THE VIRGINIA BOARD OF HEALTH PROFESSIONS
THE VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

Study into the Need to Regulate Genetic Counselors in the Commonwealth of Virginia

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AUTHORITY

By virtue of its statutory authority in §54.1-2510 of the *Code of Virginia* to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board is continuing an ongoing review of emerging health professions. The study will highlight individual professions selected by the Board for review. After receiving a sunrise proposal from the Virginia Association of Genetic Counselors, the Board selected *Genetic Counselors* for review in 2010.

The study is governed by the methodology described in the Board's *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions, 1998*. The following seven criteria (the Criteria) collectively serve as the benchmark for its decisions.

(1) Unregulated practice of the profession poses a recognizable harm or risk for harm to the consumer resulting from practices inherent in the occupation, the characteristics of the clients served, the setting or supervisory arrangements for the delivery of services, or any combination of these factors.
(2) Practice requires specialized education and training, and the public needs to be assured of initial and continuing occupational competence.
(3) Autonomous practice occurs so that the functions and responsibilities of the practitioner require independent judgment.
(4) The scope of practice is distinguishable from other licensed, certified or registered occupations.
(5) The economic impact due to restriction on the supply of practitioners and the cost of board operations is justified.
(6) Alternatives to regulation have been explored and none are found which would adequately protect the public.
(7) The least restrictive regulation that is consistent with public protection must be recommended.

EXECUTIVE SUMMARY

MAJOR FINDINGS OF THE STUDY

1. Genetic medicine is expanding rapidly.

Genetic medicine has traditionally focused on pre- and post-natal health and genetic diseases. In the past two decades, however, rapid advances in genetic technology have expanded the domain of genetic medicine into several specialties, particularly oncology and pharmacology. Continued expansion of the field could revolutionize the practice of medicine in all specialties. Personalized medicine may be possible, with a focus on prediction and prevention over diagnosis and treatment.

2. Genetic medicine is still in its infancy.

Although there are thousands of genetic tests, only a few have clinically useful applications and most are very new. Many physicians do not have significant training in genetics, and clinical guidelines are often underdeveloped and/or under disseminated. Physicians often lack the knowledge to provide adequate genetic counseling or to refer to quality genetic counseling resources. Genetic counselors have only recently expanded from their pre-and post-natal beginnings in significant numbers, and then into specialties with clinical useful tests. The total number of genetic professionals remains limited.

3. Genetic tests and commercial genetic testing services have proliferated ahead of clinical knowledge and regulation.

The genetic testing industry has expanded rapidly, including the marketing of genetic tests directly to consumers. Genetic testing companies provide some rudimentary analysis and customer service. Although it may not be intended as genetic counseling or medical advice, it may, from time to time, brush or cross the line. Patients may rely on this analysis and service in the absence of sufficient genetic counseling or referrals from licensed practitioners. The FDA is currently examining a new regulatory framework for genetic tests, placing regulations on genetic testing companies for the first time.

4. Regulation of genetic counselors may have little impact on the genetic testing industry.

Some of the services provided by genetic testing companies may cross the line into the practice of medicine. If so, these practices are already illegal if not delegated or performed by a licensed practitioner in accordance with statute and regulation. Regulation of genetic counselors in other states does not appear to have reduced access to genetic testing companies or services. Some states have directly regulated genetic tests, particularly direct-to-consumer genetic tests, and the FDA is poised to do so as well.

5. Genetic counselors provide diagnostic services as well as patient counseling.

Genetic counselors assist physicians in determining if a genetic test is appropriate and if so, which test is appropriate. They assist physicians in interpreting the results of genetic tests, either for diagnosing genetic conditions or for determining the risk of developing gene-linked conditions. Genetic counselors help patients understand the results of genetic tests and the options available to them. They help patients cope with implications of genetic tests and make referrals if appropriate.

6. Practices inherent to the profession pose a potential risk of harm to patients.

Patients rely on the advice of genetic counselors in making significant medical decisions. These include major prophylactic surgeries, decisions to get pregnant or terminate a pregnancy and decisions regarding the frequency and aggressiveness of preventative screenings for fatal diseases. Genetic counselors provide counseling and referrals to help patients cope with the difficult pragmatic, ethical and social implications related to genetic testing. Since many of these decisions are related to controversial political and moral issues, patients rely on genetic counselors to provide unbiased information and protect patient privacy.

7. Instances of harm from the unregulated practice of genetic counseling are limited or tenuous.

Instances of harm related to a lack of quality genetic counseling are numerous in the literature. However, these instances of harm stem from inadequate counseling provided by licensed practitioners, or a failure to refer for genetic counseling—not from the unregulated practice of genetic counseling. Often, physicians and patients alike rely on generic information/customer service provided by testing companies along with test results. These services are often not intended to be medical genetic counseling, but many skirt the line.

8. The potential for harm from the unregulated practice of genetic counseling could expand rapidly.

Although the FDA is currently developing a regulatory framework for genetic tests, the extent and efficacy of these regulations are as yet unknown. Genetic tests continue to proliferate in variety, scope and availability. Genetic testing companies and regulated and unregulated providers may increasingly fill the gap between physician knowledge, an inadequate supply of genetic professionals and the need for counseling services.

9. There is a limited supply of genetic counselors.

The VaAGC reports there are only 60 genetic counselors living/working in Virginia, with only about 48 providing patient care. A 2004 analysis performed by researchers at VCU estimated a need for at least 106 genetic counselors in Virginia based on Virginia's population in 2000 and contemporary use patterns. Both population and the use of genetics in medicine are expected to expand likely leading to a need for even more genetic counselors.

Although professional associations have discussed expanding programs, accredited genetic counseling programs graduate only about 225 graduates nationally each year. About 70 percent of applicants are rejected. Public comment suggests that professional organizations may raise the current standard from Master's degree education to doctoral education. This may slow the expansion of the genetic counseling pipeline and diminish the applicant pool.

10. It is unknown how genetics will be integrated into the practice of medicine.

Genetic medicine is in its infancy. As clinical applications of genetic information have expanded into new specialties, genetic counselors have expanded their scope into these specialties. Other models may develop. For example, physicians, nurses and diagnosticians with expertise within a particular specialty may incorporate genetic tests and counseling into their existing practice and knowledge base. These persons may not need expertise in all genetic tests or counseling issues, but rather pursue expertise in all tests and issues (genetic and otherwise) within a specialty area. Since environmental and lifestyle issues also play prominent roles in disease risk and progression, genetic medicine plays a contributory role to specialist practice.

11. Thirteen states regulate genetic counselors; 37 states and the District of Colombia do not.

Currently, thirteen states regulate genetic counselors. Ten states license genetic counselors, while three states provide licensure with provision amounting to title protection only. Thirty-seven states and the District of Colombia do not regulate genetic counselors.

RECOMMENDATIONS

At its May 3, 2011 meeting, the Regulatory Research Committee (RRC) of the Board of Health Professions recommended licensure for genetic counselors, based upon study findings and thoughtful application of the criteria. The RRC noted the inherent risk of harm and the common use of licensure to regulate genetic counselors in other states. The RRC also recommended genetic counselors be regulated through the Advisory Committee model under the Board of Medicine. The full Board of Health Professions adopted these recommendations at its afternoon meeting and directed staff to draft a model statute, which appears in Appendix F.

GENETIC COUNSELORS

BACKGROUND

Genetic counselors provide both patients and physicians with interpretation and counseling related to genetic tests, genetic conditions and risks associated with certain genes or gene combinations. Genetic counselors have mainly provided prenatal and perinatal counseling for persons with or at risk for developing genetic disease. Recent developments, however, have led to a rapid expansion of genetic information and its clinical uses.

In 1990, the US Department of Energy and the National Institutes of Health began the U.S. Human Genome project. The central goal of the project, completed in 2003, was to decode the human genome and accelerate the development of genome-related technology. Early on, the project leaders recognized the profound ethical, legal and sociological questions that could arise alongside the projects technological gains. A list of the ethical, legal and social issues reviewed by the project demonstrates just how far reaching genetic advances may be:

- **Fairness in the use of genetic information** by insurers, employers, courts, schools, adoption agencies, and the military, among others.
- **Privacy and confidentiality** of genetic information.
- **Psychological impact and stigmatization** due to an individual's genetic differences.
- **Reproductive issues** including adequate informed consent for complex and potentially controversial procedures, use of genetic information in reproductive decision making, and reproductive rights.
- **Clinical issues** including the education of doctors and other health service providers, patients, and the general public in genetic capabilities, scientific limitations, and social risks; and implementation of standards and quality-control measures in testing procedures.
- **Uncertainties** associated with gene tests for susceptibilities and complex conditions (e.g., heart disease) linked to multiple genes and gene-environment interactions.
- **Conceptual and philosophical implications** regarding human responsibility, free will vs. genetic determinism and concepts of health and disease.
- **Health and environmental issues** concerning genetically modified foods (GM) and microbes
- **Commercialization of products** including property rights (patents, copyrights, and trade secrets) and accessibility of data and materials.[1]

The attempt to develop wisdom alongside technology ameliorated many of these concerns; however, it could not predict or prevent all controversies related to the explosion of genetic knowledge. While genetic counselors are absorbing the explosion of knowledge, they must also be able to navigate the complex practical, ethical and legal questions arising from this knowledge. These include a proliferation of genetic tests, a lack of genetic literacy among health care providers and consumers, patient privacy, reproductive decision-making, and fair use of genetic information by potential employers of genetic counselors.

[1] Human Genome Project Information Website. "Ethical, Legal, and Social Issues". Accessed Nov. 23, 2010. http://www.ornl.gov/sci/techresources/Human_Genome/elsi/elsi.shtml

Personalized Medicine

The expansion of genetic technology is changing the way medicine is practiced. One of the most talked about applications for genetic information is the development of personalized medicine. Personalized medicine is a patient-centered approach to prevention, wellness and condition management. Genetic information may be used, along with environmental and other factors, to predict the predisposition of individuals to various conditions. Researchers currently know of about 1,500 genes that are "medically predictive" and for which some type of preventative action may be possible.[2] These include obesity, diabetes, neurodegenerative diseases, neuropsychiatric disorders, cancer and cardiovascular disease. With this knowledge in hand, health care providers and patients can tailor activities, lifestyle choices, nutrition and prophylactic interventions to prevent, delay or minimize the onset of conditions.

Genetic information is also increasing the potential for individualized treatment of diagnosed conditions. Pharmacogenomics-the process of using genetic information to create personalized drugs or drug regimens-was one of the core goals the Human Genome Project. So far, pharmacogenomics has proven most useful in predicting the effectiveness of some cancer drugs in patients with specific gene variations. Pharmacogenomic tests are also available to predict the potential individuals face for serious liver damage associated with certain Attention Deficit Hypersensitivity Disorder drugs and the effectiveness of some anti-clotting drugs in preventing heart attacks in persons with specific gene variations.[3]

Scope of Change

A May 2010 article in the *New England Journal of Medicine* noted that "genomics is inexorably changing our understanding of the biology of nearly all medical conditions".[4] There is little doubt that within the coming decades, physicians and researchers will have a far better understanding of the genetic processes underlying many diseases. However, much of the literature refers to the potential of genetic medicine rather than actual clinical use. Francis Collins, current director of the National Institutes for Health and former Director of the National Center for Human Genome Research, noted that "the consequences [of the Human Genome Project] for clinical medicine. . . have thus far been modest."[5]

The reasons for the modest application of genetic information appear to be threefold. First, only a few direct applications for treating or diagnosing non-genetic disorders have arisen—mainly in the realm of oncology. Second, unless looking for a specific condition, the amount of genetic information available is daunting. There are about 1 billion "base pairs" in the human genome, and determining the risk for disease may depend on the interactions of a multitude of genes and environmental factors. Lastly, although a large number of genes have been implicated in determining the risk of developing certain conditions, the usefulness of these genes for predicting condition onset is limited.[6] The NEJM notes that "most SNPs [genes] associated

[2] Quoting George Church, geneticist at Harvard Medical School, in Humphries, Courtney. "A Moore's Law for Genetics". *Technology Review*. Massachusetts Institute of Technology. March/April 2010. pg. 68.
[3] Singer, Emily. "Faster Tools to Scrutinize the Genome". *Technology Review*. Massachusetts Institute of Technology. March/April 2010. pp. 64,65.
[4] Feero, W. Gregory, Alan Guttmacher and Francis Collins. "Genomic Medicine-An Updated Primer". *New England Journal of Medicine*. May 27, 2010. Vol 362 No. 21. pp2001-2011
[5] Quoted in Varmus, Harold. "Ten Years On—The Human Genome and Medicine". *The New England Journal of Medicine*. May 27, 2010. Vol 362, No. 21. pp 2028, 2029.
[6] This list was developed from a review of the literature, particularly the Genomic Medicine Series appearing in May 27, 2010 issue of the New England Journal of Medicine and the Personalized Medicine Briefing in the March/2010 issue of MIT's Technology Review.

with common diseases explain a small proportion of the observed contribution of heredity to the risk of disease—in many cases less than 5 to 10%--substantially limiting the use of these markers to predict risk."[7]

Proliferation of Genetic Information

Nevertheless, the proliferation of genetic information is driving change. It took 13 years and $3 billion to sequence the first human genome.[8] As late as 2008, only 10 genomes had been sequenced.[9] Private companies are now sequencing human genomes within several months at a cost in the tens of thousands. Some companies expect to lower that cost to between $1,500 and $5,000 per genome this year. Individuals may soon be able to get a complete genome sequence for around $1,000—the cost of a routine medical test. [10]

Meanwhile, tests for individual genes—including tests for genes that may suggest a genetic predisposition towards medical conditions—are proliferating. These tests are marketed directly to consumers. A recent article in the *Lancet* noted that "one of the most obvious problems. . . is the packaging together of tests for seemingly trivial traits, such as whether you possess genetic variations for curly hair or male-pattern baldness, along with potentially life-changing tests for predicting your risk for serious, life threatening illnesses such as Alzheimer's disease."[11] For a $499 fee, the prominent company 23andMe promises that "with a simple saliva sample we'll help you gain insight into your traits, from baldness to muscle performance. Discover risk factors for 91 diseases. Know your predicted response to drugs, from blood thinners to coffee. And uncover your ancestral origins."[12] Other companies promise to discover hidden talents. See Appendix A for a complete list of health-related conditions reported by 23andMe and a company offering a similar service, GenePlanet. Many of the companies providing genetic information to consumers are start-ups, and their ability to collect, analyze, protect and interpret genetic information may be uncertain—particularly over the long term.

