Assessing Awareness of the Genetic Information Nondiscrimination Act of 2008 (GINA) among Nurse Practitioners

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ASSESSING AWARENESS OF THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008 (GINA) AMONG NURSE PRACTITIONERS

A Dissertation
Presented to
the Graduate School of
Clemson University

In Partial Fulfillment
of the Requirements for the Degree
Doctor of Philosophy
Healthcare Genetics

by
Mary Beth Wilson-Steck
May 2014

Accepted by:
Dr. Julia A. Eggert, Committee Chair
Dr. Lee Crandall
Dr. Bonnie Holaday
Dr. Veronica Parker
ABSTRACT

The first chapter of this dissertation serves as an introduction to the problem of awareness of discrimination based on genetic information in United States’ (U.S.) citizens. It also provides the rationale for the development of the three manuscripts to study the federal genetic nondiscrimination law, the Genetic Information Nondiscrimination Act of 2008 (GINA), leading to conduct of the concept analysis, awareness of discrimination based on genetic information, and finally to a pilot research study that quantitatively assesses the awareness and knowledge of GINA among nurse practitioners (NPs) in South Carolina.

The second chapter, Manuscript I, is a narrative review of GINA. The manuscript describes the legislative history, provisions and limitations of GINA, along with case studies to educate oncology nurses and oncology nurse practitioners on how to apply GINA to their patients and families.

The third chapter, Manuscript II, written after the narrative review, explores the concept of awareness of discrimination based on genetic information through an in-depth content analysis, using Wilson’s method of concept analysis with case study examples. Both Manuscripts I and II were published before healthcare provisions of the Patient Protection and Affordable Care Act of 2010 (PPACA) were implemented.

The fourth chapter, Manuscript III, is a quantitative pilot study, an empirical first look that assesses the awareness of GINA among a sample of nurse practitioners in South Carolina. This pilot study data collection was also completed before PPACA was implemented into healthcare. This manuscript is to be submitted to the Journal of the
American Association of Nurse Practitioners which has a defined word limit for publication of pilot studies.

The final chapter of this dissertation is the synthesis of all three manuscripts; related to the ethical framework of the entire dissertation, the nursing model and conceptual analysis method of the second manuscript and the sociological diffusion theory used in the third manuscript. The final chapter also contains implications for a future program of research. As a result of these manuscripts, it is anticipated that new knowledge concerning awareness of discrimination based on genetic information and the provisions and limitations of GINA will emerge; that nurses will then disseminate this knowledge to other healthcare professionals, patients and their families.
DEDICATION

This dissertation is dedicated to my children, Samuel Robert Steck and Shelby Elizabeth Steck, who informed me that I could not die without completing my PhD requirements. My children have supported me these last five years, while they were in high school and now finishing their initial college degrees. Together, we have successfully confronted and conquered tough life events, including my bout with cancer, chemotherapy, and successful stem cell transplantation. Together we are an unbreakable team. I love you both more than you will ever know.
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I would like to thank Dr. Julia A. Eggert and Dr. Rosanne Pruitt for being instrumental in starting the Interdisciplinary PhD in Healthcare Genetics degree program at Clemson University.

I would especially like to thank Dr. Julia A. Eggert, my mentor, program director and dissertation chairperson, for all the knowledge, time and assistance she has provided me during my entire doctoral journey.

I would also like to thank members of my dissertation committee, Dr. Lee Crandall, Dr. Bonnie Holaday and Dr. Veronica Parker, along with Dr. Elisabeth Chismark serving on my oral comprehensive committee. Your specialized knowledge, expertise and insight have guided me down the path to completing my dissertation work.

I would also like to thank Dr. Ran He and Dr. Holisa Wharton for being my classmates in the first cohort of students in this program. We successfully made strides and forged pathways for subsequent students in this program. I thank you for your friendship, for celebrating our joys, comforting each other through our sorrows and being the best therapeutic listeners a peer could have.

Lastly, I would like to thank my children, my “core group” from Iowa (Sandy, Cindy, Diane, Lou, Coleen, Marcia, Beth and Julie) for your support throughout my life, as well as my South Carolina friends for the last 20+ years, who have been there for my children and me through good and bad times (Lynn, Peggy, Leslie, Amy, Marina and Janet). I love you all.
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CHAPTER ONE
INTRODUCTION

In 1990, at the start of the Human Genome Project, project planners prospectively acknowledged that decoding the human genome might bring, along with achievements, the potential for misuse of genetic information. The Program Advisory Committee of this project established the Ethical, Legal, and Social Implications (ELSI) Working Group in 1989 (Norrgard, 2008; Robertson, 2003). Comprised of genome scientists, medical geneticists, ethicists, philosophers and individuals with expertise in the law, as well as consumers, one of ELSI’s duties was to develop public and professional policies related to researching the human genome and applications of research (Norrgard, 2008).

Since no one individual has a perfect genetic make-up, all individuals could face genetic discrimination at some time in their lives. The ELSI Working Group, genetic health professionals, and researchers realized early on while working on the Human Genome Project that genetic discrimination needed to be addressed before results of that project could be implemented; that citizens of the United States (U.S.) had “fear factors” in regard to personal clinical genetic testing (Lea, 2008). Individuals were also wary of taking part in research studies due to fears that their deoxyribonucleic acid (DNA) information might be used against them either in the workplace or/and the health insurance arena (National Human Genome Research Institute[NHGRI], 2009).

Participants in the ELSI Working Group also believed that this fear of discrimination based on the individual’s genetic information would diminish the importance and use of the Human Genome Project’s genetic discoveries in the healthcare arena. Before the start
of the Human Genome Project, the degree of protection in state laws in the U.S. against genetic discrimination varied broadly. Thus, a federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), hailed as the first civil rights bill of the 21st century, was passed and signed into law on May 21, 2008 by President George W. Bush to ease these “fear factors” (Norrgard, 2008).

Healthcare providers need to be aware that genetics/genomics is linked to most of the health problems of their patients. A particular group of these healthcare providers, nurse practitioners (NPs), assesses, diagnoses, treats and manages patients with genetic diseases in various clinical settings. Therefore NPs, in particular, need to integrate knowledge of genetic testing and treatments into their clinical practice (Abel, Horner, Tyler & Innerarity, 2005; Lea & Williams, 2002). Besides being aware of the ethical and social implications of diagnosing, testing and managing genetic diseases in their patients, NPs also need to be aware of the legal implications surrounding the genetic information and genetic testing of their patients (Lerman, Croyle, Tercyak, & Hamann, 2002).

NPs need to integrate their awareness and knowledge, of legal implications surrounding genetic testing of their patients, into their clinical practice settings. Also, NPs need to be aware of how their patient’s test results and genetic information can lead to discrimination by the health insurance industry and in their patients’ workplaces. This potential knowledge gap of awareness of discrimination based on genetic information and awareness of GINA in NPs leads to the overall questions that guide this dissertation:

1. What is GINA? What are the provisions and limitations of GINA? Why is it different from other federal healthcare discrimination laws? What are the
important points in GINA that NPs to be aware of in order to protect themselves and their patients?

2. What exactly is awareness of discrimination based on genetic information? How can the concept be operationally defined for NPs to use in their research and clinical practice?

3. Using the answers from Questions 1 and 2, how can the nursing discipline assess the extent to which NPs possess awareness of GINA and the concept of discrimination based on genetic information in order to advocate effectively for their patients and their patients’ families?

