 23 If Selected “Yes. I have had both non-financial and financial conflicts of interest.” in Question 15
24. Which of the following was the most helpful in guiding you about whether to disclose or not to disclose?

☐ NSGC Code of Ethics
☐ State Licensure Laws
☐ Guidelines from other Professional Organizations (ACMG, ACOG, etc.)
☐ Institutional Guidelines
☐ Hospital Ethics Boards
☐ Genetic Counseling Training Programs
☐ Other
☐ None of the above

Answer Question 24 If Prompted to Answer Question 23

25. Below are excerpts from the NSGC Code of Ethics:

Section I: Genetic Counselors Themselves
Genetic counselors value competence, integrity, veracity, dignity, and self-respect in themselves as well as in each other. Therefore, in order to be the best possible human resource to themselves, their clients, their colleagues, and society, genetic counselors strive to:

- Acknowledge and disclose circumstances that may result in a real or perceived conflict of interest.
- Avoid relationships and activities that interfere with professional judgment or objectivity.

Section II: Genetic Counselors and Their Clients
The counselor-client relationship is based on values of care and respect for the client’s autonomy, individuality, welfare, and freedom. The primary concern of genetic counselors is the interests of their clients. Therefore, genetic counselors strive to:

- Serve those who seek services regardless of personal or external interests or biases.
- Clarify and define their professional role(s) and relationships with clients, and provide an accurate description of their services.
- Enable their clients to make informed decisions, free of coercion, by providing or illuminating the necessary facts, and clarifying the alternatives and anticipated consequences.
- Refer clients to other qualified professionals when they are unable to support the clients.
- Avoid the exploitation of their clients for personal advantage, profit, or interest.

If you were to revise the current NSGC guidelines on conflicts of interest, what suggestion(s) would you provide?