The result is that consumers have greater access to genetic information than ever before. However, its usefulness in a clinical sense is largely undetermined. It will likely take decades of research and software development before genetic information is useful in a clinical sense for all but a few health consumers or a few conditions. It may take even longer to disseminate this information among health care providers.

PROFESSIONAL ORGANIZATION OF GENETIC COUNSELORS

There are two main organizations serving the Genetic Counselor community. The National Society of Genetic Counselors (NSGC) is the professional organization. The NSGC promotes the interests of its members, provides a professional network, publishes a professional journal and practice guidelines and supports continuing education activities. The NSGC also provides a code of ethics to its members (see Appendix B). The NSGC lists the following Vision and Mission:

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[7] Feero, W. Gregory, Alan Guttmacher and Francis Collins. "Genomic Medicine-An Updated Primer". *New England Journal of Medicine.* May 27, 2010. Vol 362 No. 21. pp2001-2011The quote refers to "SNPs--Single-nucleotide polymorphisms".
[8] Cass, Stephen. "Cheap DNA Sequencing will Drive a Revolution in Health Care." *Technology Review.* Massachusetts Institute of Technology. March/April 2010. Pg. 63.
[9] Gravitz, Laura. "Complete Genomics: Fast, Cheap Sequencing Services". *Technology Review.* Massachusetts Institute of Technology. March/April 2010. Pg. 67.
[10] Briefing: Personalized Medicine. *Technology Review*. Massachusetts Institute of Technology. Several Articles. See pp 67 & 68.
[11] Udesky, Laurie. "The Ethics of Direct-to-consumer Genetic Testing." The Lancet. Oct. 23, 2010. Vol 376. pp 1377-1378.
[12] 23andMe Website. www.23andme.com. Accessed Nov 2010.

The Society's Vision: Integrating genetics and genomics to improve health for all.

The Society's Mission: The National Society of Genetic Counselors advances the various roles of genetic counselors in health care by fostering education, research, and public policy to ensure the availability of quality genetic services.[13]

The American Board of Genetic Counseling (ABGC) provides the Certified Genetic Counselors (CGC) credential to qualified candidates who pass their exam and maintain their certification. The ABGC is an offshoot of the American Board of Medical Genetics (ABMG), which ceased certifying genetic counselors when it joined the American Board of Medical Specialties (ABMS) in 1993. The ABMG continues to credential physician and PhD level geneticists. Although Genetic Counselors have been certified since 1981, the ABGC conducted its first practice analysis in 2008 in conjunction with Applied Measurement Professionals, Inc. The current exam is based on the results of that analysis, with another iteration scheduled for 2011.[14] In addition to providing genetic counseling credentials, the ABGC also accredits genetic counselor training programs. For more information on both of these programs, see the respective sections on education and certification (page 13).

SCOPE OF PRACTICE OF GENETIC COUNSELORS

Genetic counselors perform in two primary functions: 1) a diagnostic function and 2) a counseling function. The diagnostic function consists of taking family and genetic histories, assessing genetic risks, providing guidance on appropriate genetic tests and interpreting the results of genetic tests. Counselors may provide these diagnostic functions as part of a health care team including licensed practitioners, or they may provide them more directly to patients under prescription or referral, or independently. The counseling function includes helping patients and families understand genetic information, adapt to genetic information and make decisions related to genetic information. Although the counseling portion includes psychological and sociological support, it emphasizes providing genetic information and options in a non-directive manner to assist patients in making decisions.

The NSGC provides a basic definition of Genetic Counselors and a scope of practice.

The NSGC defines genetic counselors as:

> . . . health professionals with specialized graduate degrees and experience in the areas of medical genetics and counseling. Most enter the field from a variety of disciplines, including biology, genetics, nursing, psychology, public health and social work. (See "How to Become a Genetic Counselor").
>
> Genetic counselors work as members of a health care team, providing information and support to families who have members with birth defects or genetic disorders and to families who may be at risk for a variety of inherited conditions. They identify families at risk, investigate the problem present in the family, interpret information about the disorder, analyze inheritance patterns and risks of recurrence and review available options with the family.
>
> Genetic counselors also provide supportive counseling to families, serve as patient advocates and refer individuals and families to community or state support services. They serve

[13] National Society for Genetic Counselors Website. Accessed Nov. 22, 2010. http://www.nsgc.org/About/VisionMissionStatement/tabid/123/Default.aspx

[14] Personal Correspondence with Seila O'neal, Executive Director of the American Board of Genetic Counseling. Nov. 10, 2010.

as educators and resource people for other health care professionals and for the general public. Some counselors also work in administrative capacities. Many engage in research activities related to the field of medical genetics and genetic counseling. (*Adopted by the National Society of Genetic Counselors, Inc. 1983*)[15]

The Scope of Practice includes a list of tasks separated into three domains: 1) to provide expertise in clinical genetics; 2) to counsel and communicate with patients on matters of clinical genetics; and 3) to provide genetic counseling services in accordance with professional ethics and values.

The chart on the next page gives a brief synopsis of each domain and a bullet point for each role. The full scope of practice document is in Appendix C.

Clinical Genetics	Counseling and Communication	Professional Ethics and Values
• Obtain family history • Gather additional relevant information • Research literature and available data • Use data to inform on risk, diagnosis and options • Assess risk of occurrence or recurrence of genetic conditions • Provide medical information on diagnosis or occurrence risk • Discuss available options • Document case information • Assist clients in evaluating options • Identify additional resources for client (e.g., support groups) • Provide public education on genetics and genetic counseling	• Identify client priorities and expectations • Identify experiences, behaviors and beliefs • Assess medical literacy • Establish rapport to explore responses to genetic information • Identify psychological needs to determine interventions/referrals • Promote client-specific decision making • Facilitate adjustment to genetic information	• Recognize and respond to ethical or moral dilemmas • Advocate for clients • Recognize personal limitations in knowledge and capabilities • Maintain professional growth • Respect confidentiality

[15] National Society for Genetic Counselors Website. Accessed Nov. 22, 2010. http://www.nsgc.org/About/FAQsaboutGeneticCounselorsandtheNSGC/tabid/143/Default.aspx

Specialty Areas

Genetic counselors have traditionally provided complementary services in obstetrics or pediatrics. The role of genetic counselors has expanded into other specialties as clinically useful advances in genetic medicine have grown. For instance, the proportion of genetic counselors self-reporting a specialty in cancer genetics jumped from ten percent in 1994 to 34 percent in 1998,[16] matching advances in testing for the BRCA1 and BRCA2 genes—prominent predictors for risk of developing breast and ovarian cancer. More recently, the NSGC added cardiology as a specialty choice in its Professional Status Survey, also matching advances in clinically useful tests for heart disease risk. Self-reported specialty areas in the 2006 NSGC Professional Status Survey appear in Table 1. Genetic counselors will follow clinical advances into other specialty areas, applying their specific knowledge of genetics to a larger variety of medical conditions

Specialty Areas	Percent Reporting
Prenatal	54%
Cancer Genetics	39%
Pediatric	34%
Adult	24%
Specialty Disease	13%
Laboratory Testing	9%
Teratogens	8%
Screening	6%
Infertility, ART/IVF	6%
Public health/ Newborn screening	6%
Neurogenetics	6%
Cardiology	4%
Psychiatric	1%

Table 1: Self-Reported Specialty Areas of Genetic Counselors, 2006.
Respondents were able to report multiple specialties.
Source: 2006 NSGC Professional Status Survey

Primary Employment Settings	N	%-age
University Medical Center	474	38%
Private Hospital/Medical Facility	252	20%
Public Hospital/Medical Facility	134	11%
Physician's Private Practice	58	5%
Health Maintenance Organization	43	3%
Federal/State/County Office	27	2%
Outreach/Satellite/Field Clinic	4	0.3%
Research Development/Biotechnology Company	10	0.8%
Pharmaceutical Company	7	0.6%
Internet/Website Company	2	0.2%
Bioinformatics Company/Health Advocacy Organization	1	0.1%
Self-employed/Private Practice	12	0.9%
Diagnostic Laboratory	95	8%
University/Non-Medical Center	39	3%
Other	38	3%

Table 2: Employment Settings of Genetic Counselors, 2006.
Source: 2006 NSGC Professional Status Survey

Work Settings

In 2006, 69 percent of genetic counselors reported working in hospitals and university medical centers. Another 10.3 percent reported working in a physician's office, HMO, or clinic. Almost 12 percent reported employment in a laboratory or research setting. Only 2.7 percent reported working for biotechnology, pharmaceutical, bioinformatics or internet companies. Less than one percent (0.09%) reported being self-employed or in private practice. Of those in clinical practice, it appears that an overwhelming majority are employed as part of health care teams. See Table 2 for a more detailed listing of employment settings.

[16] Cooksey, Judith. *The Genetic Counselor Workforce. Training Programs, Professional Practice, and Issues Affecting Supply and Demand.* Illinois Center for Health Workforce Studies. Feb. 2000. pg. 13.

OVERLAPPING SCOPES OF PRACTICE

Two other professions share roles and duties similar to Genetic Counselors: nurses specializing in genetics and medical geneticists. Physicians also provide genetic counseling services.

Nursing

The Genetic Nursing Credentialing Commission (GNCC) offers two genetic specialty credentials. The Genetics Clinical Nurse (GCN) credential is available to Registered Nurses with baccalaureate degrees. The Advanced Practice Nurse in Genetics (APNG) credential is available to Advanced Practice Nurses with Masters Degrees. Both of these credentials are based on completion of a professional portfolio and do not include a certification exam (see certification, pg 12).

In contrast to Genetic Counselors, nurses are educated as generalist health care professionals and gain specialist knowledge in genetics through work experience or specialty training. Although genetic nursing and genetic counseling have much in common, genetic nurses have a nursing focus. Genetic counselors focus on selecting and interpreting genetic tests and helping patients adapt to and make decisions with genetic information. Genetic nurses integrate genetic information into health care, including treatments, prevention and wellness. They take a broad view when analyzing disease risk factors (including environmental and behavioral factors) and provide nursing care to persons with genetic conditions. Like genetic counseling, the role of genetic nursing in oncology and obstetrics is more pronounced than in other areas.

The International Society of Nurses in Genetics (ISONG) provides a concise list of the roles and tasks of GCNs and APNGs, below. Note that genetic counseling, along with facilitating and interpreting genetic tests are tasks reserved to APNGs.

A. What Can Genetic Nurses Do For You?

- obtain a detailed family history and construct a pedigree (family history diagram)
- assess and analyze hereditary and nonhereditary disease risk factors
- identify potential genetic conditions or genetic predisposition to disease
- provide genetic information and psychosocial support to individuals and families
- provide nursing care for patients and families at risk for or affected by diseases with a genetic component
- provide genetic counseling (Advanced Practice Nurses)
- facilitate genetic testing and interpret genetic test results and laboratory reports (Advanced Practice Nurses) [17]

A very small number of nurses have pursed credentials in genetics. The GNCC website lists 15 GCNs and 36 APNGs. None of them are located in Virginia.[18]

[17] International Society of Nurses in Genetics. Website. "Professional Practice". Accessed Nov. 19, 2010. http://www.isong.org/ISONG_professional_practice.php
[18] Genetic Nursing Credentialing Commission Website. Accessed Nov. 19, 2010. http://www.geneticnurse.org/geneticsnursegcn.html

Medical Geneticists

The American Board of Medical Genetics (ABMG), a member organization of the American Board of Medical Specialties, offers specialty certifications in medical genetics to physicians (MD and DO) and to Ph.D level laboratory personnel. The certifications are categorized into three groups:

- Clinical Genetics (Available to MDs and DOs only)
- Laboratory Specialties (Available to MDs, DOs and PhDs)
  - Clinical Biochemical
  - Clinical Cytogenetics
  - Clinical Molecular Genetics
- Subspecialty Certifications
  - Molecular Biochemical Genetics
  - Molecular Genetic Pathology (with the American Board of Pathology)

The ABMG previously certified PhD Medical Geneticists. PhD Medical Geneticists are similar to Clinical Genetists, and complete continuing education units in clinical genetics now that the PhD Medical Geneticist program has ceased. The Laboratory Specialists mainly work in diagnostic laboratories, performing, monitoring and interpreting genetic tests. Clinical Geneticists and PhD Medical Geneticists practice genetic medicine. They most often work with patients exhibiting or at risk for genetic disorders. However, as genetic information is becoming more integrated with preventative medicine and individualized treatments, the scope of clinical genetics is expanding. Additionally, clinical geneticists are often involved in research in their field. The American College of Medical Genetics provides the following list of activities in its scope of practice for Clinical Geneticists.

> The role of the medical geneticist is broad and may include:
>
> 1. Presymptomatic risk assessment, including family history risk assessment, genetic test selection and interpretation for individuals and family members, follow-up screening protocols, and treatment options.
>
> 2. Reproductive risk assessment including family history risk assessment, ethnicity specific screening, teratogen/pregnancy risk assessment, testing options, discussion of options for managing reproductive risk, and counseling regarding fetal therapeutic interventions to facilitate informed consent and empower decision-making.
>
> 3. Newborn (or other) population screening, including test interpretation, therapeutic intervention, and family counseling and carrier testing.
>
> 4. Proband evaluation including three generation pedigree, genetic physical examination, genetic/syndrome diagnosis, test selection and interpretation, case management, enzyme replacement or other therapeutic interventions, and family counseling.[19]

[19] American College of Medical Genetics. *Medical Genetics Scope of Practice*. Accessed Nov. 19, 2010. http://www.acmg.net/StaticContent/SOP-for-WEB.pdf

The ABMG also provides privileging guidelines for genetic counselors, GCNs and APNGs. The number of ABMG certified practitioners in Virginia as of November 2009 appears in Table 3. There are a total of 26 PhD Medical Geneticists and Clinical Geneticists in Virginia.

	Clinical Biochemical Geneticists	Clinical Biochemical /Molecular Geneticists	Clinical Cyto-geneticists	**Clinical Geneticists**	Clinical Molecular Geneticists	Medical Biochemical Geneticists	**PhD Medical Geneticist**
Virginia	2	1	14	**21**	5	0	**5**

Table 3: The number of Board-certified geneticists in Virginia. PhD Medical Geneticists and MD Clinical Geneticists provide clinical services.

