



Response to Commercial Genetic Testing and the Future of the Genetic Counseling Profession

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Wolff and Wolff (2018) is a timely evaluation and perspective on the current state of commercial genetic testing. The authors have described the accelerated evolution of the genetic testing market with the advancement of technologies, the rapid expansion in knowledge and testing options, drastic increases in competition and the introduction of substantial marketing campaigns, and a system of health care reimbursement that requires innovation. The speculation and analysis of future state based on the publically available information from just the four laboratories Wolff and Wolff (2018) describe is limited. However, it does seem certain that the genetic testing industry will continue to grow and experience frequent change which will have significant predictable and unanticipated impacts on the genetic counseling field.

Specifically, Wolff and Wolff (2018) speculate on the impact that commercial genetic testing companies' financial status, market share, and long-term stability will have on their internal genetic counselor staff and the genetic counseling profession as a whole. Wolff and Wolff (2018) largely assert that the future of the commercial genetic testing climate, given the unsustainability of profits and the shift to "one test-many analyses/interpretation model," will lead to fewer genetic counselors being employed by laboratories.

In order to clarify our position, it may be helpful to define in broad terms the type of roles genetic counselors (GC) are commonly employed in by genetic testing laboratories. These groups are based on our experiences within the laboratory setting and can be surmised from publications including

Waltman et al. (2016), Riley et al. (2015), Zetsche et al. (2014), and the 2016 Professional Status Survey (NSGC).

Group 1 One group of genetic counselors described by Wolff and Wolff (2018) are GCs who perform direct patient-facing counseling who are employed by a laboratory. This group can be further broken down into GCs who provide traditional clinical genetic counseling in clinical offices, as contracted by their laboratory employers, and genetic counselors who provide pre-and/or post-test counseling to patients via a telegenetics model after the patient's doctor has ordered a laboratory test. Per Waltman et al. (2016), this group of genetic counselors do not appear to identify themselves as "laboratory genetic counselors." Only 4% of the respondents to the survey of laboratory genetic counselors by Waltman et al. indicated they speak to patients about test results and direct patient care was not recorded as a primary job duty. This is an important distinction, as Wolff and Wolff (2018) reference the 2016 Professional Status Survey (NSGC) and Mackison and Stoll 2016, citing the increase in the number of GCs working for laboratories and the decrease in the number of GCs counseling patients directly. But this is a problematic use of these numbers, as the genetic counselors who are employed by clinical service arms of laboratory companies, as in the provided LabCorp example, are unlikely to have been included in the numbers from Mackison and Stoll (2016). That being said, their role and employment could certainly be influenced by the genetic testing market, given their ultimate employer.

Group 2 A relatively new but apparently growing group are genetic counselors employed by genetic testing laboratories for job roles specific to sales and marketing (Waltman et al. 2016). Within this group are genetic counselors who work as direct salesmen for a laboratory as well as those who serve as physician liaisons or genetic specialists (Landy Schmitt and Lazarin 2017). In general, genetic counselors working in sales and marketing focus on client experiences in order to generate business for their laboratory's tests or services. This may

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involve engaging and providing education to many different individuals and groups, including both genetics and non-genetics providers, health insurance companies, and other laboratories (Landy Schmitt and Lazarin 2017).

Group 3 An important group of laboratory-based genetic counselors work directly as part of a genetic testing laboratory, performing a variety of roles specific to the production of genetic testing, but not including direct patient counseling. Specific job duties are dependent on the type of testing the laboratory performs and the structure of their institution, but largely include assessment of appropriateness of testing, customer liaison, case management, variant interpretation, and report writing (Waltman et al. 2016; Balcom et al. 2017). This specific group of genetic counselors has seen tremendous growth in the profession during the past few years (NSGC 2016). A recent study of genetic counselors who had left their jobs in the past 2 years showed an increase in genetic counselors working in the laboratory from 20.6 to 47.4% (Cohen and Tucker 2018).

Our Challenges to Wolff and Wolff (2018)

While Wolff and Wolff (2018) provide an interesting and novel analysis of the potential future climate in genetic testing, we reach a different conclusion on its potential impact to genetic counselors.

The Support for Patient Counseling Services will Decrease Laboratories that employ genetic counselors to counsel patients (group 1) can receive reimbursement for their services which helps justify their employment independently from testing volumes. Reimbursement for genetic counseling patient services has its own challenges, particularly in light of the Cigna policy, but the ability to obtain reimbursement for this service may help protect these patient-facing genetic counselors despite financial uncertainty faced by commercial laboratories.

If some laboratories provide post-test telegenetic counseling to patients as a courtesy service, Wolff and Wolff's (2018) speculation that this specific service could be discontinued in order to lower testing costs seems plausible. That being said, given the highly competitive marketplace that Wolff and Wolff (2018) describe, as well as the decline in the number of genetic counselors providing direct patient counseling, laboratories may choose to in fact retain genetic post-test counseling services available to patients, as a valuable differentiator over their competitors. Speculation that genetic testing demand will increase due to lower cost barriers coupled with the companies' stated intent to improve customer experience create an opportunity for patient genetic counseling to be a valued service. Such

differentiators are important, particularly in light of other competitive advantages having recently declined in value as cited by the authors. These include a shift away from large and diverse testing menus in favor of whole exome (WES) or whole genome sequencing (WGS) as well as a decrease in value on proprietary phenotype/genotype information. Additionally, new service delivery models such as direct-to-consumer and physician-mediated genetic testing may also increase the demand for post-test counseling and support to both patients and their providers.