Graduate nursing faculty recognized that current and future NP students should be aware of and knowledgeable about healthcare genetics and genomics as they prepared to practice in their expanded nursing roles. These students needed an ethical assessment framework to support them to deliver appropriate genetic/genomic healthcare. Having such an ethical assessment framework, essential competencies, integrated into their curricula help nursing students develop expert delivery of healthcare, as well as nursing research expertise (Lea, 2008). Thus, a consensus panel, made up of leaders in the genetic/genomic nursing arena, established the “Essential Genetic and Genomic Competencies for Nurses with Graduate Degrees” (Greco, Tinsley, & Siebert, 2011). The resultant competencies were modeled after “Essential Nursing Competencies for Genetics and Genomics” for baccalaureate nurses, conceptualized from the theoretical framework of Rogers’ Diffusion of Innovation Theory (Jenkins & Calzone, 2007).
A total of 38 competencies for advance practice nurses were developed in the following areas: risk assessment, genetic education, genetic counseling, genetic testing and results interpretation, clinical management of genetic patients and genetic/genomic ethical, legal, and social implications (Greco, Tinley, & Seibert, 2011). Appropriate competencies suggested from this consensus panel, as well as Rogers’ Diffusion of Innovation theory which was the theory used to guide the formulation of essential competencies, provide the foundation for the three independent manuscripts comprising this dissertation research (Jenkins & Calzone, 2007). All three manuscripts in this dissertation meet, partially or entirely, at least one of the essential competencies for the graduate education of NPs. Commonalities in the three manuscripts focus on awareness of discrimination based on genetic information and awareness of GINA when delivering competent genetic/genomic nursing care. These three manuscripts advance the nursing discipline’s knowledge concerning genetic/genomic discrimination in patients and patients’ families.

The first manuscript (Chapter 2) is entitled “The Need to Be Aware and Beware of the Genetic Information Nondiscrimination Act” (Steck & Eggert, 2011). This narrative review provides genetic/genomic information about GINA to oncology nurses and oncology NPs, reflecting the fact that cancer is a genetically-derived disease. It discusses the fear of genetic testing by cancer patients, the legislative history of GINA, proponents and opponents of GINA, as well as the provisions and limitations of GINA that oncology nurses and oncology NPs need to know in order to better advocate for their patients and their patients’ families (Steck & Eggert, 2011). This manuscript specifically
meets the competency, “All nurses with graduate degrees in nursing inform health care and research policy related to ELSI issues in genetics/genomics” (Greco, Tinley, & Siebert, 2011).

The second manuscript (Chapter 3), entitled “Concept Analysis: Awareness of Discrimination Based on Genetic Information” recognizes how NPs’ attitudes and values that are related to genetic/genomic science may affect the care that they provide to their patients (Steck, 2012). This manuscript is based on the statement made by Baldwin (2008) that “researchers need to consider what it is they’re researching using concept analysis before starting work.” The resulting concept analysis manuscript discusses the history of discrimination by registered nurses (RNs) and NPs in regard to not only their patients, but also how they discriminate against their peers. Recent research studies demonstrate that RNs and NPs discriminate against their patients and within the nursing profession based on race, religion, gender, ethnicity and other social constructs (Thornburn Bird, Bogar & Delahanty, 2004; Hocking, 2003; Puhl & Brownell, 2001). Thus a concept analysis, epistemically operationalizing the concept of awareness of discrimination based on genetic information, was derived in order to be utilized in the third manuscript of this dissertation, the quantitative research pilot study.

The resultant operational definition of the concept of awareness of discrimination based on genetic information, using Wilson’s method of concept analysis, is “to know differences against people or distinguish between people based on their ancestral, heritable, communicated facts or knowledge” (Steck, 2012). Wilson’s method of concept analysis not only includes a dissection of words used in the concept, but also
determines how the resultant operational definition is used in model, contrary, and/or borderline cases when an individual is discriminated based on their genetic information. This awareness concept can also be applied to an existing nursing theory, in this case, Roy’s Adaptation Model. The concept, awareness of discrimination based on genetic information, is an addition to Roy’s holistic view that an individual is made up of inter-correlated parts, including an individual’s genetic make-up, and possible discrimination based on that genetic information or make-up (Phillips, 2010). The second manuscript meets the essential competency, “Nurses with graduate degrees need to maintain a solid foundation in genetics/genomics to provide safe and competent care to clients” (Greco, Tinley & Seibert, 2011).

The third manuscript (Chapter 4) is entitled “Awareness of the Genetic Information Nondiscrimination Act of 2008 in Nurse Practitioners: A Pilot Study.” The purpose of this exploratory pilot study was to assess the awareness and knowledge of GINA among NPs in South Carolina utilizing Rogers’ Diffusion of Innovations to as a theoretical basis to guide the study (Macleod-Clark & Hockey, 1989). Thus, this third manuscript is initial vital step to meeting the competency in the ethical framework, “Nurses prepared at the doctoral level are expected to provide leadership in the conduct of research and translation of genetic/genomic findings into practice” (Greco, Tinsley, & Siebert, 2011).

The third manuscript begins with a literature review of peer-reviewed published research studies that assess the awareness and/or knowledge of GINA among consumers, genetic counselors and/or physicians. No research study in the literature review assessed
the awareness and/or knowledge of GINA among nurse practitioners, particularly those NPs in specialized clinical practice that utilize genetic testing, as well as those newly-graduated NPs who have had healthcare genetics integrated into their graduate curriculum after GINA became law. Thus, a need was identified to measure the awareness and knowledge of GINA among NPs and to close a gap in the literature.

The following descriptive research study, guided by Rogers’ Diffusion of Innovation theory, utilized descriptive statistics and variable selection methods to assess awareness of GINA, by utilizing a pilot study sample. A questionnaire was constructed, using a focus group and an expert panel, to assess the awareness and knowledge of GINA, using a volunteer sample of NPs from South Carolina. The results from this pilot study will be used to identify variables from Rogers’ Diffusion of Innovation theory that play roles in the awareness and knowledge of GINA in NPs in South Carolina. Steps used to create the questionnaire, from its theoretical construct development to its corresponding item generation and through to the questionnaire’s pilot testing are specifically and thoroughly addressed in an additional manuscript to be submitted for publication (Table 1.1).
Table 1.1

**Questionnaire Development Steps**

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<td>Select and study a well-grounded theory to develop hypotheses, constructs and concepts related to the phenomenon being measured</td>
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<td>2.</td>
<td>Generate an item pool from review of literature</td>
<td>To propose self-report/response data collection items that facilitate responses representing variables that influence awareness of GINA.</td>
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<td>3.</td>
<td>Determine the format for measurement</td>
<td>To determine what scales are most compatible with the theory: constructs and concepts</td>
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<td>4.</td>
<td>Initial questionnaire item pool reviewed by experts</td>
<td>To establish content validity</td>
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<td>5.</td>
<td>Consider inclusion of validation items/field test revised questionnaire</td>
<td>Test reliability in a small sample Interact with subjects regarding readability, item burden and testing problems</td>
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<tr>
<td>6.</td>
<td>Administer final revised online questionnaire to pilot sample</td>
<td>To evaluate for construct validity and reliability Use findings to evaluate future development steps</td>
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Chapter 5 synthesizes the collective conclusions from the three manuscripts to make this dissertation a complete body of work. Implicit knowledge gaps from the three manuscripts are identified, including a plan for future research concerning the awareness of discrimination based on genetic information, as well as the awareness and knowledge of GINA among NPs. The primary goal of this body of work is to analyze the problem of discrimination based on genetic information, by formulating an operational definition of this concept that nurses may use in their clinical practice, and empirically assessing NPs’ awareness and knowledge of GINA. A secondary gain is to advance the discipline of nursing’s knowledge of healthcare genetics through use of Rogers’ Diffusion of Innovations theory, researching what variables lead NPs to adopt of a new innovation, GINA. A tertiary gain is to demonstrate how these three manuscripts incorporate essential competencies for graduate nurses to advance nursing research.
References