THE ROLE OF DTC GENETIC TESTING COMPANIES

The Genetics & Public Policy Center lists 29 companies offering direct-to-consumer genetic tests. Some of these companies operate overseas, and provide their services through mail-order saliva samples. Other use brick and mortar specimen collection centers. Some of these companies offer only one or a few tests for specific conditions. Others offer a broad test covering a wide array of conditions. Some, but not all, of these encourage consumers to seek genetic counseling or the advice of physicians if they are concerned about any findings. They also provide web-based dashboards that provide user-friendly snapshots of risk analysis combined with drill-down options for pursing further analysis and links to related research and resources.

A recent GAO investigative report on DTC genetic tests has brought further federal attention to DTC genetic testing. The GAO submitted DNA from fictitious donors to several testing companies and used undercover methods to explore the marketing techniques of DTC genetic test companies. According to the GAO, they "did not conduct a scientific study but instead documented observations that could be made by any consumer."[20] The investigation found that different companies often provided contradictory information to consumers. One of the GAOs fictitious consumers "was told that he was at below-average, average, and above-average risk for prostate cancer and hypertension."[21] This suggests that the tests are either not accurate or are improperly interpreted. The GAO also found that some companies failed to provide promised "expert" consultation.

The GAO reported the following findings:

- Test results are misleading and of little use to consumers.
  - Different companies often provide different results for identical DNA.
  - Risk predictions sometimes conflict with diagnosed medical conditions or family history.
  - Fictitious African American and Asian donors did not receive complete test results, but were not advised of this prior to purchase.
  - "Company 1" provided conflicting predictions for the same DNA within the same test result report.
  - Follow-up consultations provide only general information.

[20] Ibid, pg. 1.
[21] United States Government Accountability Office. *Direct-to-consumer Genetic Tests: Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices.* GAO-10-847T. July 22, 2010.

- "Personalized" supplements, bogus endorsements and scientifically invalid claims were among deceptive marketing practices.

Genetic Test Interpretation Provided to Consumers

For this report, Department of Health Professions staff examined two online "demos" provided by two genetic testing companies: 23andMe and GenePlanet. Screenshots from these demos appear in Appendix D. This provided some insight into the utility of the information reported—assuming it is correct. Readers should keep in mind that a recent GAO investigation found that different companies often provided contradictory information regarding risk and these tests are not tested for efficacy or regulated by the US Food and Drug Administration.

The demos include website tools focusing on ease of use and "user-friendliness" but may provide misleading analysis of an individual's health risks. The first listing in the GenePlanet demo, for instance, reports a genetic test having high confidence that an individual has a 90% increased risk of multiple sclerosis. It adds a "personal risk" indicator line in the red to get the point across. The presentation seems almost by design to create an added sense of fear in consumers. Although the author is not a clinician, a quick search of the literature demonstrates that the incidence and prevalence of MS varies widely by population. Additionally, the risk of any individual developing multiple sclerosis is miniscule, rendering a 90 percent increase in risk meaningless outside of the realm of epidemiology. Although the statistics presented may be technically accurate, the presentation may cause undue alarm in consumers and do not seem designed to provide a meaningful evaluation of health risks.

Similarly, the demo shows a decreased risk for prostate cancer, with an indicator showing the individual is in the "green". Yet an individual with a decreased risk of prostate cancer compared the population still has a relatively good chance of developing prostate cancer. If an individual with a similar analysis chose to forgo screening for prostate cancer and pursue MS screening based on these tests, the individual would have an increased chance of death.

Individuals using the GenePlanet dashboard may drill down to find more information, including an analysis of risk (e.g., 11.04 % for prostate cancer) as well as "personal medical advice" (e.g., despite decreased risk, get screened for prostate cancer after age 45). It also includes more generic information on the disease and the genetics behind the analysis, along with citations.

The 23andMe dashboard provides a more accurate picture, including a presentation of individual risk. However, it may still confuse users. For instance, the dashboard shows an "Elevated Risk" for stomach cancer (in bright red font) and a "Decreased Risk" for Type 2 Diabetes (in bright green font). Yet the individual risk listed for stomach cancer is only 0.08 percent while the individual risk for Type 2 Diabetes is 14.5 percent. Drilling down in the 23andMe demo provides an odds calculator and information on the magnitude of genetic influence over other environmental factors that contribute to risk. It also includes a "What You Can Do" section, a list of resources (including a link to search for genetic counselors) a technical report with citations and a "MD's perspective" providing generic information on the disease.

Simply, by basing their presentation on comparison to population these companies emphasize minute variation that is not meaningful to individuals in a clinical sense. Color coding, using red and green, only adds to the effect. Additionally, environmental, familial or other factors related to risk may outweigh any genetic factors.

Recent Regulatory Activity

The US Food and Drug Administration has the authority to regulate genetic tests as a medical device, but has not aggressively pursued enforcement. Rather, regulation has historically been based on the Clinical Laboratory Improvement Amendments (CLIA) designed to maintain quality standards of clinical laboratories. Recently, however the FDA has taken a more aggressive stance towards genetic tests. In May, 2010, the FDA halted an effort by Walgreens to market an on-the-shelf genetic test. In July, the FDA sent letters to several providers of DTC genetic tests that provide information on medical conditions, indicating that these are medical devices subject to FDA regulation. The full scale of FDA regulation of genetic testing is still under consideration. This activity coincided with an investigation into "Personal Genetic Testing Kits" by the Subcommittee on Oversight and Investigations of the US House of Representatives' Committee on Energy and Commerce.[22]

Additionally, several states have banned or limited use of DTC genetic tests. New York and Maryland, for instance, determined some services to be the practice of medicine requiring a prescription from physicians. California licenses DTC genetic testing companies.

Regulation of genetic counselors would likely have minimal impact on DTC genetic testing. The tests are not currently regulated as medical tests and analysis of genetic information is not currently regulated as the practice of medicine. If genetic tests are medical tests or genetic analysis the practice of medicine, current regulations related to medical tests and the practice of medicine would likely ameliorate many of the concerns related to DTC genetic tests—for instance, by requiring tests to be accurate and consistent and requiring oversight by a regulated health care provider.

If these tests are not medical tests, and if analysis of genetic information is not the practice of medicine, then the issue of consumer protection is the purview of other agencies—the Department of Agriculture and Consumer Affairs, the State Corporation Commission or the Department of Professional and Occupational Regulation. These organizations may be better able to protect the rights of individuals to access their own genetic information while protecting them from false or misleading information.

The US Food and Drug Administration is taking tentative steps towards regulating some genetic tests as medical devices. The FDA's regulatory tools allow it to fine-tune regulatory controls to individual tests—placing more restrictions on those tests that pose the most risk of harm to consumers and none on those that pose insignificant or no risk. The Commonwealth of Virginia may wish to examine whether and which DTC genetic tests and related services constitute the practice of medicine.

[22] Appel, Jacob. "The Silent Rise of the DNA Nannies: Government wants to play keep-away with our genes". *The Washington Times*. Wed. Nov. 17, 2010. http://www.washingtontimes.com/news/2010/nov/17/the-silent-rise-of-the-dna-nannies/

EDUCATION

The American Board of Genetic Counselors accredits graduate-level Master's degree programs in Genetic Counseling. All programs must be directed by a Certified Genetic Counselor and have a medical director who is a physician ABMG certified in clinical genetics. Programs must consist of at least four academic semesters (or equivalent) spanning a 21 month time period. Programs must include clinical training involving at least 50 cases encompassing a variety of clinical activities and settings.

School	State
Medical College of Virginia/ Virginia Commonwealth University	Virginia
John Hopkins University/ National Human Genome Research Institute	Maryland
University of Maryland School of Medicine	Maryland
Howard University	District of Columbia
University of North Carolina at Greensboro	North Carolina

Table 4: Genetic Counseling Programs in Virginia & Bordering States

There are currently 32 ABGC accredited programs in the United States and three in Canada. These graduate about 200 students annually. There is one program in Virginia, one in Washington DC, two in Maryland and one in North Carolina (see Table 4).

CERTIFICATION

The American Board of Genetic Counselors is the only organization providing certification to genetic counselors. Prior to 1993, the American Board of Medical Genetics certified both genetic counselors and medical geneticists. In 1991 the American Board of Medical Specialties, which provides specialist certifications for physicians, invited the ABMG to join the organization and provide medical genetics specialty certifications to physicians. The ABMS prohibited the ABMG from certifying non-doctoral candidates, so it spun off its genetic counseling certification into the ABGC in 1993.[23]

The ABGC provides the Certified Genetic Counselors (Diplomates) credential (CGC). In 2009, the ABGC instituted new time-limited eligibility requirements for new candidates. Additionally, the ABGC ended its International Genetic Counseling Certification Examination program, limiting eligibility to students who graduate from ABGC accredited programs.

Generally speaking, graduates of ABGC accredited programs may attempt the certification exam three times within five years of graduation, or a fourth time if the candidate completes a specified amount of continuing education. There are some technical modifications to the time-limitations for uncertified persons who graduated prior to 2007 and persons who were previously certified but allowed certifications to lapse. In some cases these require candidates to complete continuing education or to obtain letters of recommendation. Once eligibility is determined by the ABGC, candidates are granted "Active Candidate Status" (ACS) which is a requirement for temporary licenses in some states and for professional activity by some employers.

An overview of eligibility requirements appears in Table 5. Information on the ABMG certification and the nursing credentials is included for comparison. Please note that the nursing credentials provided by the GNCC are based on a professional portfolio—there is no examination of knowledge or skills—and may include additional measures of achievement such as publication of papers and performance verification.

[23] American Board of Genetic Counseling Website. "History" Accessed Nov. 18, 2010. http://www.abgc.net/english/View.asp?x=1607

Certification	Provider	Educ-ation	Residency	Clinical Logbook	Other Requirements	Fee
Certified Genetic Counselor	ABGC	MS	-	50 cases (Education)	Verification of Training	$1,365
Clinical Genetics	ABMG	MD or DO	48 months	Yes	3 letters of Recommendation	$2,415
Laboratory Specialties	AMG	MD, DO or PhD	24 months	Yes	3 letters of Recommendation	$2,415
Advanced Practice Nurse in Genetics	GNCC	RN with Masters	300 hours of Genetic Practicum	50 Cases	50 CE hours in Genetics, 4 written case studies	$550
Genetics Clinical Nurse	GNCC	BSN	5 yrs experience in genetics	50 Cases	3 letters of reference, 45 CE hours in Genetics, 4 written case studies	$550

Table 5: Eligibility for Certified Genetic Counselor and related credentials

The ABGC exam consists of 200 multiple-choice questions (30 pretest). The exam content outline includes the following major categories. The full content outline appears in appendix E.

I. Case Preparation & History A. Case Preparatory Work B. Contracting C. Medical History D. Pedigree & Family History	**II. Risk Assessment & Diagnosis** A. Risk Assessment B. Diagnosis & Natural History Discussion C. Inheritance/Risk Counseling	**III. Testing** A. Testing Options B. Test Interpretation and Results Discussion
IV. Psychosocial Assessment & Support A. Psychosocial Assessment B. Psychosocial Support/ Counseling	**V. Ethical/Legal/Research/ Resources** A. Resources & Follow-up B. Ethical/Legal C. Research/Study Coordination D. Education/ Policy	

REGULATION IN OTHER STATES

Currently, 13 states have passed legislation regulating genetic counselors. At least seven have passed legislation in the past two years and have only recently implemented programs or not implemented them at all. All states require licensure, but three of these states have exemptions that in effect create title protection only. All states reference the ABGC accredited education and/or ABGC certification for eligibility. All but New Jersey and Hawaii also reference ABMG accredited education and/or ABMG certification as a medical geneticist for eligibility. New Jersey and Hawaii may, however, include or exempt medical geneticists through rulemaking provisions as these new statutes are implemented. There have been no reports of discipline.

Two of the states provide specific moral or religious freedom clauses. The Oklahoma statute specifically prohibits anything that would force a genetic counselor to advise about or refer for abortions. The Illinois statute provides a specific exemption for counseling by religious officials, as long as they do not represent themselves as genetic counselors or as providing genetic counseling. Many states refer directly to the NSGC Code of Ethics, while most incorporate the NSGC code of ethics indirectly through ABGC certification requirements. The NSGC Code of Ethics includes a requirement to "refer clients to other qualified professionals when they are unable to support the clients." An overview of state regulation of genetic counselors appears in Figure 1 (below) and Table 6 (next page).