The Support for Genetic Counselors in Sales and Marketing will Decrease It is evident from Table 1 of Wolff and Wolff (2018) that companies place a high value on marketing and sales. In a competitive market, as long as there is the potential for profit, sales and marketing will be pursued. Laboratories have employed GCs in this role (group 2) to gain an edge on the industry; having employees who are skilled in genetics and communication, fluent in the ever-advancing testing options, is valuable. Unless counselors functioning in these roles are either substantially more costly or perform inferior to others with different credentials, one might anticipate an increased demand for GCs working in these roles given the increasing competition within the field.

The Support for Genetic Counselors in Report Writing and Variant Interpretation Will Decrease Wolff and Wolff (2018) venture that lack of investor funding could reduce the employment of genetic counselors in report writing and variant interpretation or conversely, that analytic and interpretative services may increase the demand for laboratory-based genetic counselors to fill these roles. We predict the latter. With the increased need for interpretation of genetic testing results, laboratory-based genetic counselor (group 3) numbers will likely continue to rise. The authors discuss a decrease in laboratory "benchwork" given the efficiencies gained by high-throughput genetic testing methods; however, this type of wet-lab work is not routinely performed by genetic counselors. With the move from large panels to WES/WGS platforms, a greater demand for interpretive services is likely to follow. A portion of this interpretive work will fall to genetic counselors given the precedence for GCs currently serving in this role as well as the lower costs associated with employing genetic counselors as part of a multi-disciplinary interpretive team as opposed to incremental laboratory directors (Dewey et al. 2014; Zetzsche et al. 2014). Even though interpretive services are a non-billable expense, the cost of employing genetic counselors in these essential roles would only comprise a small portion of the 300–400 million dollar expense budget reported by the larger laboratories.

The Development of Somatic Oncology Testing Will Reduce the Need for Genetic Counselors

Wolff and Wolff (2018) remark that with laboratories moving into the somatic oncology realm, their need for laboratory-based genetic counselors will be reduced. Contrarily, GCs are also moving into the non-hereditary arena and the interpretation of somatic variants. While it requires an advanced skillset and the exploration of a topic that typically has minimal coverage during genetic counselor graduate training, the foundation in molecular genetics has allowed multiple genetic counselors to move into this area with success. This is evidenced by a growing number of professional activities surrounding the topic, including the recent creation of a somatic subcommittee of the NSGC Cancer Special Interest Group, multiple webinars on the topic in 2016 and 2017, educational sessions on somatic variants at the 2016 and 2017 NSGC Annual Education Conferences, and an upcoming article on somatic variant interpretation in *Perspectives in Genetic Counseling* (Balcom et al. 2018).

The Changing Paradigm of Genetic Testing Will Require Genetic Counselors to Be Highly Adaptive to a Changing Work Environment

Wolff and Wolff (2018) list concerns for laboratory genetic counselors as the commercial genetic testing landscape changes. However, an unsteady landscape is not new to genetic counselors. The market has been changing rapidly over the past few years, and we are already seeing its impact on the genetic counseling profession. Many of the laboratory-based jobs that GCs have recently filled did not exist 3 to 4 years ago (Cohen and Tucker 2018). These genetic counseling positions have been created despite, or possibly even because of, the competitive marketplace or potential lack of profitability. Genetic counselors have responded to the new genetic testing era by assuming and often creating new roles within the laboratory setting, supporting areas such as test utilization, somatic testing, and pharmacogenomics. We agree with Wolff and Wolff (2018) that the laboratory environment requires the ability to be highly adaptive, but assert that genetic counselors have been doing this for many years. It is genetic counselors' adaptability that has led to the marked increase in laboratory-based genetic counseling positions, as laboratories have recognized the value of genetic counselors within their organizations.

In closing, Wolff and Wolff (2018) assert that the commercial genetic testing climate will lead to fewer genetic counselors being employed by laboratories. While we agree with the authors' overall assessment of the changing testing climate and the important points raised through their comparison of four commercial laboratories, we believe that genetic counselors will continue to be successful in this genetic testing industry. This is evidenced by the recent expansion of

laboratory-based roles and continued novel applications of the GC skillset. While there may be some uncertainty as to whether profits and capital will be sufficient to support all current laboratory business activities, given the recent increase in employment of laboratory genetic counselors, it seems unlikely that they would be the first laboratory service or support staff to be discontinued. The successful integration of genetic counselors into the genetic testing environment in multiple facets over the past two decades (Zetzsche et al. 2014) has successfully driven continued demand for genetic counselors in the laboratory environment, thus providing evidence for the value and indispensable services GCs bring to critical laboratory operations and customer experience. We do not believe this will cease to be the case anytime soon.

Compliance with Ethical Standards

Conflict of Interest M. Goodenberger, B. Thomas, and T. Kruisselbrink receive royalties from the book, *Practical Genetic Counseling for the Laboratory*. B. Thomas receives compensation from GeneMatters as an Advisory Board consultant.

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