CHAPTER TWO
THE NEED TO BE AWARE AND BEWARE OF THE GENETIC INFORMATION NONDISCRIMINATION ACT


Abstract

Genetic advancements during the latter part of the 20th century and the beginning of the 21st century have presented individuals, the medical community, and legislators at state and federal levels, with numerous genetic discrimination predicaments. Oncology nurses need to be knowledgeable about GINA (The Genetic Information Nondiscrimination Act of 2008) and its applications to clinical practice. GINA is the first federal law passed to protect United States’ citizens with inherited disorders from being treated unfairly due to their genetic make-up. Understanding the legislation known as GINA, including how it modifies existing federal laws governing health insurance coverage and employment discrimination, can assist oncology nurses in providing important education and advocating for their patients and extended families. Federal agencies that govern and enforce GINA’s provisions will be identified. Case situations are included to demonstrate how to apply information concerning GINA to the oncology patient/family considering or having already completed genetic testing. Concerns about missing elements in GINA and their impact will also be addressed, so oncology nurses can offer colleagues and patients an explanation of the pros and cons of the new law.
Since GINA was completely enacted in 2009; oncology nurses need to be aware of GINA’s provisions and its associated shortcomings in order to assist their patients and the families to make informed decisions regarding genetic testing. Privacy of genetic information is a timely issue, though not easy to understand, so provisions of GINA need to addressed and carefully evaluated.

**Introduction and Statement of the Problem**

Genetic testing is used to identify genetic propensities to predict risk for future disease, diagnose genetic conditions with guidance for treatment decisions, provide information for reproductive decisions, profile individuals or their tumors, for selection of medication and/or personalizing medication dosage for best results (Genetics & Public Policy Center [GPPC], 2008). There are now more than 1,500 genetic tests available. According to Dr. Francis Collins, Past-Director of the National Human Genome Research Institute and current Director of the National Institutes of Health, “Many people have been unwilling to participate in medical research or be tested clinically, even when at substantial risk of serious disease, because of fears their genetic information might be used against them” (The Threat of Genetic Discrimination, 2007). Because of this fear, many patients who have obtained genetic testing have done so anonymously or under assumed names due to concerns about discrimination from employers and insurance companies. These patients face additional financial strain if they choose to pay for their genetic tests out-of-pocket, since genetic testing and counseling can cost thousands of dollars for testing a single gene mutation, whether a change in the genetic code is present or not (U.S House of Representatives, 2007).
**Background**

Genetic discrimination can occur in multiple situations. Of special concern is when employers have used genetic information to deny employment, discharge current employees, or deny workers’ compensation benefits. One well-known case of genetic discrimination concerns Lawrence-Berkeley Laboratories, a state and federal research institution. Between 1968 and 1993, this institution included tests for syphilis, sickle cell genetic markers and pregnancy in its pre-employment and annual medical examinations without the employees’ knowledge or consent. Employees were told only that they were “having cholesterol testing.” The use of testing without informed consent, was revealed and condemned in a major lawsuit decision in 1998, in which the court held that the employer’s actions constituted the “most basic violation possible” of the employee’s rights to privacy guaranteed under the Constitution (Coalition for Genetic Fairness [CGF], 2008).

In a retrospective, cohort study conducted by Armstrong et al. (2003), fear of genetic discrimination played an important factor in the decision whether to undergo genetic testing to determine familial breast cancer. The researchers found over half the 636 women who had undergone genetic counseling described fear of genetic discrimination as a reason for refusing genetic testing. The women who refused testing expressed concerns about life insurance discrimination if their genetic test results were made available to insurance companies (Armstrong et al., 2003).

Fear of genetic discrimination can also cause adverse financial impacts on individuals and the health care system even though there is the potential for saving health
care dollars. The early detection and prevention via genetic testing results could lessen the financial costs caused by late diagnosis and chronic illnesses like cancer. Avoidance of genetic tests due to discrimination fears may cause thousands of dollars in additional detection and treatment health care costs. Individuals treated at a later stage of cancer often face financial crisis; increased cost-sharing and out-of-pocket medical bills that create significant medical debt. According to one not-for-profit organization, the Genetic Alliance, dedicated to promoting health care for persons with genetic disorders, medical debt is a leading source of personal financial bankruptcy in the United States, leading to home foreclosures and possible financial difficulties (Genetic Alliance [GA], 2008). Lost income during extended illnesses, like cancer, can also become an issue. Some individuals, such as those at high risk to develop an inherited cancer syndrome that receive and use genetic testing information results without fear of discrimination, may prevent personal financial difficulties. Thus, Americans can benefit from personal genetic testing if they know that their health insurance and employment will not be at risk because of positive genetic test results.

While GINA offers some protection against genetic discrimination, it is incomplete protection. Many people may have to choose between undergoing genetic testing that could lead to early detection and prevention of a cancer or forgoing genetic testing to economically protect their families from adverse genetic discrimination (Rothstein, 2008).
Need for GINA

Many Americans, while optimistic that their genetic information could improve their health, also express concern that the same genetic information could be used to discriminate against them. They fear that health insurers would refuse to either insure them or would cancel existing health insurance if they are found to be predisposed to future onset of a genetic disease. Similarly, Americans fear that employers would only retain or hire those individuals who are not pre-disposed to genetic disease in order to have healthy, productive employees. As a result of these fears, most Americans, in addition to scientists and health advocacy groups expressed a need for federal legislation to protect all Americans from genetic discrimination (National Human Genome Research Institute [NHGRI], 20).

Federal nondiscrimination legislation was proposed as a solution to prevent cases of genetic discrimination previously documented and to prevent fears of future genetic discrimination by employers and insurance companies. Individuals realized the privacy protections of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) did not prohibit health insurers from requiring genetic testing or from denying coverage based on genotypic information (CGF, 2008). On the state level, a majority of state legislatures responded to concerns of individual genetic discrimination by health insurers, employers or both, but states’ laws did not provide uniform protections to American families at the national level. Unfortunately, the patchwork of state laws left some individuals vulnerable to genetic discrimination. One provision of GINA is that it would
not preempt more protective state laws so that in any situation an individual would receive maximum protection allowed by federal and state laws (Rothstein, 2008).

Currently, 18 states have no genetic privacy laws. Seventeen states require signed informed consent from an individual before insurers or employers can request a genetic test or genetic information can be obtained. Genetic information is considered personal property in Alaska, Colorado, Florida, Georgia and Louisiana. Nineteen states have civil and/or criminal penalties for violation of genetic privacy laws. Washington is the lone state that treats genetic information the same as other health information. A complete table of each state’s discrimination laws regarding genetic and health insurance discrimination laws and states’ genetic employment laws is located at the National Conference of State Legislature website (http://www.ncsl.org/default.aspx?tabid=14287) (National Conference of State Legislatures, 2008).