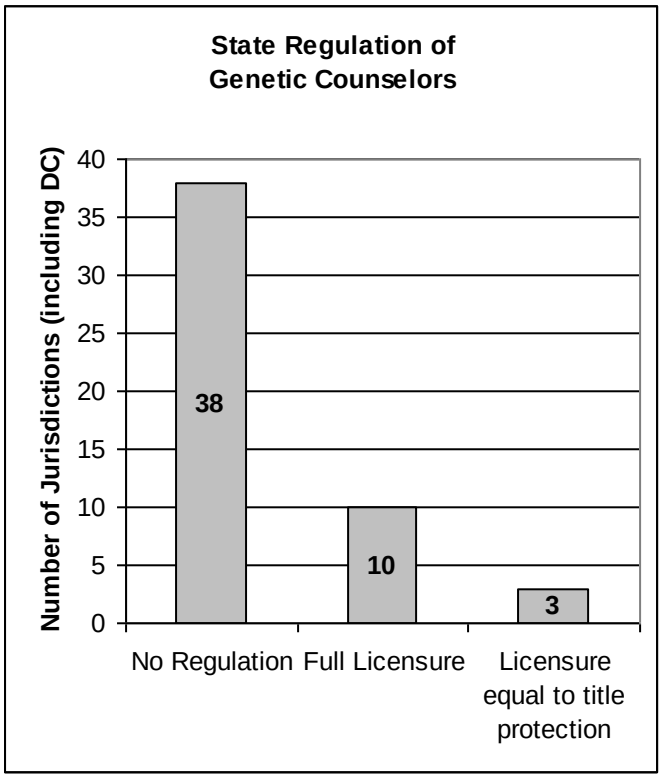


Figure 1: State Regulation of Genetic Counselors

	Level	**Include ABMG Geneticists?**	**Specific Religious Official Exemption**	**Regulated Under**	Effective Date	Notes
Oklahoma	License	Yes	-	Dept. of Health, Professional Counselor Licensing Division	November 1, 2006	GC cannot be forced to refer for abortion, specific provisions allow override of AGBC and ABMG standards
Tennessee	License	Yes	-	Board of Medical Examiners	July 1, 2007	
Illinois	License*	Yes	Yes	Division of Professional Regulation	September 29, 2004	Allows employment of persons not licensed as long as they do not hold themselves out as genetic counselors (amounts to title protection)
Massachusetts	License	Yes	-	Board of Registration of Genetic Counselors	October 11, 2006	
Delaware	License	Yes	-	Board of Medical Licensure & Discipline	June 30, 2011	
New Jersey	License	No	-	State Board of Medical Examiners	Upon implementation	
Indiana	License	Yes	-	Medical Licensing Board	June 30, 2010	
South Dakota	License	Yes	-	SD Board of Medical & Osteopathic Examiners	2009	
Utah	License	Yes	-	Genetic Counseling Board	January 1, 2002	
New Mexico	License	Yes	-	Medical Board	July 1, 2009	
Washington	License	Yes	-	Secretary of Health	August 1, 2010	
California	License*	Yes	-	Dept. of Public Health	Passed in 2000, Not yet implemented	Regulations not implemented due to lack of provisions for temporary practice in the law.
Hawaii	License*	No	-	Department of Health	2011	Does not restrict practice, just title protection

Table 6: Overview of State Regulation of Genetic Counselors
*Amounts to Title Protection only

ECONOMIC IMPACT OF REGULATION

The Virginia Association of Genetic Counselors reports that there are approximately 60 genetic counselors "living and/or working" in Virginia. Of these, approximately 80 percent, or 48 counselors, work at least part-time in clinical settings. If the employment patterns in Virginia follow national trends, approximately 41 would work in hospitals and university medical centers and the rest in physician, HMO or government offices. Actual employment patterns in Virginia are unknown, and a few may work in private practice, for testing laboratories or in other clinical settings.

Since regulatory boards are self-supporting, the small number of practitioners makes an independent board cost prohibitive. If regulation is pursued, advisory board status within the Board of Medicine or the Board of Counseling would be more appropriate methods. Most states that do regulate genetic counselors have placed them within the regulatory framework with medicine; however, Oklahoma regulates genetic counselors through its Professional Counselor Licensing Division. In 2009, the Department of Health Professions' Finance Department estimated annual costs of an advisory board under the Board of Medicine with 500 regulated practitioners at approximately $12,000.

Salaries & Barriers to Entry

The 2006 NSGC Professional Status Survey reports that genetic counselors earned an average salary of $59,548. While this is somewhat lower than the average wages of all persons with masters degrees ($70,186 in 2007)[24] this may be at least partially explained by the recent emergence of the profession. In 2006, over half of genetic counselors were under the age of 34, while only 10 percent were over age 50. Over two-thirds had less than ten years experience. Genetic counselors with 5-9 years of experience earned $61,268 on average and those with 10+ years earned $70,414. Top earners reported earning $150,000. In 2007, persons age 25 to 34 holding master's degrees earned $55,401 on average. Additionally, about 96 percent of the genetic counselor population was female in 2006. Females holding masters degrees earned about $32,000 less than males in 2006, $54,772 to $86,966 respectively. The NSGC Professional Status Survey reported male genetic counselors earned $63,871 on average while female genetic counselors earned $58,722 in 2006.

Regardless, salary is generally high enough to justify the normal costs associated with graduate education and licensing fees for health providers. The number of educational programs has grown from 18 in 1983 to 25 in 2003 to 32 in 2008. In 2008, there were approximately 225 graduates from accredited genetic counseling programs, and about 70 percent of applicants were rejected.[25] This suggests that the workforce is constrained by the educational pipeline and not by an inability to attract applicants. The earnings and status privileges associated with licensure are not likely to improve the availability of Certified Genetic Counselors if the educational pipeline is restrictive. Licensure may restrict the supply of genetic counseling services from persons without certifications or without graduate level education.

[24] U.S. Census Bureau, Current Population Survey; <http://www.census.gov/population/www/socdemo/educ-attn.html>.
[25] Erin Hammers, Rapporteur. *Innovations in Service Delivery in the Age of Genomics: Workshop Summary*. Roundtable on Translating Genomic-based Research for Health; Institute of Medicine. 2009. pg. 13.

Workforce Adequacy

Using an assessment performed by Kaiser Permanente regarding its genetic workforce needs, researchers at Virginia Commonwealth University (in an initiative known as GeneSEAN) estimated that Virginia needed 106 genetic counselors to meet its needs based on population figures from the 2000 US Census.[26] That number has likely risen along with Virginia's population and the breadth of genetic knowledge.

Despite reporting this figure, GeneSEAN also pointed out some of the difficulties in analyzing workforce needs. The breadth and depth of genetic information is expanding rapidly, and the practice of medicine is changing as a result. It is difficult to know how much this will result in an increased need for genetic specialists—including genetic counselors—and how much it will simply result in genetic information being incorporated into the training and daily practice of other health practitioners. GeneSEAN researchers summed up the quandary (emphasis added):

> *A major question regarding future workforce planning for geneticists revolves around what role they will play in the overall health care scheme in the future. If clinical geneticists continue to provide comprehensive genetic care for an ever-increasing patient population as medical technology expands, then a much larger workforce is needed;* ***however, many experts believe a more likely scenario is one in which geneticists play a larger role in educating PCPs, who will then incorporate more extensive genetic care into their daily practice.*** *With some reports of general practitioners spending an average of 7 minutes per patient, appropriate genetic care would obviously require significant changes in generalist practice patterns for the latter scenario to be acceptable. The future role of genetic counselors, and thus workforce needs, is also uncertain, although recent trends suggest that genetic counselors are increasingly working directly with other non-genetic medical specialists as part of health care delivery teams.*[27]

The implications of this problem for professional regulation are twofold: (1) it is difficult to know if the demand for genetic counselors, and the number of genetic counselors, will continue to grow, justifying a regulatory program and, (2) it is difficult to know if genetic information will be incorporated into the normal practice of currently unregulated health practitioners. The later implication is the most important. It is conceivable that both regulated and unregulated practitioners (e.g., ophthalmic assistants, cardiovascular technicians, clinical and laboratory scientists, dietitians and nutritionists, anesthesiologist assistants) may incorporate genetic knowledge into their normal practice. This could include technologists or assistants providing genetic test selection and interpretation or counseling services within specific specialties. A specialist assistant, for instance, could become expert in all diagnostic tests related to his specialty, including genetic tests. Considering the novelty and potential of genetic medicine, regulation may dampen professional innovation in the genetic sphere or may slow the incorporation of genetic technology throughout the health system. Simply, it may be too soon to ascertain whether a sole broad profession for genetic counseling is preferred, or whether the roles of genetic counselors will be incorporated by those currently performing diagnostic or patient education services.

[26] Virginia GeneSEAN, *Genetic Services and Education—An Assessment of Needs. A Comprehensive Assessment of Medical Genetic Services and Education in the Commonwealth of Virginia*. March 2006. Available at: http://www.vahealth.org/gns/vgac.htm
[27] Ibid, pg. 29.

RISK OF HARM

Risk of harm to the consumer is the "gateway" criterion for regulating any occupation or profession in Virginia. By statute, § 54.1-100 of the Code of Virginia, the risk must come from the unregulated practice of the profession (i.e. regulation should diminish the risk of harm) and the risk of harm must be direct and readily apparent. The Board of Health Professions has adopted specific guidance for the health professions:

Criterion One: Risk for Harm to the Consumer
The unregulated practice of the health occupation will harm or endanger the public health, safety or welfare. The harm is recognizable and not remote or dependent on tenuous argument. The harm results from: (a) practices inherent in the occupation, (b) characteristics of the clients served, (c) the setting or supervisory arrangements for the delivery of health services, or (d) from any combination of these factors.

Practices Inherent to the Occupation

Genetic counselors provide critical medical services to physicians and other providers and to patients. Today, clinically valid genetic tests help practitioners, predict the risk of developing certain conditions, predict the efficacy and side effects of certain drugs and diagnose genetic conditions. Genetic counselors assist physicians and other providers with selecting and interpreting genetic tests used for medical diagnosis, risk prediction and drug selection. They also assist patients directly in selecting and interpreting genetic tests for risk prediction. The latter currently involves helping patients determine if it is worthwhile to discover the risk of passing on genetic conditions to children, or to identify risks for breast cancer, colorectal cancer and other conditions.

Genetic Counselors and Risk Prediction

Genetic counselors often help patients determine whether they should pursue genetic testing to determine the risk of developing certain conditions or of conceiving a child with genetic conditions. Genetic counselors begin with a preliminary analysis of risk including a family history and other options. If the preliminary analysis indicates a potential risk, genetic testing may be pursued. Less invasive tests may be used to rule out low-risk candidates for more invasive tests (primarily amniocentesis in pregnant women). Prior to pursing genetic tests, genetic counselors also prepare patients for the psychological, social and ethical implications of available options and of the genetic knowledge itself. Options available to patients may be extreme and irreversible. Currently, genetic tests may be used by practitioners and patients to consider:

- Whether to conceive a child or to conceive by non-traditional means
- Mastectomy (breast removal)
- Oophorectomy (ovary removal)
- Colectomy (colon removal)

As clinically useful genetic tests proliferate, more prophylactic options may be available to practitioners and patients.

Inaccurate analysis indicating high risk may result in unnecessary procedures. Inaccurate analysis indicating low risk may create a false sense of security. Patients with unrecognized risks following genetic tests may not pursue prophylactic options or forgo increased screenings for cancers or other conditions. Couples considering pregnancy may conceive with an elevated risk of the child inheriting genetic conditions, or they may forgo in utero testing to identify conditions.

Genetic Counselors and Condition Diagnosis

Genetic counselors also assist physicians and other providers with selecting and interpreting genetic tests to make diagnoses of existing genetic conditions. This may occur pre- or post-natal up into adulthood for certain conditions. The diagnosis process may also begin with the genetic counselor providing a preliminary analysis of risk for certain conditions, or a physician may simply request assistance with navigating the constantly changing choices in genetic testing. In some cases, genetic tests (particularly pre-natal amniocentesis tests) are invasive and may put the patient or fetus at risk.[28] In its sunrise proposal, the VaAGC noted that genetic tests may be the sole basis for diagnosis for some conditions. For pre-natal diagnosis, genetic counselors will discuss available options to patients both prior to and after pursuing genetic tests. These options may include adoption, termination of pregnancy or support for raising a child with a genetic disease.

Psychological Implications of Genetic Tests

The results of genetic tests and the implications of available options may have profound psychological effects on patients. Genetic counselors prepare patients for these effects, point patient to additional resources (e.g., support groups) and may refer patients to mental health experts.

Court Cases

Staff uncovered 25 court cases dating back to 1977 regarding the failure of physicians and other practitioners to recommend genetic testing, properly infer risk or diagnose a genetic condition. Several of these included genetic counselors or medical geneticists in the suit; however, genetic counselors were usually co-defendants with physicians. Most often, these were "wrongful life" suits made by persons (or on behalf of persons) born with undiagnosed genetic diseases or "wrongful birth/conception" claims for damages by parents of children with undiagnosed genetic diseases or improperly assessed risk of disease. None of the suits referenced post-natal genetic testing. Only two suits indicated genetic counselors specifically, although some referenced genetic medical centers or teams that may have included genetic counselors. Of the two specifically involving genetic counselors, one found no deficiency in standard of care. In the other, a woman brought suit in New York in 1987 against genetic counselors employed by a medical center. The woman, who believed abortion is only moral in extreme circumstances, aborted her pregnancy based on an improper assessment of a severe genetic-related condition. The genetic counselors based their advice on medication use by the patient during pregnancy, advice later determined to be wrong.[29]

Characteristics of the Clients Served

Genetic counselors do not work with a particularly vulnerable patient population. However, the decisions made by patients may have a variety of social and ethical implications and may carry an increased risk of stigmatization. Patients depend on genetic counselors for non-directive advice that takes into account their personal and cultural beliefs and values.

One of the decisions clients may make with the assistance of genetic counselors is whether to terminate or not terminate a pregnancy. Since diagnosis of genetic conditions may come late in a pregnancy, this may

[28] Skotko, Brian G. "With New Prenatal Testing, Will Babies with Down Syndrome Slowly Disappear?" *Archives of Disease in Childhood*. June 15, 2009. 10.1136
[29] Martinez v. Long Island Jewish Hillside Medical Center. Court of Appeals of New York, 1987.

include late term abortions. Abortion is a perennial political and moral issue that ignites passion on both sides of the debate. The NSGC Code of Ethics requires non-directive counseling that respects client beliefs and cultural values. It also requires genetic counselors to make referrals to other qualified practitioners if they are unable to support their clients. This would presumably involve an unwillingness to counsel their clients on legal medical procedures.

The rights of the disabled are a related, if more obscure, issue that ignites no less passion. Pre-natal testing for genetic disease may be performed to prepare parents for a child born with genetic diseases. However, a 1999 study of the existing literature worldwide found that "92 percent of women who receive a definitive prenatal diagnosis of DS [Down Syndrome] choose to terminate their pregnancies."[30] This has resulted in a 15 percent reduction in the number of children born with Down Syndrome, or a 49 percent decrease compared to expected births considering the number of births and the age of women giving birth.[31] Similar outcomes are likely for other genetic conditions. For some, this brings up the ghost of eugenics. For others, such actions save both parents and offspring from unnecessary suffering and distress.

Thus, patients face a variety of socially explosive ethical concerns related to pre-natal genetic testing. These include whether to terminate a pregnancy, what conditions may warrant termination of pregnancy and how late in a pregnancy termination remains ethical. These patients have an increased need for medical privacy. They also require information, counseling and guidance that is unbiased and non-directive.

A recently published study noted:

> "On anonymous surveys, 63% [sic] of physicians and 86% of genetic professionals claim that they try to adhere to nondirective counseling. By contrast, 13% of physicians and 13% of genetic professionals admit to overemphasizing the negative aspects of DS [Down Syndrome] in hopes that pregnant women would seek a termination. Further, 10% of physicians and 2% of genetic professionals indicate that they overemphasize the positive aspects of DS in hopes that pregnant women will continue with their pregnancies. An additional 4% of physicians said that they actively 'urge' mothers to continue."[32]

Settings or Supervisory Arrangements

The greater majority of genetic counselors practice as part of a medical team in hospitals, physician offices or other health delivery facilities. A small number work for genetic testing, insurance or pharmaceutical companies and less than one percent are in independent practice.