Who Does GINA Affect?

It is impossible to say how many Americans are affected by genetic discrimination. A literature search using CINAHL, Academic Search Premier, Medline and other search engines for this data located no statistics. However the literature states that those Americans who fight discriminatory practices and win often have to invest significant time, money and effort to assert their rights (National Partnership for Women and Families [NPWF], 2008). Unfortunately, not every afflicted individual will have the knowledge of discriminatory practices and/or resources available to assert these rights. Some will find themselves uninsured or unemployed because of their genetically induced risk for disease and associated healthcare related costs (NPWF, 2008).
Legislative History of GINA

Representative Louise Slaughter (D-NY), a microbiologist, first introduced legislation to address genetic discrimination in 1995 during the 104th Congress (NHGRI, 2009). In 1996, Senator Olympia Snowe (R-ME) introduced similar legislation in the Senate. Both bills addressed health insurance discrimination, however neither bill passed. Similar legislation was introduced in both Congressional chambers in the next four successive Congresses. In the 109th Congress, Representative Judy Biggert (R-IL) introduced the bill in the House of Representatives (H.R), and although it again passed in the Senate under Senator Stowe’s efforts, GINA still did not pass the H.R. During the 110th Congress, after passing through the three jurisdiction committees of Education and Labor, Energy and Commerce, and Ways and Means, GINA passed through both chambers of Congress, the Senate on April 24, 2008 and the House on May 1, 2008. With the perseverance of Representatives Slaughter and Biggert and Senator Snowe, a bipartisan Congressional effort and a strong coalition of interested organizations, GINA was “born” after a gestation period of 13 years in the United States Congress (Couzin, 2008; CGF, 2008) (Figure 2.1). Although GINA is not a perfect nondiscrimination law, it is an example of how legislative advocacy and a coalition of organizations effectively fought for a common cause. The result was a more comprehensive genetic nondiscrimination law on a federal level, rather than having fifty different individual state nondiscrimination laws.
Figure 2.1

**GINA Legislative History**

The Genetic Information Nondiscrimination Act (GINA), also known as Public Law 110-233, was signed into law by President George W. Bush on May 21, 2008. The late Senator Ted Kennedy (D-Mass.) applauded GINA as ‘the first civil rights bill of the new century of the life sciences”. This law makes it illegal for health insurers or employers to discriminate against individuals based on their genetic information. The health insurance provisions of the bill, Title I, took effect 12 months after the signing date on May 21, 2009. The protections in employment, Title II, took effect 18 months after the signing date on November 21, 2009 (CGF, 2008). Title II applies to private employers, local and state governments with 15 or more employees. It also applies to labor unions, employment agencies, labor-management programs, Congress and federal executive agencies (The U.S. Equal Employment Opportunity Commission, 2009).

GINA is not a perfect genetic discrimination bill, there are still loopholes. The goal of comprehensive genetic nondiscrimination is difficult with a health finance system where individual health insurance is medically underwritten. Current employment laws do not protect the complete privacy of employees’ health information and GINA’s provisions do not apply to life, long-term-care and disability insurance.

Proponents and Opponents

GINA had many “official actors” in the federal legislature and thousands of “unofficial actors”, who were personally concerned about their own future or realized genetic discrimination. In 1997, when genetic discrimination bills did not pass the 106th Congress, the largest organized “unofficial actor”, the Coalition for Genetic Fairness (CGF) was formed. CGF includes a number of diverse organizations, including Alpha-l
Association, Genetic Alliance, Hadassah, National Partnership for Women and Families, National Society of Genetic Counselors and the National Workrights Institute. CGF’s objective is to educate the public and Congress about genetic discrimination, so that introduced genetic nondiscrimination legislation can be seriously considered. Since its founding, the CGF has united hundreds of organizations and thousands of individuals as one voice against genetic discrimination (CGF, 2008). These organizations recognize that their mutual goal among diverse groups is to accomplish passing genetic nondiscrimination legislation; a goal out of reach for any one of the organizations (CGF, 2008).

In 2005, the CGF expanded to include industry and employers. Once these groups were educated about GINA, they supported its proposed legislation. Besides a majority of legislators and the CGF, GINA was supported by more than 500 organizations, medical groups, individuals and companies, including the American Medical Association, the American Nurses Association, the National Education Association and the March of Dimes (Lengell, 2008).

GINA legislation was opposed by insurance companies and the Genetic Information Non-Discrimination in Employment Coalition (GINE), made up of the National Association of Manufacturers, the National Retail Association and others. This coalition included the United States Chamber of Commerce (U.S. C. of C.) who argued that the bill’s language was too broad, did not support many state laws and provided for severe punitive damages. Opponents also claimed worried plaintiffs would turn common, ordinary disputes over insurance coverage into full-blown civil-rights cases
(United States Chamber of Commerce, 2007). The U. S. C. of C.’s executive director for labor policy stated disappointment with current provisions of GINA, noting other concerns of the U.S.C. of C. were not addressed before the bill was passed (Board of National Affairs, 2008).

GINA’s Provisions

Genetic information is information about an individual or family members’ genetic tests, the occurrence of disease in family members or the individual and/or participation of a family member in research that includes genetic testing, counseling or education (Rothstein, 2008; GPPC, 2008). Genetic information does not include information about the sex or age of an individual. A genetic test refers to a test that assesses genotypes, mutations, polymorphisms and/or any chromosomal changes in an individual (GPPC, 2008). There are four main concerns, regarding use of genetic information in employment and health insurance which drove efforts to obtain genetic nondiscrimination legislation. These same concerns could also be applied in future campaigns regarding use of genetic information in life, disability and long-term care insurance (Rothstein, 2008).

The first concern focused on individuals worrying about having pieces of their health records combed through by insurance companies probing for any evidence of genetic information (Rothstein, 2008). For example, a patient, who had multiple family members in multiple generations with breast and ovarian cancer, should be concerned about having this information identified when the insurance company was requesting documentation of medical necessity for a gall bladder “attack”. Because the physician’s
office staff was so busy, the entire patient chart was faxed to the insurance company instead of only necessary pieces of medical chart information.

The second fear was genetic testing could be required as a provision of employment. Once the results are received, the patient finds out information about personal health risks they did not want to know. Third was the worry that a future employer or health insurance underwriter would misinterpret a person’s genetic information, using it to disqualify them for a job or insurance coverage (Rothstein, 2008). Oncology professionals know a genetic mutation in a gene does not mean an individual will develop cancer. The possibility of developing a cancer does not mean an individual could not perform a job for which they are qualified, and should not disqualify them for insurance. Finally was the fear that inquiring about and having a genetic test would exclude them from insurance benefits available to those who have never had any genetic testing. Individual were concerned that even with negative results would prevent them from obtaining adequate insurance (Rothstein, 2008).

GINA addresses the above concerns by prohibiting use of an individual’s genetic information to set eligibility on premiums or contribution amounts for group and individual health insurers. Health insurers are prohibited by GINA from requesting or requiring an individual to take any genetic test. However, a health insurer or group health plan involved in research may request, but not require a genetic test, in conjunction with specific research activities. The research must comply with Federal regulations regarding protections of human subject and must notify the Federal government in writing that it is conducting research. Of note, oncology patients (beneficiary or legal
guardian) participating in clinical trials should receive written requests for voluntary
 genetic testing should be made in writing to the participant, beneficiary or legal guardian,
 with the clear statement that research genetic testing would have no effect of eligibility
 for benefits and would not affect premiums (United States Department of Labor [U.S. DOL], 2009)

 Employers are also prohibited in the use of an individual’s genetic information,
 (family history, genetic testing, counseling or education, and participation in any clinical
 research), in any employment decision such as hiring, firing, job assignments or
 promotions. Finally, GINA prohibits employers from requesting, requiring, or
 purchasing genetic information about an individual’s family members (up to and
 including 4th degree relatives), as well as genetic tests of any fetus of a pregnant family
 member or legally held embryo from assisted reproductive technology of an individual
 (Rothstein, 2008).

 What GINA does not do is prohibit medical underwriting based on an individual’s
 current health status; someone diagnosed with breast cancer after genetic testing
 identified a BRCA mutation may still have their insurance cancelled due to the disease
 but not the genetic testing. It does not mandate insurance coverage for any specific
 medical test or treatment. GINA does not interfere with a health care professional
 requesting that an individual or family member undergo a genetic test. It does not limit a
 health care professional, who may be employed by a health plan or insurance company,
 from notifying an individual about diagnostic or predictive genetic tests or providing
 information to an individual about a genetic test as part of a wellness program. It does
not subject employers to rules and regulations that are any different from other civil
civil rights laws. Workplace collection of genetic information for toxic monitoring programs,
employer-sponsored wellness programs, administration of federal and state Family and
Medical Leave laws, and certain cases of unintended acquisition of genetic information is
not prohibited. However the employer may not use or disclose the genetic information
for any purpose (GPPC, 2008). GINA does not include protection from genetic
discrimination in life insurance, disability insurance or long-term care insurance.
GINA’s provisions do not apply to members of the United States Military, to veterans
obtaining health services through the Veteran’s Administration, or care through the
Indian Health Service (GPPC, 2008) (Table 2.1).
Table 2.1

Provisions and Limitations of GINA

<table>
<thead>
<tr>
<th>Provision</th>
<th>Not Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prohibits use of an individual’s genetic information in setting eligibility or premium amounts by group and individual health insurers.</td>
<td>Does not prohibit medical underwriting based on current health status or mandate coverage for any particular medical test or treatment.</td>
</tr>
<tr>
<td>Prohibits health insurers from requesting or requiring an individual to take a genetic test.</td>
<td>Does not interfere with ability of a health care professional to request an individual or family undergo genetic testing.</td>
</tr>
<tr>
<td>Prohibits use of an individual’s genetic information by employers in employment decisions such as hiring, firing, job assignments, and promotions.</td>
<td>Does not limit health care professional, employed by a health plan, from notifying an individual about genetic tests or providing information about a genetic test as part of a wellness program.</td>
</tr>
<tr>
<td>Prohibits employers from requesting, requiring, or purchasing genetic information about an individual employee or family member.</td>
<td>Does not:</td>
</tr>
<tr>
<td></td>
<td>• Subject employers to remedies and procedures different from civil rights laws such as Title VII and the Americans with Disabilities Act.</td>
</tr>
<tr>
<td></td>
<td>• Prohibit workplace collection of genetic information for toxic monitoring programs, employer-sponsored wellness programs, and administration of federal and state Family and Medical Leave laws.</td>
</tr>
<tr>
<td></td>
<td>• Include protection from genetic discrimination in disability or long-term care insurance.</td>
</tr>
</tbody>
</table>

This law went into effect for health insurers on May 21, 2009. The law in regards to employment genetic discrimination went into effect in November 2009. THIS LAW DOES NOT APPLY TO MEMBERS OF THE MILITARY, VETERAN’S ADMINISTRATION, OR THE INDIAN HEALTH SERVICE.

Changes to Existing Federal Laws

One existing law impacted by GINA is the Employee Retirement Income Security Act (ERISA). Amendments include provisions that prohibit group health insurance issuers from denying coverage or discriminating in premium pricing or policy due to an individual’s genetic information. GINA also prohibits these issuers from requesting or requiring a pre- or post-enrollment individual to have genetic testing and prohibits the insurers from accessing the genetic information by request, requirement or the purchase of their genetic information. This means person with a family history of inherited cancers, like breast and ovarian, cannot be required by their insurance companies to have genetic testing. In addition, the insurance company cannot request, require, or purchase the results of genetic tests.

Amendments to the Public Health Service Act (PHSA) include prohibiting health insurance companies from offering coverage to individuals based on their genetic information. GINA prevents these insurance companies from excluding coverage of preexisting conditions based on genetic information. GINA states that genetic information should be treated as health information under (Health Information Portability and Accountability Act (HIPAA). This means genetic test results, a pedigree indicating an inherited cancer syndrome, or family history of cancer cannot be the only reason to deny insurance coverage. In addition, patients cannot be denied coverage for a “preexisting condition”, based on genetic test results showing positive for a mutation (GPPC, 2008). GINA also prohibits using genetic information for Medicare purposes
and to issuers of Medigap policies, amending both the Internal Revenue Code and Social Security Act (Laurent, Klamath & Sullivan, 2008; U. S. DOL, 2009) (Table 2.2).

GINA’s health insurance provision does not apply to three groups of Americans. Prior to genetic testing, oncology nurses need to carefully determine if their patients or family are planning to receive or are receiving health care through the United States Military, Veteran’s Administration, or Indian Health Service (GPPC, 2008).
Table 2.2

Changes to Existing Federal Laws

<table>
<thead>
<tr>
<th>Law</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee Retirement Income Security Act (ERISA)</td>
<td>Prohibits group health insurers from denying coverage or discrimination in price policy or premium change due to individual’s genetic information.</td>
</tr>
<tr>
<td>Public Health Service Act (PHSA)</td>
<td>Prohibits health insurers from offering individual coverage based on genetic information.</td>
</tr>
<tr>
<td>Health Information Portability and Accountability Act (HIPAA)</td>
<td>Genetic information should be treated as health information.</td>
</tr>
</tbody>
</table>

Based on “Genetic Information Nondiscrimination Act of 2008” by D. Laurent, J Klamath, & C. Sullivan, 2008
Enforcement of GINA

GINA’s health provisions are enforced through agencies whose laws were amended, thus affected, by GINA. The Departments of Labor, Treasury and Health and Human Services enforce Title I of GINA and the Equal Employment Opportunity Commission (EEOC) is responsible for the enforcement of Title II (NHGRI, 2009). The privacy provisions in Title II of GINA enforced through HIPAA, include civil fines of $100/violation incidence and criminal fines to $250,000 with 10 years in prison for violations of a commercial and malicious nature (Laurent, Klamath & Sullivan, 2008), Also in Title II is the provision that individuals have the right to pursue private litigation (NHGRI, 2009). ERISA and PHSA enforce discrimination provisions with fines of $100/day/person, ranging from $2,500 to $15,000 with a maximum of $500,000 for unintentional discrimination violations. Penalties for violations of discrimination due to reasonable cause or neglect are authorized by The Secretary of Labor (Laurent, Klamath & Sullivan, 2008).