Currently, many genetic tests are available only by prescription or referral. Direct-to-consumer genetic tests are also available, although these are not currently regulated as medical devices. The FDA has made recent moves indicating it will regulate more DTC genetic tests as medical devices. Regulation of genetic tests will have more of an impact on DTC genetic testing, as this will bring them into the medical regulatory paradigm and require tests to be accurate and effective. Regulation of genetic counselors may not diminish any risk of harm, medical or otherwise, from DTC genetic tests. On the contrary, the addition of state-regulated

[30] Ibid. Citing Research in Mansfild, Hopfer & Mareau. "Termination rates after prenatal diagnosis of Down syndrome, spina bifida, anencephaly, and Turner and Klinefelter syndromes: a systematic literature review. European Concerted Action: DADA (Decision-making After the Diagnosis of fetal Abnormality). Countries studied were U.S., U.K., New Zealand, France, and Singapore.
[31] Ibid.
[32] Skotko, Brian G. "With New Prenatal Testing, Will Babies with Down Syndrome Slowly Disappear?" *Archives of Disease in Childhood*. June 15, 2009. 10.1136

expert, good-faith counseling may only add an air of legitimacy to an industry which has yet to demonstrate the consistency, accuracy or clinical usefulness of its products.

Most of the harm attributed to improper genetic counseling in the medical sphere is harm caused by physicians or other regulated providers insufficiently trained in genetics. Examples of practitioner misuse and misinterpretation of genetic tests are scattered throughout the literature, including within the Sunrise proposal provided by the VaAGC. While it is evident that more training in genomics is warranted in the health workforce, regulation of genetic counselors would not prevent regulated practitioners from providing genetic counseling within their scope of practice. This hints at a lack of training among already regulated practitioners or an underuse of genetic counselors, but not a risk of harm from the unregulated practice of genetic counselors.

POLICY OPTIONS

At its May 3, 2011 meeting, the Board of Health Professions' Regulatory Research Committee considered the following policy options:

1. Delay a recommendation

The FDA is currently considering a new regulatory framework for genetic tests. From time to time, the FDA has issued regulations related to personnel requirements, and restrictions on who may order and receive test results. By using a classification system, the FDA often places more restrictions on the most complex and dangerous tests, while placing fewer restrictions on less complex/dangerous ones, allowing it to target harm more precisely than professional regulation. It may be worthwhile to examine any forthcoming FDA regulations before embarking on a new regulatory program.

2. No Regulation

There have been no reports of harm from the unregulated practice of genetic testing. Rather, reports of harm have come from inadequate counseling provided by regulated practitioners, generic information provided by genetic testing companies, failure to refer to genetic counseling or by simply not receiving counseling. This harm is symptomatic of a lack of genetic counseling services, not of incompetent or unscrupulous practice of unregulated counselors.

A shortage is apparent in the literature and by a comparison of the supply of genetic counselors to the demand projected by VCU researchers. Regulation may further limit the supply of genetic counseling services, especially if increases in educational requirements come to fruition. In the current environment, the economic impact of regulation may outweigh any benefits, especially as FDA regulation may place further restrictions on the availability of genetic tests.

3. Registration

Registration does not set any entry standards, but requires persons using a particular title, fulfilling certain roles or performing certain tasks to register with the state. Thus it does not ensure minimal qualifications, but it does provide information about practitioners, recourse for patients, and a method of preventing unscrupulous or incompetent persons from practicing.

Genetic testing and genetic counseling is largely unregulated at this time. Customer service representatives, regulated and unregulated practitioners of varying qualifications and specialties, and trained

genetic professionals are all providing genetic information to patients at some level. Registration would allow the Board to legally define genetic counseling and gain an understanding of who is performing genetic counseling services in the Commonwealth. It would give patients recourse in the event of unscrupulous or incompetent counseling. It would provide information on complaints or harm, allowing the Board to better gauge when the potential for harm from unregulated practice may be resulting in actual unregulated practice and harm.

4. Voluntary Certification/Title Protection

Voluntary certification/title protection restricts the ability of practitioners to use certain restricted titles unless they meet standards for education and/or certification set by regulation. Certified providers may be registered by the state, providing additional recourse for complainants, or title protection may be by statute only with rosters maintained by private certification boards.

Voluntary certification/title protection prevents unqualified providers from representing themselves as having certain qualifications to practice. In this case it would mainly restrict customer service representatives and other providers at genetic testing companies from referring to themselves as genetic counselors. Additionally, it may provide information to patients, and may protect them from choosing unqualified providers. However, patients must have knowledge of which providers are available and the ability to access qualified providers to make informed choices about providers.

Voluntary certification does not prevent persons using unprotected titles from providing genetic counseling. However, by regulating genetic counselors as a health profession and defining a scope of practice, it may provide an opportunity to place some restrictions on undelegated genetic counseling.

5. Licensure

Licensure confers a monopoly over a scope of practice to practitioners meeting certain qualifications and registered with a regulatory board. It is the most restrictive form of regulation and the one most likely to restrict the supply of practitioners.

Practices inherent to the profession of genetic counseling pose a significant risk of harm to patients. Although harm was not immediately attributable to the unregulated practice of genetic counseling, public comment and the literature did provide evidence of harm due to inadequate genetic counseling provided by regulated practitioners, or to a lack of counseling services. This suggests that incompetent, untrained or unscrupulous persons providing genetic counseling do pose a risk of harm to patients.

Licensure provides the most protection to patients from unregulated practice, but also places the most significant regulatory burden on practitioners, organizations and patients. To recommend licensure, genetic counseling must meet all seven criteria established by the Board. In particular, the Board may wish to consider whether the risk of harm justifies the restriction of the supply of practitioners, whether FDA regulation of genetic tests may provide an adequate alternative, or whether less restrictive forms of regulation may provide adequate protection.

RECOMMENDATIONS

At its May 3, 2011 meeting, the Regulatory Research Committee (RRC) of the Board of Health Professions recommended licensure for genetic counselors, based upon study findings and thoughtful application of the criteria. The RRC noted the inherent risk of harm and the common use of licensure to regulate genetic counselors in other states. The RRC also recommended genetic counselors be regulated through the Advisory Committee model under the Board of Medicine. The full Board of Health Professions adopted these recommendations at its afternoon meeting and directed staff to draft a model statute which appears in Appendix F.

Appendix

APPENDIX A: CONDITIONS TESTED BY TWO DTC GENETIC TESTING COMPANIES

23ANDME "HEALTH REPORTS: COMPLETE LIST"
HTTPS://WWW.23ANDME.COM/HEALTH/ALL/

The 23andMe service includes genetic analysis on all of the following diseases and conditions. This list grows every month as new research is published.

*** Established Research Reports**
Established Research reports give you information about conditions and traits for which there are genetic associations supported by multiple, large, peer-reviewed studies. Because these associations are widely regarded as reliable, we use them to develop quantitative estimates and explanations of what they mean for you.

Preliminary Research Reports
Preliminary Research reports are based on peer-reviewed, published research where the findings still need to be confirmed by the scientific community. They also include topics where there may be contradictory evidence. Topics may move from Preliminary Research to Established Research when and if sufficient follow-up studies are performed. New discoveries in genetics are being published all the time and we strive to keep our customers updated with the latest information on genetics and health.

View reports by ethnicity

Carrier Status (24)
Alpha-1 Antitrypsin Deficiency *
BRCA Cancer Mutations (Selected) *
Bloom's Syndrome *
Canavan Disease *
Connexin 26-Related Sensorineural Hearing Loss *
Cystic Fibrosis *
Factor XI Deficiency *
Familial Dysautonomia *
Familial Hypercholesterolemia Type B *
Familial Mediterranean Fever *
Fanconi Anemia (FANCC-related) *
G6PD Deficiency *
Gaucher Disease *
Glycogen Storage Disease Type 1a *
Hemochromatosis *
Limb-girdle Muscular Dystrophy *
Maple Syrup Urine Disease Type 1B *
Mucolipidosis IV *
Niemann-Pick Disease Type A *
Phenylketonuria *
Rhizomelic Chondrodysplasia Punctata Type 1 (RCDP1) *
Sickle Cell Anemia & Malaria Resistance *
Tay-Sachs Disease *
Torsion Dystonia *

Drug Response (18)
Abacavir Hypersensitivity *
Alcohol Consumption, Smoking and Risk of Esophageal Cancer *

Antidepressant Response
Beta-Blocker Response
Caffeine Metabolism
Clopidogrel (Plavix®) Efficacy *
Floxacillin Toxicity
Fluorouracil Toxicity *
Heroin Addiction
Lumiracoxib (Prexige®) Side Effects
Naltrexone Treatment Response
Oral Contraceptives, Hormone Replacement Therapy and Risk of Venous Thromboembolism *
Postoperative Nausea and Vomiting (PONV)
Pseudocholinesterase Deficiency *
Response to Hepatitis C Treatment *
Response to Interferon Beta Therapy
Statin Response
Warfarin (Coumadin®) Sensitivity *

Traits (42)

Alcohol Flush Reaction *
Asparagus Metabolite Detection
Avoidance of Errors
Birth Weight
Bitter Taste Perception *
Blood Glucose
Breastfeeding and IQ
C-reactive Protein Level
Earwax Type *
Eye Color *
Eye Color: Preliminary Research
Food Preference
Freckling
HDL Cholesterol Level
HIV Progression
Hair Color
Hair Curl *
Hair Curl: Preliminary Research
Hair Thickness
Height
Lactose Intolerance *
Leprosy Susceptibility
Longevity
Malaria Complications
Malaria Resistance (Duffy Antigen) *
Male Pattern Baldness *
Measures of Intelligence
Measures of Obesity
Memory
Muscle Performance *
Non-ABO Blood Groups *
Norovirus Resistance *
Odor Detection

Pain Sensitivity
Persistent Fetal Hemoglobin
Photic Sneeze Reflex
Refractive Error
Resistance to HIV/AIDS *
Response to Diet and Exercise
Sex Hormone Regulation
Smoking Behavior *
Tuberculosis Susceptibility

Disease Risk (91)

Abdominal Aortic Aneurysm
Age-related Macular Degeneration *
Alcohol Dependence
Alopecia Areata
Ankylosing Spondylitis
Asthma
Atopic Dermatitis
Atrial Fibrillation *
Atrial Fibrillation: Preliminary Research
Attention-Deficit Hyperactivity Disorder
Back Pain
Basal Cell Carcinoma
Behçet's Disease
Bipolar Disorder *
Bipolar Disorder: Preliminary Research
Bladder Cancer
Brain Aneurysm
Breast Cancer *
Breast Cancer Risk Modifiers
Celiac Disease *
Celiac Disease: Preliminary Research
Chronic Lymphocytic Leukemia
Chronic Obstructive Pulmonary Disease (COPD)
Cleft Lip and Cleft Palate
Cluster Headaches
Colorectal Cancer *
Creutzfeldt-Jakob Disease
Crohn's Disease *
Developmental Dyslexia
Endometriosis
Esophageal Cancer: Preliminary Research
Esophageal Squamous Cell Carcinoma (ESCC) *
Essential Tremor
Exfoliation Glaucoma *
Follicular Lymphoma
Gallstones
Generalized Vitiligo
Gestational Diabetes
Gout
Hashimoto's Thyroiditis

Heart Attack *
High Blood Pressure (Hypertension)
Hypertriglyceridemia
Intrahepatic Cholestasis of Pregnancy
Keloid
Kidney Disease
Larynx Cancer
Lou Gehrig's Disease (ALS)
Lung Cancer *
Lupus (Systemic Lupus Erythematosus) *
Male Infertility
Melanoma *
Melanoma: Preliminary Research
Multiple Sclerosis *
Nasopharyngeal Carcinoma
Neural Tube Defects
Neuroblastoma
Nicotine Dependence
Nonalcoholic Fatty Liver Disease
Obesity *
Obesity: Preliminary Research
Obsessive-Compulsive Disorder
Oral and Throat Cancer
Osteoarthritis
Otosclerosis
Paget's Disease of Bone
Parkinson's Disease *
Parkinson's Disease: Preliminary Research
Peripheral Arterial Disease
Placental Abruption
Preeclampsia
Primary Biliary Cirrhosis
Progressive Supranuclear Palsy
Prostate Cancer *
Psoriasis *
Restless Legs Syndrome *
Rheumatoid Arthritis *
Schizophrenia
Selective IgA Deficiency
Sjögren's Syndrome
Stomach Cancer (Gastric Cardia Adenocarcinoma) *
Stomach Cancer: Preliminary Research
Stroke
Tardive Dyskinesia
Thyroid Cancer
Tourette's Syndrome
Type 1 Diabetes *
Type 2 Diabetes *
Ulcerative Colitis *

Uterine Fibroids
Venous Thromboembolism *

B. A list of diseases, talents and medications, tested by GenePlanet

http://www.geneplanet.com/

1. Genetic testing for disease susceptibility

ARMD Alzheimer`s disease Ankylosing spondylitis Asthma Coronary artery disease Atrial fibrillation Bipolar disorder Breast cancer Celiac disease	Crohn`s disease Depression Dyslexia Endometrial cancer Gallstones Hypertension Long QT interval Lung cancer	Multiple sclerosis Peripheral arterial disease Prostate cancer Psoriasis Restless leg syndrom Rheumatoid arthritis Type 1 diabetes Type 2 diabetes

2. Genetic testing for medicament response

Beta blockers and heart Beta blockers and tension Efficacy of Aspirin	Headache and triptans Statins against heart attack The effect of antidepressants	The secret of Viagra Warfarin efficacy

3. Genetic testing for traits and talents

Alcohol flush reaction Avoidance of errors Birth weight Bitter taste perception Caffeine metabolism Earwax type Effect of breastfeeding on IQ Episodic memory performance	Eye colour Fat intake and BMI Freckles HDL cholesterol level Lactose intolerance Malaria resistance Measures of intelligence	Memory of older people Muscle explosiveness Norovirus resistance Odour detection Pain sensitivity Skin colour Nicotine dependence

With Geneplanet genetic testing, you can reveal what is written in your genes, it helps you understand the effect of genes on your life and advises how to make the most of your genetic advantages.