Examples of protected genetic tests under GINA are the mutations associated with Hereditary Breast and Ovarian Cancer and hereditary nonpolyposis colorectal cancer (HNPCC), genetic properties of an existing tumor that could to help determine therapy, Huntington’s Disease mutation and carrier screening for disorders, such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy and Fragile X syndrome. Routine tests such as complete blood counts, cholesterol and liver-function tests are not protected under GINA. Also not protected under GINA is DNA analysis of infectious agents such as bacteria, viruses, and fungi. Following this reasoning, an HIV test is not covered under
GINA, since HIV is not human DNA, rather a retrovirus that inserts itself into human
(GPPC, 2008). Under GINA, a genetic test is also not an analysis of proteins or
metabolites that relate directly to a disease or pathology that could be detected by a health
care professional on an annual exam or follow-up appointment (NHGRI, 2009) (Table
2.3).
Table 2.3

Protected and Non-protected Genetic Tests in GINA

<table>
<thead>
<tr>
<th>Protected Genetics Tests</th>
<th>Non-protected Genetic Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples: Genetic tests for Hereditary Breast and Ovarian Cancer, Hereditary Nonpolyposis</td>
<td>Routine tests – Complete blood counts, blood chemistries, cholesterol and liver function tests. Analysis of proteins or metabolites relating directly to a disorder or disease.</td>
</tr>
<tr>
<td>Colorectal Cancer, Huntington’s Disease, etc.</td>
<td></td>
</tr>
<tr>
<td>Carrier screening tests such as those for cystic fibrosis, sickle cell anemia, spinal muscular atrophy and Fragile X syndrome</td>
<td>Infectious agent tests for bacteria, virus (including HIV), and fungi.</td>
</tr>
</tbody>
</table>

* The term “genetic tests” refers to the analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect mutation, changes to chromosomes and genotypes.

Despite a comprehensive prohibition on employer acquisition of genetic information, it is very likely that employers would continue to obtain genetic information due to conversations (water-cooler talk) and inadvertently through serendipitous discovery when searching for results to common laboratory tests. In accordance with section 102(d)(3) of the Americans with Disability Act (ADA), after a conditional offer of employment, employers are permitted to require, as a condition of employment, that individuals submit to a medical examination and sign an authorization for the release of their health records. According to Rothstein (2008), each year in the United States, potential employees sign an estimated 10.2 million authorizations for release of their health records. Because of the increased networking of electronic medical records, the disclosure of health records is becoming extensive. Even if employers requested only nongenetic records, there’s no assurance this would be done. Since it is time-consuming to search for, identify and pull out of the chart specific information to send in response to requests, it is easier to send the whole record. Perhaps the persons sending the complete medical records are unaware and not appreciative of GINA’s provisions. A current concern of individuals is that employers could have inadvertent access to genetic test results. This still remains a major issue for many individuals when GINA is enacted. Complete protection of genetic information requires banning employer requests for comprehensive records at the pre-employment and other stages of employment, annual check-ups or wellness programs. Health information technology needs to research, adopt and ensure the disclosure of only job-related health information with legal ramifications for disclosure of genetic information to be adopted (Rothstein, 2008).
The Future of GINA

Since GINA was signed by President George W. Bush in 2008, federal bureaucratic agencies began implementing GINA under a new administration in 2009. Will GINA change as the “players” or “official actors” in the federal government changed? The proposed Obama health care plan addresses the problem of genetic discrimination in two ways. First, it prohibits private insurance companies from excluding individuals from coverage based on pre-existing health conditions, something GINA does not presently provide. Secondly, if insurance companies cannot exclude individuals based on preexisting conditions, then claims cannot be denied payment based on those preexisting conditions (Obama/Biden Plan, 2009).

Enactment of GINA declared a national policy against discrimination in health insurance and employment based on genetic information. However, GINA still has many associated risks. First, GINA could increase the stigma associated with genetic conditions by treating the genetic information separately and differently from other health information. Second, individuals convinced of GINA’s value may undergo predictive genetic testing and inadvertently have their test results leaked to present or future employers. Finally, only time will tell if GINA’s protections adequately address the issues of genetic discrimination in employment and health insurance.
References


CHAPTER THREE

CONCEPT ANALYSIS: AWARENESS OF DISCRIMINATION BASED ON GENETIC INFORMATION

(Submitted 1/1/2011, accepted for publication 4/7/2011, published in April-June, 2012 issue of Nursing Forum)

Abstract

All nurses have the responsibility to deliver nondiscriminatory genetic healthcare. Patients perceive discriminatory nursing practices when they are being treated differently and unfairly. Nurses are expected to integrate genetic information about their patients into their clinical decision making. Thus it is both timely and imperative that nurses have an operational definition of the concept, “awareness of discrimination based on genetic information.”

An operational definition of the concept was derived and Wilson’s method of concept analysis was utilized to show how the operational definition may be applied in three different case models. Awareness of discrimination based on genetic information can be operationally defined as “to know differences against people or distinguish between people based on the ancestral, heritable, communicated facts or knowledge.”

This concept analysis of words and terms used in genetic health care may serve as a framework for further genetic/genomics healthcare concepts under exploration.

Introduction

In the first decade of the 21st century, two major events have changed the paradigm of health and well-being for United States (U.S.) citizens. The first event to
occur was the completion of the Human Genome Project in 2003. This event established a new conceptualization of healthcare services, by adding genetic consideration to incidence, etiology, diagnosis, and treatment of many common diseases, such as cardiovascular disease and many types of cancer (ISONG). The second event was signing the Genetic Information Nondiscrimination Act (GINA) of 2008 into law, providing federal protections to U.S. citizens, by outlawing discrimination based on genetic information when seeking health insurance and employment (Rothstein, 2008).

In response to these events, the Code of Ethics for Nurses, developed by the International Council of Nurses and the American Nurses Association, now states that all nurses have the responsibility to deliver nondiscriminatory genetic healthcare. Additionally, the International Society of Nurses in Genetics (ISONG) has issued a position statement declaring that professional nurses should be aware of laws pertaining to genetic information and also become aware of potential discrimination linking genetic information with race, gender, ethnicity and other social constructs (Access to Genomic Healthcare, 2010; Privacy and Confidentiality of Genetic Information, 2010).

Discrimination exists within the nursing profession. Numerous research studies have shown that nurses discriminate against their patients and also within the nursing profession in eight broad categories: race, religion, gender, social class, lifestyle behaviors, nationality, physical disability and political beliefs. Nurses have also been shown to discriminate against patients based on their health status; whether they are human immunodeficiency virus positive, overweight or possess a mental illness (Thornburn Bird, Bogar & Delahanty, 2004; Hocking, 2003; Puhl & Brownell, 2001).
Patients perceive discriminatory nursing practices when they are being treated differently and unfairly. However, such discriminatory practices are difficult to prove since they are often implicit, indirect and subtle (Kingma, 1999; Klitzman, 2010). When and if nurses become aware of these discriminatory practices toward patients’ status, in particular patients’ genetic healthcare status, they can then take appropriate actions towards reducing these painful and often harmful practices (Kingma, 1999; Lea, 2008).

Because the nursing profession is essential to the delivery of nondiscriminatory genetic healthcare, nurses will be expected to integrate genetic information about individuals into their clinical decision making (Williams, 2002; Lea, 2008). Thus, it is both timely and imperative that nurses today have an operational definition and essence of the concept, “awareness of discrimination based on genetic information”, the concept this paper will explore.

“Awareness” may be considered a special form of awareness, reflexive awareness. Consciousness has a more restricted meaning, from the Latin words ‘cum’ and ‘sciere’ translated “to know about”. Consciousness in humans may be considered an experience also, like awareness’ experience, but is an experience that is evoked by thinking “about” one’s experience, to distance oneself from the current awareness experience, as if to observe it in third person (Vaneechoute, 2000).

**Background**

Because the concept, “awareness of discrimination based on genetic information” is not currently found as an entry in dictionaries, the individual words, “awareness,
discrimination, genetic and information” and the term “genetic information” will be analyzed and then synthesized into an operational definition.

Awareness is defined in The Oxford English Dictionary (OED, 2010) as” the quality or state of being aware; consciousness”. By introspection you experience what you have been experiencing in the world, including internal and external objects (The Cambridge Dictionary of Philosophy, 1995). “Aware” derives from the Anglo Saxon word “gewaer”, first used in the 11th century, meaning “being informed”. From the 13th century to present day, awareness is also synonymous with “to know” relating to experiences: the act of experiencing (Vaneechoute, 2000).

Awareness and consciousness have also been used as synonyms, though consciousness may be considered a special form of awareness, reflexive awareness. Consciousness has a more restricted meaning, from the Latin words ‘cum’ and ‘sciere’ translated “to know about”. Consciousness in humans may be considered an experience also, like awareness’ experience, but is an experience that is evoked by thinking “about” one’s experience, to distance oneself from the current awareness experience, as if to observe it in third person (Vaneechoute, 2000).

Discrimination, derived from the Latin word, ‘discrination-em’, translates to “of action”, can be defined as the action of perceiving, noting or making a difference or distinction between things, made with the mind or in action. Specifically, discrimination has been used to describe an act of distinguishing against people based on race, color, sex, or social status (OED, 2010). A synonym for discrimination is “against”. Discrimination frequently is defined in legal literature as an action, based on real or
perceived differences from a certain standard, unfavorable to the person who deviates from that standard (Spaak, 2006).

Genetic refers to the basic units of heredity, genes (Williams, Skirton, & Masny, 2006). Used as an adjective, it is defined as relating to common an evolutionary or ancestry origin. Information is defined as knowledge communicated concerning some particular event or fact, it can be synonymous with intelligence or news (OED, 2010). Currently, the term, genetic information, is not found as an entry in dictionaries. Genetic information is defined mainly in a legislative sense. GINA defines genetic information as, ‘information about an individual’s genetic test and the genetic tests of an individual’s family members, as well as information about any disease, disorder, or condition of an individual’s family members (i.e. an individual’s family medical history up to a 4th degree relative). A genetic test is defined by GINA as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations or chromosomal changes (GINA, 2010; Rothstein, 2008). Genetic information is heritable, biological information; it can be identified at any point throughout a person’s lifespan from pre-conception until after death (Lea, 2008). Genetic information is considered to be different from other health information, due to the unique quality of genetic information that identifies an individual, the stability of the DNA to be stored indefinitely and the ability of DNA to generalize specific genetic information to families, genetically-related communities, as well as ethnic and racial populations (Spaak, 2006). A descriptive definition of the phrase, “discrimination based on genetic information” has been applied to date in the legal arena to individuals who experience the denial of rights, privileges, or
opportunities based solely on genetic information, the term is not applied to individuals who have developed symptoms of a genetic disease (Erwin et al., 2010).

**Operational Definition**

After studying the definitions, uses and attributes of the individual words and term used in the concept under exploration, an operational definition for “awareness of discrimination based on genetic information” can be derived. Awareness of discrimination based on genetic information can be considered as “to know differences against people or distinguish between people based on their ancestral, heritable, communicated facts or knowledge.”

**Concept Analysis Method**

Wilson’s method of concept analysis is appropriate to analyze the concept being explored, since awareness of discrimination based on genetic information has not been previously explored using concept analysis. This method incorporates an introductory, simple, flexible, yet thorough way of dissecting and restructuring a new concept, with the goal of understanding the concept and its application. Wilson’s method begins by isolating the concept for analysis, first examining situations from literature where the concept is used. Wilson recommended using actual cases or developing cases designed to highlight the differences the concept under analysis makes to a situation or event. Invented cases are only constructed when there are not enough actual cases available to illustrate the concept. Epistemically, these cases formulate evidence of the concept under review. This evidence is then used to help justify a belief or theory (Hupcey, Morse, Lenz & Tason, 1996; Risjord, 2009).
Utilizing a nursing theory as framework is fundamental to new nursing knowledge development. The Roy Adaptation Model’s broad nature allows examination of awareness of discrimination based on genetic information from an expanded holistic nursing perspective. The individual at risk for developing genetic disease is viewed as a thinking and feeling individual with interrelated parts that comprise a unified whole. An individual with an imperfect genetic make-up can be viewed as an adaptive system, using coping processes that act to maintain adaptation to the physiological and self-concept modes (Hannon-Engel, 2008). The concept of awareness of discrimination based on genetic information can add evidence to Roy’s scientific assumption that awareness of self is rooted in thinking and feeling, that helps mediate human action (Phillips, 2010, p. 341).

**Methodology**

Search strategy for this concept analysis, included articles written in English, published from 1995-2010. Limiters were full text, references available and peer reviewed journals. The starting year of 1995 was chosen to retrieve published articles that regarded discrimination based on genetic information, since questions about how results of the Human Genome Project (1990-2003) were being raised while the human genome was being sequenced. Exclusion criteria used was that articles retrieved had to applicable to discrimination and genetic information definitions used in the United States. Other countries such as the United Kingdom and Australia have their own specific genetic information nondiscrimination laws, using different definitions of genetic information.
Electronic databases used in the search were: Academic Search Premier, CINAHL Plus with Full Text, Cochrane Database of Systematic Reviews, ERIC, Health Source: Nursing/Academic Edition, MEDLINE, PsycINFO, LexisNexis and OED for individual concept word definitions. In addition, ProQuest Database, specifically Dissertations and Abstracts, was included in the search. MeSH terms, Boolean operators and wild carding in several combinations used the terms aware*AND discriminat* AND gene* which yielded 111 abstracts. However since awareness is the main concept under examination, “awareness” was put in the Title field (TI), OR discrimination AND genetic information was put in any field which yielded 2588 articles. Awareness (TI) AND discrimination AND genetic information yielded zero articles. So, awareness (TI) AND discrimination OR genetic information was used, yielding 427 articles, which, after being scanned for inclusion and exclusion criteria yielded 30 articles, in which a search for secondary sources was conducted. In addition this author searched through articles previously used by the author to complete other papers, which yielded another 10 articles.

Findings

Wilson stated that in order for a concept analysis to be conducted, the concept question must be answered from factual, constructed or invented cases. The concept question for the analysis then would be: what constitutes awareness of discrimination based on genetic information? The following cases are from real situations that have occurred.
Model Case

Model cases help provide a clear example of a concept. Mary is an example of individual awareness of discrimination based on genetic information. Mary has a family history of breast cancer; both her mother and aunt have been diagnosed with the disease. Mary considers being tested for the BRCA-1 gene, hoping to take prophylactic measures to reduce her risk of developing breast cancer if the genetic test result was positive. Currently the BRCA-1 gene testing is only performed by Myriad Corporation, who holds that patent for that particular genetic test. She debates paying for the test herself, but as a recent law school graduate, she cannot afford it. Mary decides not to undergo testing as she fears a positive test result would be reported by her company’s insurance carrier and could possibly jeopardize her changes for future promotion at her law firm (Faces of Discrimination, 2004).