APPENDIX B: NGSC CODE OF ETHICS

A Code of Ethics is a document which attempts to clarify and guide the conduct of a professional so that the goals and values of the profession might best be served.

Preamble

Genetic counselors are health professionals with specialized education, training, and experience in medical genetics and counseling. The National Society of Genetic Counselors (NSGC) is the leading voice, authority and advocate for the genetic counseling profession. As such, the NSGC is an organization that furthers the professional interests of genetic counselors, promotes a network for communication within the profession, and deals with issues relevant to human genetics. With the establishment of this code of ethics the NSGC affirms the ethical responsibilities of its members and provides them with guidance in their relationships with self, clients, colleagues, and society. NSGC members are expected to be aware of the ethical implications of their professional actions and to adhere to the guidelines and principles set forth in this code.

Introduction

A code of ethics is a document that attempts to clarify and guide the conduct of a professional so that the goals and values of the profession might best be served. The NSGC Code of Ethics is based upon the relationships genetic counselors have with themselves, their clients, their colleagues, and society. Each major section of this code begins with an explanation of one of these relationships, along with some of its values and characteristics. These values are drawn from the ethical principles of autonomy, beneficence, nonmaleficence, and justice. Although certain values are found in more than one relationship, these common values result in different guidelines within each relationship.

No set of guidelines can provide all the assistance needed in every situation, especially when different relationships appear to conflict. Therefore, when considered appropriate for this code, specific guidelines for prioritizing the relationships have been stated. In other areas, some ambiguity remains, allowing for the experience of genetic counselors to provide the proper balance in responding to difficult situations.

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:

Seek out and acquire sufficient and relevant information required for any given situation.

1. Continue their education and training.
2. Keep abreast of current standards of practice.
3. Recognize the limits of their own knowledge, expertise, and therefore competence in any given situation.
4. Accurately represent their experience, competence and credentials, including training and academic degrees.
5. Acknowledge and disclose circumstances that may result in a real or perceived conflict of interest.
6. Avoid relationships and activities that interfere with professional judgment or objectivity.
7. Be responsible for their own physical and emotional health as it impacts on their professional performance

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:

1. Serve those who seek services regardless of personal or external interests or biases.
2. Clarify and define their professional role(s) and relationships with clients, and provide an accurate description of their services.
3. Respect their clients' beliefs, inclinations, circumstances, feelings, family relationships and cultural traditions.
4. Enable their clients to make informed decisions, free of coercion, by providing or illuminating the necessary facts, and clarifying the alternatives and anticipated consequences.
5. Refer clients to other qualified professionals when they are unable to support the clients.
6. Maintain information received from clients as confidential, unless released by the client or disclosure is required by law.
7. Avoid the exploitation of their clients for personal advantage, profit, or interest.

Section III: Genetic Counselors and Their Colleagues

The genetic counselors' relationships with other genetic counselors, students, and other health professionals are based on mutual respect, caring, cooperation, and support. Therefore, genetic counselors strive to:

1. Share their knowledge and provide mentorship and guidance for the professional development of other genetic counselors, students and colleagues.
2. Respect and value the knowledge, perspectives, contributions, and areas of competence of colleagues and students, and collaborate with them in providing the highest quality of service.
3. Encourage ethical behavior of colleagues.
   Assure that individuals under their supervision undertake responsibilities that are commensurate with their knowledge, experience and training.
4. Maintain appropriate limits to avoid the potential for exploitation in their relationships with students and colleagues.

Section IV: Genetic Counselors and Society

The relationships of genetic counselors with society include interest and participation in activities that have the purpose of promoting the well-being of society and access to health care. Therefore, genetic counselors, individually or through their professional organizations, strive to:

1. Keep abreast of societal developments that may endanger the physical and psychological health of individuals.
2. Promote policies that aim to prevent discrimination.
3. Oppose the use of genetic information as the basis for discrimination.
4. Participate in activities necessary to bring about socially responsible change.
5. Serve as a source of reliable information and expert opinion for policymakers and public officials.
6. Keep the public informed and educated about the impact on society of new technological and scientific advances and the possible changes in society that may result from the application of these findings.
7. Support policies that assure ethically responsible research.
8. Adhere to laws and regulations of society. However, when such laws are in conflict with the principles of the profession, genetic counselors work toward change that will benefit the public interest.

Adopted 1/92 by the National Society of Genetic Counselors, Inc.; Revised 12/04, 1/06

APPENDIX C: NSGC Scope of Practice Document

Genetic Counselors' Scope of Practice

This "Genetic Counselors Scope of Practice" statement outlines the responsibilities of individuals engaged in the practice of genetic counseling. Genetic counselors are health professionals with specialized education, training and experience in medical genetics and counseling who help people understand and adapt to the implications of genetic contributions to disease.[1] Genetic counselors interact with clients and other healthcare professionals in a variety of clinical and non-clinical settings, including, but not limited to, university-based medical centers, private hospitals, private practice, and industry settings. The instruction in clinical genetics, counseling, and communication skills required to carry out the professional responsibilities described in this statement is provided in graduate training programs accredited by the American Board of Genetic Counseling (ABGC)[2] or the equivalent, as well as through professional experience and continuing education courses.

The responsibilities of a genetic counselor are threefold: (i) to provide expertise in clinical genetics; (ii) to counsel and communicate with patients on matters of clinical genetics; and (iii) to provide genetic counseling services in accordance with professional ethics and values. Specifically:

Section I: Clinical Genetics

1. Explain the nature of genetics evaluation to clients. Obtain and review medical and family histories, based on the referral indication, and document the family history using standard pedigree nomenclature.

2. Identify additional client and family medical information relevant to risk assessment and consideration of differential diagnoses, and assist in obtaining such information.

3. Research and summarize pertinent data from the published literature, databases, and other professional resources, as necessary for each client.

4. Synthesize client and family medical information and data obtained from additional research as the basis for risk assessment, differential diagnosis, genetic testing options, reproductive options, follow-up recommendations, and case management.

5. Assess the risk of occurrence or recurrence of a genetic condition or birth defect, using a variety of techniques, including knowledge of inheritance patterns, epidemiologic data, quantitative genetics principles, statistical models, and evaluation of clinical information, as applicable.

6. Explain to clients, verbally and/or in writing, medical information regarding the diagnosis or potential occurrence of a genetic condition or birth defect, including etiology, natural history, inheritance, disease management and

potential treatment options.

7. Discuss available options and delineate the risks, benefits and limitations of appropriate tests and clinical assessments. Order tests and perform clinical assessments in accordance with local, state and federal regulations.

8. Document case information clearly and concisely in the medical record and in correspondence to referring physicians, and discuss case information with other members of the healthcare team, as necessary.

9. Assist clients in evaluating the risks, benefits and limitations of participation in research, and facilitate the informed consent process.

10. Identify and access local, regional, and national resources such as support groups and ancillary services; discuss the availability of such resources with clients; and provide referrals, as necessary.

11. Plan, organize and conduct public and professional education programs on medical genetics, patient care and genetic counseling issues.

Section II: Counseling and Communication

1. Develop a genetic counseling agenda with the client or clients that includes identification and negotiation of client/counselor priorities and expectations.

2. Identify individual client and family experiences, behaviors, emotions, perceptions, values, and cultural and religious beliefs in order to facilitate individualized decision making and coping.

3. Assess client understanding and response to medical information and its implications, and educate client appropriately.

4. Utilize appropriate interviewing techniques and empathic listening to establish rapport, identify major concerns and engage clients in an exploration of their responses to the implications of the findings, genetic risks, and available options/interventions.

5. Identify the client's psychological needs, stressors and sources of emotional and psychological support in order to determine appropriate interventions and/or referrals.

6. Promote client-specific decision making in an unbiased non-coercive manner that respects the client's culture, language, traditions, lifestyle, religious beliefs and values.

7. Use knowledge of psychological structure to apply client-centered techniques and family systems theory to facilitate adjustment to the

occurrence or risk of occurrence of a congenital or genetic disorder.

Section III: Professional Ethics and Values

1. Recognize and respond to ethical and moral dilemmas arising in practice, identify factors that promote or hinder client autonomy, and understand issues surrounding privacy, informed consent, confidentiality, real or potential discrimination and potential conflicts of interest.

2. Advocate for clients, which includes understanding client needs and perceptions, representing their interests in accessing services, and eliciting responses from the medical and social service systems as well as the community at large.

3. Recognize personal limitations in knowledge and/or capabilities and seek consultation or appropriately refer clients to other providers.

4. Maintain professional growth, which includes acquiring relevant information required for a given situation, keeping abreast of current standards of practice as well as societal developments, and seeking out or establishing mechanisms for peer support.

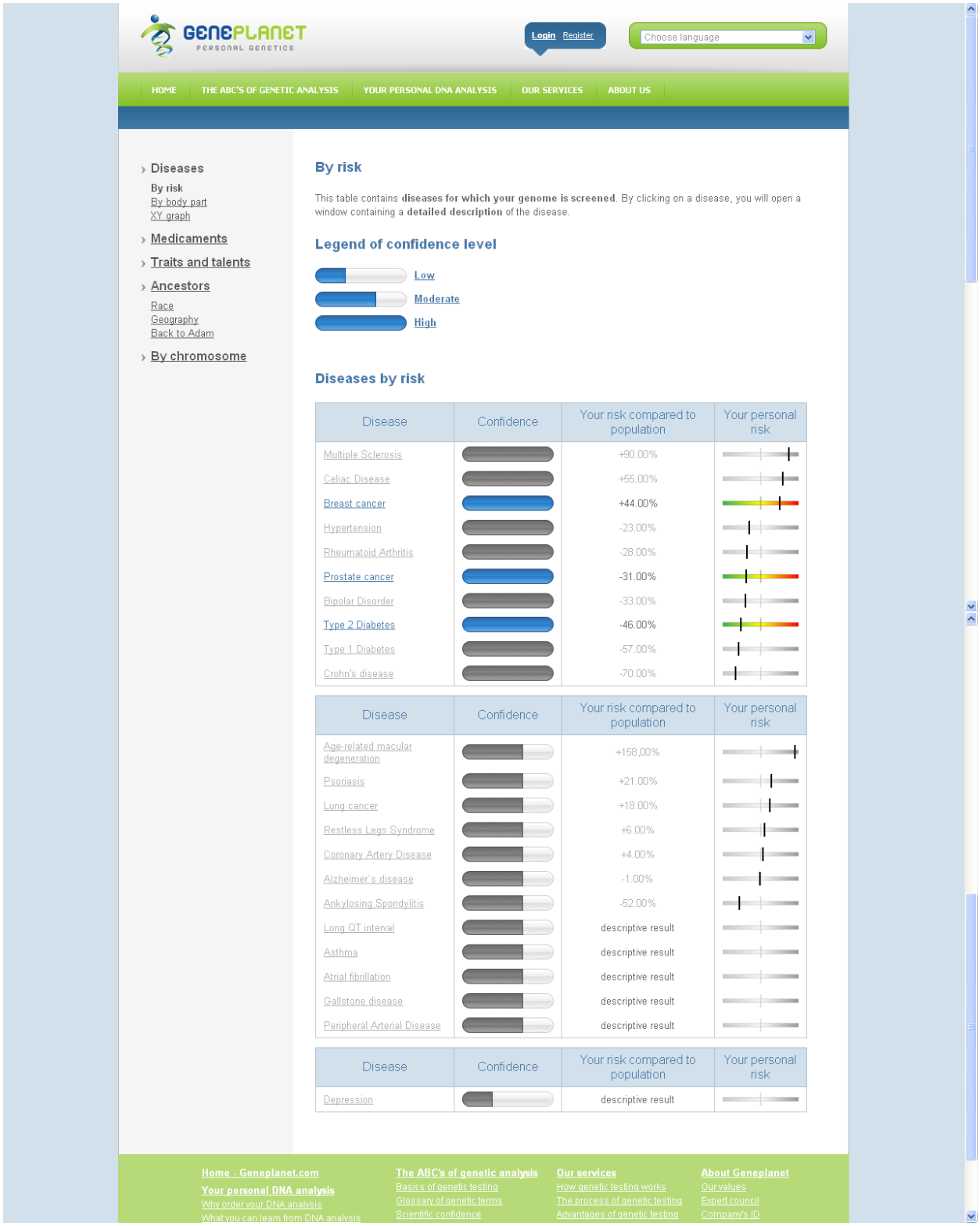
5. Respect a client's right to confidentiality, being mindful of local, state and federal regulations governing release of personal health information.

This Scope of Practice statement was approved in June 2007 by the National Society of Genetic Counselors (NSGC) - the leading voice, advocate and authority for the genetic counseling profession. It is not intended to replace the judgment of an individual genetic counselor with respect to particular clients or special clinical situations and cannot be considered inclusive of all practices or exclusive of other practices reasonably directed at obtaining the same results. In addition, the practice of genetic counseling is subject to regulation by federal, state and local governments. In a subject jurisdiction, any such regulations will take precedence over this statement. NSGC expressly disclaims any warranties or guarantees, express or implied, and shall not be liable for damages of any kind, in connection with the information set forth in this Scope of Practice statement or for reliance on its contents.

Genetic counseling is a dynamic profession, which undergoes rapid change with the discovery of new genetic information and the development of new genetic tests and treatment options. Thus, NSGC will periodically review and, where appropriate, revise this statement as necessary for consistency with current **PRACTICE INFORMATION.**

APPENDIX D: SCREENSHOTS FROM GENETIC TESTING WEB DEMOS ACCESSED 11/24/2010

GENEPLANET: [HTTP://WWW.GENEPLANET.COM/PRESENTATION/DISEASES/BY_RISK](http://www.geneplanet.com/presentation/diseases/by_risk)



GENEPLANET
PERSONAL GENETICS

Login Register

Choose language

HOME | THE ABC'S OF GENETIC ANALYSIS | YOUR PERSONAL DNA ANALYSIS | OUR SERVICES | ABOUT US

- Diseases
  - By risk
  - By body part
  - XY graph
- Medicaments
- Traits and talents
- Ancestors
  - Race
  - Geography
  - Back to Adam
- By chromosome

All diseases | Previous disease | Next disease | Prostate cancer

Prostate cancer

Confidence level: Strong

The prostate is a gland of the male reproductive system. It is located ventrally of the rectum and it surrounds the urethra just below the urinary bladder. Its main role is the secretion of some components of the seminal fluid. In older men, especially after the age of 50, prostate hypertrophy (i.e. enlargement) often occurs due to the effects of the male hormone testosterone, among other influences. In some cases, however, prostate cancer can develop as well. Prostate cancer is a disease characterized by the changes in the genetic material of prostate cells and consequently uncontrolled division and invasion of cancer cells into the surrounding tissues. Due to its location and extensive network of blood and lymph vessels, it is a very aggressive, fast-spreading cancer.

More ...

My data | Therapy and prevention | Background | Genetic analysis

Your current risk

11.04%

Population current risk

16.00%

Your genetic risk

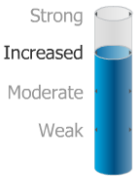
-31.00%

Personal medical advice *read more >>>*

Your genetic analysis showed that you have a slightly decreased risk for prostate cancer compared to the average male population. The circumscribed cancerous changes in the prostate are very common in men after the age of 50; thus, even a decreased risk does not absolutely protect you from this disease. If the growth of these cells is widely spread and metastases appear, the prognosis of this cancer is very grim. Thus, it is recommended for all men after the age of 45 to undergo annual screening for prostate cancer. Only an early detection of this cancer enables timely surgical removal of the prostate and a complete cure.

GenePlanet Medical Team *read more >>>*

Consult with our experts

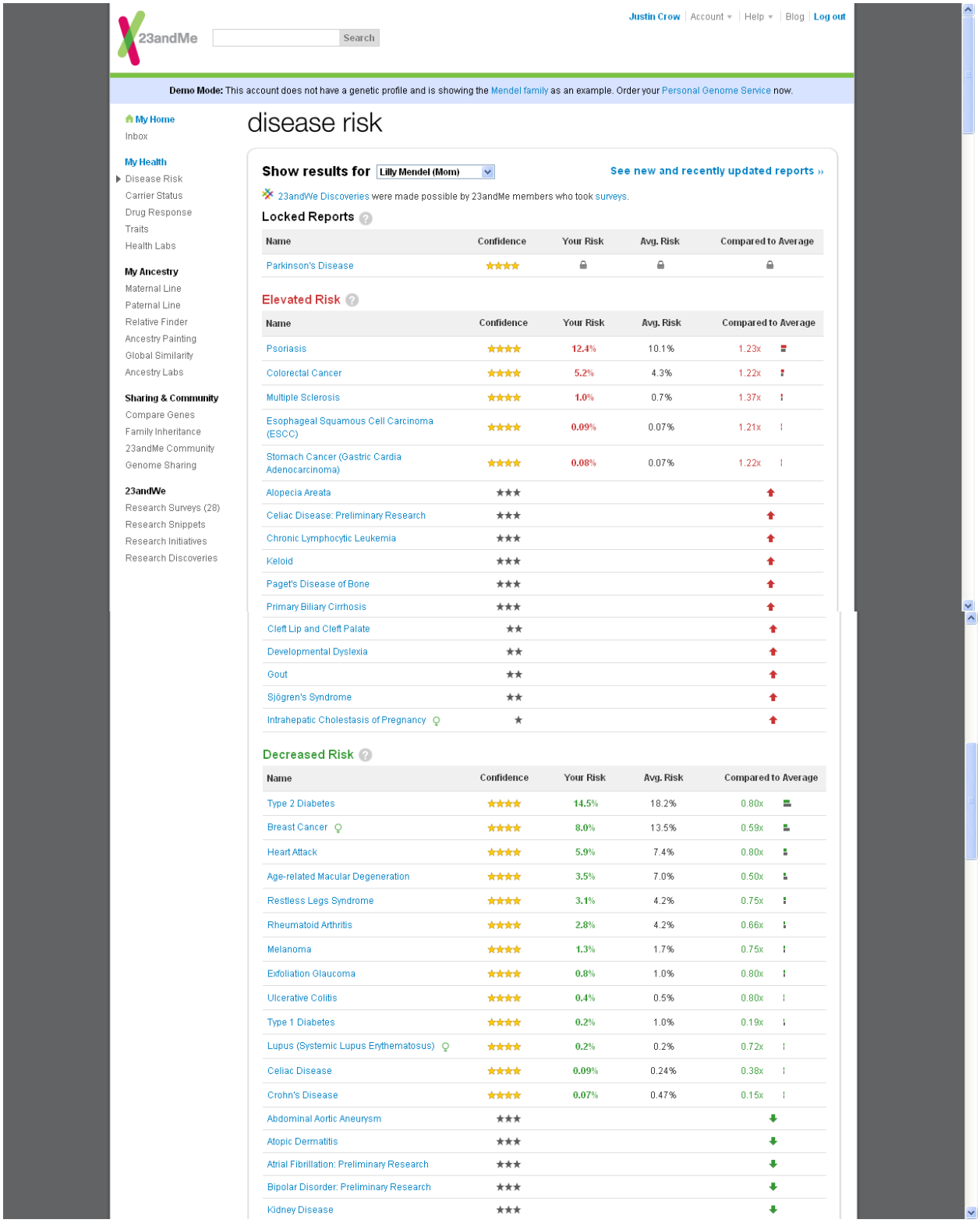


The influence of genes

Increased

Prostate cancer belongs to the class of diseases whose appearance is attributable to the genes to a **large extent.** Heritability of such diseases is relatively high, but it usually does not surpass 50%. Genes often determine congenital malformations that are unresponsive to environmental influences; however, an **adequate behaviour** and lifestyle can nevertheless substantially influence the appearance of the disease.

23andMe: https://www.23andme.com/user/signup/ (Requires account signup)



Justin Crow | Account | Help | Blog | Log out

23andMe Search

Demo Mode: This account does not have a genetic profile and is showing the Mendel family as an example. Order your Personal Genome Service now.

My Home
Inbox

My Health
Disease Risk
Carrier Status
Drug Response
Traits
Health Labs

My Ancestry
Maternal Line
Paternal Line
Relative Finder
Ancestry Painting
Global Similarity
Ancestry Labs

Sharing & Community
Compare Genes
Family Inheritance
23andMe Community
Genome Sharing

23andWe
Research Surveys (28)
Research Snippets
Research Initiatives
Research Discoveries

disease risk

Show results for Lilly Mendel (Mom) — See new and recently updated reports »

23andWe Discoveries were made possible by 23andMe members who took surveys.

Locked Reports

Name	Confidence	Your Risk	Avg. Risk	Compared to Average
Parkinson's Disease	★★★★	🔒	🔒	🔒

Elevated Risk

Name	Confidence	Your Risk	Avg. Risk	Compared to Average
Psoriasis	★★★★	12.4%	10.1%	1.23x
Colorectal Cancer	★★★★	5.2%	4.3%	1.22x
Multiple Sclerosis	★★★★	1.0%	0.7%	1.37x
Esophageal Squamous Cell Carcinoma (ESCC)	★★★★	0.09%	0.07%	1.21x
Stomach Cancer (Gastric Cardia Adenocarcinoma)	★★★★	0.08%	0.07%	1.22x
Alopecia Areata	★★★			
Celiac Disease: Preliminary Research	★★★			
Chronic Lymphocytic Leukemia	★★★			
Keloid	★★★			
Paget's Disease of Bone	★★★			
Primary Biliary Cirrhosis	★★★			
Cleft Lip and Cleft Palate	★★			
Developmental Dyslexia	★★			
Gout	★★			
Sjögren's Syndrome	★★			
Intrahepatic Cholestasis of Pregnancy ♀	★			

Decreased Risk

Name	Confidence	Your Risk	Avg. Risk	Compared to Average
Type 2 Diabetes	★★★★	14.5%	18.2%	0.80x
Breast Cancer ♀	★★★★	8.0%	13.5%	0.59x
Heart Attack	★★★★	5.9%	7.4%	0.80x
Age-related Macular Degeneration	★★★★	3.5%	7.0%	0.50x
Restless Legs Syndrome	★★★★	3.1%	4.2%	0.75x
Rheumatoid Arthritis	★★★★	2.8%	4.2%	0.66x
Melanoma	★★★★	1.3%	1.7%	0.75x
Exfoliation Glaucoma	★★★★	0.8%	1.0%	0.80x
Ulcerative Colitis	★★★★	0.4%	0.5%	0.80x
Type 1 Diabetes	★★★★	0.2%	1.0%	0.19x
Lupus (Systemic Lupus Erythematosus) ♀	★★★★	0.2%	0.2%	0.72x
Celiac Disease	★★★★	0.09%	0.24%	0.38x
Crohn's Disease	★★★★	0.07%	0.47%	0.15x
Abdominal Aortic Aneurysm	★★★			
Atopic Dermatitis	★★★			
Atrial Fibrillation: Preliminary Research	★★★			
Bipolar Disorder: Preliminary Research	★★★			
Kidney Disease	★★★			

(page continues—includes disclaimer)

23andMe Search

Justin Crow | Account | Help | Blog | Log out

Demo Mode: This account does not have a genetic profile and is showing the Mendel family as an example. Order your Personal Genome Service now.

My Home
Inbox

My Health
Disease Risk
Carrier Status
Drug Response
Traits
Health Labs

My Ancestry
Maternal Line
Paternal Line
Relative Finder
Ancestry Painting
Global Similarity
Ancestry Labs

Sharing & Community
Compare Genes
Family Inheritance
23andMe Community
Genome Sharing

23andWe
Research Surveys (28)
Research Snippets
Research Initiatives
Research Discoveries

disease risk

Type 2 Diabetes ★★★★

Established Research report on 9 reported markers, updated June 4th, 2009.

Your Data | How It Works | Timeline | MD's Perspective | Resources | Technical Report | Next ▸ Ulcerative Colitis

About Type 2 Diabetes

Printable Version

The most common type of diabetes, type 2 diabetes mellitus occurs when chronically high blood sugar levels cause a breakdown of the body's natural response to eating sweets and starches. Left untreated, type 2 diabetes can result in kidney failure, blindness, and circulatory problems that increase the risk of heart attack or stroke. In the United States, almost 21 million children and adults have diabetes, but the rate of new diagnoses is increasing.

Learn more about the biology of Type 2 Diabetes...
Major discoveries in Type 2 Diabetes...

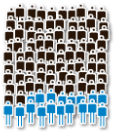
You're 0% complete! Visit the Research Snippets page to contribute to more genetic research discoveries.

Suggest a question topic.

Your Genetic Data

Show information for Lilly Mendel (Mom) assuming European ethnicity and an age range of 20-79
Where's mine?

Lilly Mendel (Mom)
14.5 out of 100
women of European ethnicity who share Lilly Mendel (Mom)'s genotype will develop Type 2 Diabetes between the ages of 20 and 79.



Average
18.2 out of 100
women of European ethnicity will develop Type 2 Diabetes between the ages of 20 and 79.

What does the Odds Calculator show me?

Use the ethnicity and age range selectors above to see the estimated incidence of Type 2 Diabetes due to genetics for women with **Lilly Mendel (Mom)**'s genotype. The 23andMe Odds Calculator assumes that a person is free of the condition at the lower age in the range. You can use the name selector above to see the estimated incidence of Type 2 Diabetes for the genotypes of other people in your account.

The 23andMe Odds Calculator only takes into account effects of markers with known associations that are also on our genotyping chip. Keep in mind that aside from genetics, environment and lifestyle may also contribute to one's chances of developing type 2 diabetes.

Genes vs. Environment

26 % Attributable to Genetics

The heritability of type 2 diabetes is estimated to be 26%. This means that environmental factors contribute more to differences in risk for this condition than genetic factors. Genetic factors that play a role in type 2 diabetes include both unknown factors and known factors such as the SNPs we describe here. Environmental factors include obesity, gestational diabetes, giving birth to at least one baby weighing nine pounds or more, high blood pressure, abnormal cholesterol levels, physical inactivity, polycystic ovarian syndrome, other clinical conditions associated with insulin resistance, a history of impaired glucose tolerance or impaired fasting glucose, and a history of cardiovascular disease. (sources)

What You Can Do

Assuming the ethnicity setting above is correct, your test results indicate you are not at increased risk for type 2 diabetes. Note, however, that non-genetic factors and family history can also influence your risk. Type 2 diabetes is a major health problem—more than 20 million children and adults in the United States are affected, and the rate of new diagnoses is increasing. There are steps you can take to reduce your risk.

Ask your doctor about screening tests

The American Diabetes Association recommends diabetes screening for:

- everyone 45 years of age and older, particularly those with a BMI greater than 25
- people younger than 45 who are overweight and who also have other risk factors, such as a family history of the disease, high cholesterol or blood pressure, or a history of gestational diabetes.

Testing can be a fasting blood glucose test, an oral glucose tolerance test or a hemoglobin A1C test.

Estimate your risk

Use the questionnaire available from Your Disease Risk, Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine to get an estimate of your risk for type 2 diabetes.

Keep your weight in check

The Diabetes Prevention Program, a federally-funded study published in 2002, found that people at high risk for diabetes who exercised for

You can use this BMI calculator to determine if your weight is in the healthy range.

Learn your family medical history

According to the American Diabetes Association, a family history of type 2 diabetes is one of the strongest risk factors for getting the disease in people living a Western lifestyle. In these societies, the risk of developing type 2 diabetes is about one in seven if a parent had the disease and was diagnosed before age 50, and about one in 13 if the parent was diagnosed at a later age. The risk is even higher if both parents had the disease. The U.S. Surgeon General's My Family Health Portrait tool can help you assemble your family medical history.

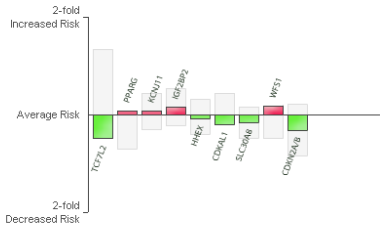
Connect with relevant groups

- American Diabetes Association
  800-DIABETES
- Diabetes Action, Research, and Education Foundation

Talk with a genetic counselor

A genetic counselor can help you understand more about your 23andMe reports and respond to your genetic health questions. 23andMe is collaborating with Informed Medical Decisions, Inc., to give you direct access to board-certified genetic counselors that have been specifically trained to guide you through your 23andMe results. Click here to learn more about their independent genetic counseling services.

Marker Effects



What does this chart show?

The chart shows the approximate effects of the selected person's genotype at the 9 reported markers. Higher, red bars indicate increased risk from the average, while lower, green bars indicate decreased risk from the average. The light gray bars show the maximum possible effects for the possible genotypes at the marker.

Recent Posts Tagged With Type 2 Diabetes

Diabetes/Alzheimers link
Tag: Type 2 Diabetes
By little bit | Add an answer

On Epigenetic mechanisms in the development of T2D
Tag: Type 2 Diabetes
By William Martin | 3 responses

Role of Toxins in Type 2 Diabetes More Important Than Genetic Markers
Tag: Type 2 Diabetes
By abradley | 2 responses

» View all posts tagged with Type 2 Diabetes
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TCF7L2 — Marker: rs7903146

How the gene TCF7L2 affects the onset of type 2 diabetes is not completely understood. TCF7L2 has been shown to play a role in the development of the islets of Langerhans, which contain the cells in the pancreas that make insulin. As a result, people who possess the TT or CT genotypes at the SNP in this gene produce less insulin when given a dose of glucose. This means that they have a poor insulin response to begin with, and will thus be less efficient at handling large amounts of sugar. Exactly how the T version of the SNP leads to different insulin responses is not known at this time.

Additionally, pregnant women with one copy of the T version of this SNP have 1.6 times the odds of developing gestational diabetes during pregnancy, while those with two copies have 2.1 times the odds. Mothers with gestational diabetes may have complications during childbirth and bear a child with an unusually high birth weight.

Babies born to a mother who had gestational diabetes may have a number of serious medical conditions, including breathing problems and low blood sugar. The Lucile Packard Children's Hospital has information on gestational diabetes and the conditions often seen in babies born to diabetic mothers.

The studies whose data we report as applicable to those of "European" ancestry confirmed the association between this SNP and type 2 diabetes in samples from Finland, Sweden, the United Kingdom, and the United States. The studies whose data we report as applicable to those of "Asian" ancestry confirmed the association in samples from Japan, Korea, and Hong Kong. The studies whose data we report as

Citations

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Munoz et al. (2006) . "Polymorphism in the transcription factor 7-like 2 (TCF7L2) gene is associated with reduced insulin secretion in nondiabetic women." *Diabetes* 55(12):3630-4.

Shaat et al. (2007) . "A variant in the transcription factor 7-like 2 (TCF7L2) gene is associated with an increased risk of gestational diabetes mellitus." *Diabetologia* 50(5):972-9.

Wellcome Trust Case Control Consortium (2007) . "Genome-wide association study of 14,000 cases of seven common diseases and 3,000 shared controls." *Nature* 447(7145):661-78.

Horikoshi et al. (2007) . "A genetic variation of the transcription factor 7-like 2 gene is associated with risk of type 2 diabetes in the Japanese population." *Diabetologia* 50(4):747-51.

(PAGE CONTINUES, INCLUDES DISCLAIMER)

APPENDIX E: ABGC EXAM CONTENT OUTLINE

CASE PREPARATION AND HISTORY

C. CASE PREPARATORY WORK

1. **Evaluate referral information to determine**
    a) **appropriateness**
    b) **urgency**
    c) **need for consultation with other experts (e.g., cardiologist, dermatologist, etc.)**
    d) **need to obtain additional information**
    e) **need to include relevant family members in the evaluation**
    f) **need to include interpreters**
2. **Review medical records**
3. **Review of literature and other resources**
4. **Develop preliminary risk assessment and/or differential diagnosis**
5. **Confirm eligibility and availability of genetic testing and/or research studies**
6. **Arrange preliminary diagnostic tests**

D. CONTRACTING

1. **Establish rapport through verbal and non-verbal interaction or through interpreters**
2. **Establish a mutually agreed upon genetic counseling agenda with the client**
3. **Elicit client concerns, expectations, and perceptions**
4. **Determine knowledge-base of client**
5. **Assess client's ethno-cultural background, traditions, health beliefs, attitudes, lifestyles, and values**
6. **Outline the genetic evaluation process**
7. **Decrease anxiety for concerns articulated by the client such as**
    a) **on-going emotional distress**
    b) **stress precipitated by the referral**
    c) **abnormal test results**
    d) **perceived goals of genetic testing**
8. **Discuss**
    a) **costs of genetic services**
    b) **benefits of using health insurance for payment of genetic services**

E. MEDICAL HISTORY

1. **Elicit/Review General History**
    a) **Specific Health Problems and Age of Onset**
    b) **Hospitalizations and Surgeries**
    c) **Congenital Anomalies/Birth Defects**
    d) **Current Medications (i.e., type, indication, dosage, duration)**
2. **Elicit/Review Pregnancy History**
    a) **Maternal age at delivery**
    b) **Serum screening**
    c) **Ultrasound findings**
    d) **Number and outcome of pregnancies**
    e) **Maternal illnesses/conditions**
3. **Elicit/Review Gynecologic History: Infertility**
4. **Elicit/Review Cancer History**
    a) **date of/age at diagnosis**
    b) **anatomic location**
5. **Elicit/Review Exposure History**
    a) **Type (e.g., carcinogens, teratogens, occupational, environmental)**
    b) **Dose, duration, and timing**

F. PEDIGREE AND FAMILY HISTORY

1. **Tailor questioning for the individual case**
2. **Elicit history**
3. **Facilitate recall (e.g., symptoms, diagnoses, treatments)**
4. **Document ethnicity and consanguinity**
5. **Construct a complete pedigree using standardized pedigree nomenclature**
6. **Identify the following:**
    a) **family dynamics**
    b) **emotional responses**
    c) **diagnoses requiring confirmation**

RISK ASSESSMENT AND DIAGNOSIS

G. RISK ASSESSMENT

1. **Analyze Pedigree**
    a) **Assess etiology (e.g., hereditary, familial, sporadic)**
    b) **Determine mode of inheritance**
    c) **Identify ethnicity and consanguinity based risks**
2. **Integrate medical, laboratory, and genetic information**
3. **Modify differential diagnosis**
4. **Perform Quantitative Risk Assessment**
5. **Select risk assessment model based on client data (e.g., empiric data, Bayesian analysis, Gail model)**
6. **Calculate risk (e.g., personal health, reproductive, susceptibility)**

H. DIAGNOSIS AND NATURAL HISTORY DISCUSSION

1. **Formulate counseling agenda**
2. **Integrate natural history, characteristics, and symptoms of working diagnosis**
3. **Incorporate client specific findings and needs**
4. **Develop management plan**
5. **Convey information about the following:**
    a) **diagnosis/indication**
    b) **etiology**
    c) **natural history**
    d) **variable expressivity**
    e) **penetrance**
    f) **prognosis**
    g) **prevention**
    h) **treatment**
    i) **management**
6. **Assess client understanding and response**
7. **Tailor management plan according to client circumstances**
8. **Modify counseling based on client's understanding and response**

I. INHERITANCE/RISK COUNSELING

1. **Educate clients about**
    a) **basic genetic concepts**
    b) **modes of inheritance**
2. **Counsel clients about the following**
    a) **genetic risks (e.g., carrier, reproductive, predictive)**
    b) **risk modifiers**
    c) **disease risks**
3. **Evaluate client risk perception and response**
4. **Address client misconceptions about their risks**
5. **Modify counseling based on client's understanding and response**

TESTING

J. TESTING OPTIONS

1. **Explain testing options (pre- and post-natal)**
    a) **Diagnostic**
    b) **Screening**
    c) **Predictive (e.g., pre-symptomatic, susceptibility)**
    d) **Research**
2. **Identify most informative persons for testing**
3. **Explain possible testing outcomes and implications**
4. **Discuss potential costs, risks, benefits, and limitations of testing**
5. **Help client anticipate the range of emotional effects client and/or family members may experience**
6. **Facilitate decision making regarding genetic test**
7. **Facilitate genetic testing**
8. **Select the test**
9. **Select laboratory for testing**
10. **Discuss test with laboratory**
11. **Identify specimens for testing**
12. **Facilitate informed consent**
13. **Assess client understanding and response**
14. **Modify counseling based on client's understanding and Response**

K. TEST INTERPRETATION AND RESULTS DISCUSSION

1. **Interpret clinical significance of test results depending on situational variables (e.g., methodology, clinical context, family history, paternity) and literature/resources**
2. **Discuss results to include**
    a) **Sensitivity and specificity**
    b) **Implications of positive, negative, and/or ambiguous results**
3. **Recommend additional testing**
4. **Assess client understanding and response**
5. **Modify counseling based on client's understanding and response**

PSYCHOSOCIAL ASSESSMENT AND SUPPORT

L. PSYCHOSOCIAL ASSESSMENT

1. **Recognize factors that may affect the counseling interaction**
2. **Assess client and/or family**
    a) **Emotional (e.g., grief, guilt, anger, depression)**
    b) **Support systems**
    c) **Defense mechanisms and coping strategies**
    d) **Cultural/religious beliefs and values**
3. **Evaluate social and psychological histories**
4. **Assess clients' psychosocial needs and recognize need . for referral**

M. PSYCHOSOCIAL SUPPORT/COUNSELING

1. **Address client emotion and/or behavior using:**
    a) **primary empathic responses (e.g., paraphrasing, summarizing, content and feeling reflections)**
    b) **advanced empathic response**
    c) **direct statements**
    d) **questions**
    e) **emotion-specific techniques (e.g., anger, grief, bereavement, anxiety, guilt, shame)**
2. **Utilize reframing to broaden counselees' perceptions**
3. **Employ anticipatory guidance**
4. **Utilize cross-cultural genetic counseling techniques**
5. **Promote competence and autonomy with direct, supportive statements**
6. **Address family communication issues**
7. **Facilitate client decision making**
8. **Promote client/family coping and adjustment**

ETHICAL/LEGAL/RESEARCH/RESOURCES

N. RESOURCES AND FOLLOW-UP

1. **Communicate follow-up plan**
2. **Present case information (e.g., to clients, to healthcare providers, to insurers)**
3. **Deliver oral case summary**
4. **Compose written case summary**
5. **Adhere to the medical and legal requirements of case documentation**
6. **Advocate for clients in medical and non-medical settings**
7. **Evaluate resources and services**
    a) **support groups**
    b) **community agencies**
    c) **other medical experts**
    d) **client education materials**
8. **Refer to other professionals and agencies**

O. ETHICAL/LEGAL

1. **Comply with privacy and confidentiality regulations regarding personal health information**
2. **Inform clients of potential limitations to maintaining privacy and confidentiality of genetic information**
3. **Discuss real and potential discrimination risks**
4. **Comply with National Society of Genetic Counselors Code of Ethics**
5. **Employ ethical principles to address clinical dilemmas**
6. **Seek consultation with experts (e.g., hospital ethics board, NSGC Ethics Committee)**
7. **Practice in accordance with published position statements (e.g., testing of minors, duty to re-contact)**
8. **Practice in accordance with published practice guidelines**

P. RESEARCH/STUDY COORDINATION

1. **Comply with federal regulations for protection of human subjects in research**
2. **Maintain a database**

Q. EDUCATION/POLICY

1. **Conduct public and professional education**
2. **Provide training/supervision**
3. **Provide didactic instruction**
4. **Develop education materials**

APPENDIX F: MODEL STATUTORY LANGUAGE

§ 54.1-29xx. Powers of Board concerning Genetic Counseling.

A. The Board shall take such actions as may be necessary to ensure the competence and integrity of any person who claims to be a genetic counselor or who holds himself out to the public as a genetic counselor or who engages in the practice of genetic counseling and to that end the Board shall license persons as genetic counselors.

B. The Board shall prescribe by regulation the qualifications governing the licensure of genetic counselors. The regulations may include requirements for approved education programs, experience, examinations and periodic review for continued competency.

§ 54.1-29xx. Restriction of titles.

It shall be unlawful for any person not holding a current and valid license from the Board to practice genetic counseling or to claim to be a genetic counselor or to assume the title, "Genetic Counselor", the title “Certified Genetic Counselor,” the title “Licensed Genetic Counselor” or to use, in conjunction with his name, the letters "CGC”.

For purposes of this chapter, the practice of genetic counseling is defined as counseling patients and their families regarding genetic conditions and providing genetic assessment upon referral from a person licensed by this title and acting within his scope of practice. Counseling regarding genetic conditions includes education about the prognosis and treatment options of diagnosed genetic conditions and referral to mental health and social support resources. Genetic assessment includes counseling on the indications, appropriateness, risks, and indications of family and patient histories and of diagnostic tests, including genetic tests; coordination of diagnostic tests; and counseling on the individual preventative options available to patients based on individual genotypes and associated risks.

§ 54.1-29xx. Advisory Board on Genetic Counseling; appointment; terms; duties; etc.

A. The Advisory Board on Genetic Counseling shall assist the Board in carrying out the provisions of this chapter regarding the qualifications, examination, and regulation of licensed genetic counselors.

The Advisory Board shall consist of five members appointed by the Governor for four-year terms. Three members shall be at the time of appointment genetic counselors who have practiced for not less than three years, one member shall be a physician licensed to practice medicine within the Commonwealth, and one member shall be appointed by the Governor from the Commonwealth at large.

The Governor's appointments shall be staggered as follows: two members for a term of one year, one member for a term of two years, and two members for a term of three years. Thereafter, appointments shall be for four-year terms.

Vacancies occurring other than by expiration of term shall be filled for the unexpired term. No person shall be eligible to serve on the Advisory Board for more than two consecutive terms.

B. The Advisory Board shall, under the authority of the Board, recommend to the Board for its enactment into regulation the criteria for licensure as a genetic counselor and the standards of professional conduct for holders of licenses.

The Advisory Board shall also assist in such other matters dealing with genetic counseling and genetic testing as the Board may in its discretion direct.

§ 54.1-29xx. Exceptions to genetic counselor's licensure.

The licensure requirements for genetic counselors provided herein shall not:

A. Prohibit the practice of genetic counseling as an integral part of a program of study by students enrolled in an accredited genetic counseling education program approved by the Board. Any student enrolled in accredited genetic counseling education programs shall be identified as "Student Genetic Counselors" and shall only provide genetic counseling under the direct supervision of an appropriate clinical instructor recognized by the education program;

B. Prevent or prohibit a Ph.D. medical geneticist certified by the American Board of Medical Geneticists from practicing within his scope of practice.