In this case, Mary is aware; she knows her family’s health history, a form of genetic information that can impel an individual to undergo further testing for a gene known to cause breast cancer. Mary is also aware of the possibility of discrimination based on the genetic information obtained from the genetic testing, that would be reported back to her employer’s insurance company, affecting her ability to qualify for life, disability, and long-term care insurance when the claim for genetic testing is filed.

Contrary Case

Wilson also suggested including contrary cases which might clearly identify which cases do not meet the definition of the concept being analyzed. An individual whose genetic information becomes known to other persons outside the healthcare arena
may unknowingly face discrimination. For example, a single mother in Washington filled out her job application truthfully, acknowledging a family history of Huntington’s disease. She was passed over, in her small company, for promotions and pay raises without explanation, despite being named employee of the year and receiving excellent performance evaluations. This mother was discriminated against on the basis of her family’s health history, a form of genetic information. She was not aware that her family history was a source of genetic information that could be used to discriminate against her. In this case, the risk of discrimination provides motivation for individuals, aware of their family health history, to keep their personal genetic information a secret. Because DNA is essential to human life, it is seen as being the determinate to everything that human is or will become (Fedder, 2000).

**Borderline Case**

A borderline case is an example that contains most of the concept’s elements, but not all of them. The following cases help clarify defining attributes of the concept. One such case concerns a nurse working at an oncology clinic who encountered a young woman whose mother and sister died of breast cancer. The young woman refused to sign in at the front office. The nurse explain that registration was required and that the woman’s genetic information would be kept entirely confidential. The women then became extremely emotional, saying she believed she would expose herself and her child to discrimination if her visit to the clinic was documented. The nurse tried to encourage the woman to stay, but she left the office without testing or counseling and without scheduling an oncology screening (Faces of Discrimination, 2004).
The other borderline case involves Gail, a physician with a family history of breast and ovarian cancer, who faced potential discrimination because of her incomplete medical records. Gail decided to take a genetic test to determine her risk for breast and ovarian cancer. In order to avoid discrimination regarding her insurability, she took the test under an assumed name and purposely kept her family history information out of her medical record. Before Gail received her genetic test results, Gail’s gynecologist noticed a possible abnormality on her ultrasound during a routine visit. As Gail’s risk factors for cancer and her genetic test were not noted on her medical chart, her doctor was unaware of a possible hereditary risk and did not recommend follow-up testing nor a course of treatment. Since Gail was a physician, she was aware of the significance of her exam results and knew what she needed to do to protect herself. However for individuals not in a healthcare profession, this case could result in a patient’s lost opportunity for follow-up resulting from a missed detection of a life-threatening disease.

In these borderline cases, some attributes of the concept are missing. In the first case, it is the oncology nurse who is not aware of possible discrimination the young woman and her children could face if she registered at the clinic and underwent genetic screening. The young woman was not aware that registering in at the clinic is not considered genetic information. Gail, the physician, although aware of possible discrimination based on genetic information, is not aware that by undergoing anonymous genetic testing, with results not revealed to her gynecologist, she could face discrimination and new health risks by not qualifying for follow-up treatment, based on keeping her genetic information secret (Faces of Discrimination, 2004).
These cases illustrate that, in order to be aware of discrimination based on genetic information, all elements of the concept must be present. Patients and healthcare professionals need to know how differences in individuals based on their family health history and genetic tests can be used to discriminate against them, either in the healthcare arena by not getting the appropriate treatment, or in the insurance or employment sectors.

Although most of these cases were reported before GINA was enacted, they are still applicable to this concept analysis, as most healthcare professionals and the public are not aware that GINA protects against health insurance and employment discrimination. However, GINA does not protect individuals from being discriminated against when qualifying for life, disability, and long-term care insurance. In addition, employment discrimination does not apply to employers who have less than 15 employees (GINA, 2010; Rothstein, 2008).

Limitations

A limitation of this analysis is that the data search and concept analysis was completed by one individual from only one perspective. But, as awareness of discrimination based on genetic information is a new unexplored concept, this single perspective can serve as a launching point for other concept analyses, using different concept analysis methods to expand on and to incorporate descriptions of the concept in subsequent nursing research and discussions (Bonis, 2008).

An additional limitation is that most cases and the definition of discrimination and genetic information are taken from legal aspect. As genetic consideration for illness and knowledge of GINA becomes commonplace in healthcare settings, cases of
discrimination based on genetic information may be researched and reported from a healthcare aspect.

**Future Development of the Concept**

Future concept analyses expanding on this concept could include self-awareness, integrated awareness, reflexive awareness or situational awareness of discrimination based on genetic information. In addition, instead of using awareness as an element of the concept which is “to know”, as U.S. citizens become aware of GINA’s provisions and limitations, the term consciousness, “to know about” could add further insight into this concept. Also, further nursing research is warranted to improve awareness in the healthcare arena, understanding the causes, and health consequences of discrimination based on genetic information (Thorburn Bird, 2004).

**Conclusion**

This concept analysis serves as a starting point for future concept analysis of words and terms used in genetic healthcare. As most common illnesses have a single or multiple genetic commonalities, nurses need to incorporate issues concerning genetics when providing patient care. Roy’s Adaptation Model is an appropriate framework to guide this concept analysis, but other nursing theories and models may also guide further genetic-related concept analyses. Using Roy’s Adaptation Model, the cases presented in this analysis provide addition content to the model, representing real examples of how genetic information, only a part of our whole self, can affect an individual’s health holistically.
As genetic research expands and preventive and treatment strategies for genetic diseases are developed, it will be increasingly important that discrimination and/or the fear of discrimination not be a roadblock to reaping the benefits (Clifton, VanBeuge, Mladenka & Wosnik, 2010). Genetic information will continue to change with each new genetic discovery. The nursing discipline needs to develop knowledge to guide genetic nursing practice for all individuals in all healthcare settings (Williams, 2002). As health professionals, nurses have a responsibility to put their own house in order first, to increase the awareness and knowledge of discrimination based on genetic information (Hocking, 2003).
References


Fedder, R.S. (2000). To Know or Not to Know: Legal Perspectives on Genetic Privacy of an Individual’s Genetic Profile. The Journal of Legal Medicine, 21, 557-592.


CHAPTER FOUR

ASSESSING AWARENESS OF THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008 (GINA) AMONG NURSE PRACTITIONERS: A PILOT STUDY

(To be submitted to the Journal of the American Association of Nurse Practitioners)

Abstract

Purpose

To assess the awareness of the Genetic Information Nondiscrimination Act of 2008 (GINA) among nurse practitioners (NPs) in South Carolina.

Methodology

A cross-sectional descriptive pilot research study, using 65 NP volunteers from two nurse practitioner association in South Carolina used a web-based questionnaire, based on Rogers’ Diffusion of Innovations theory, to assess the awareness of GINA among NPs, the independent variable, with dependent variables of the NP volunteer: terminal academic degree, specialized clinical practice setting, years of clinical practice, age and adopter category and types of communication channels used to find clinical practice information.

Conclusions

Only 34% (N=22) of NPs volunteering for the study were aware of GINA. Fisher exact and chi square statistics found that awareness of GINA in NPs was not related to the NP’s terminal academic nursing degrees, the NPs’ clinical specialties where germline genetic testing is common versus uncommon, the years of the NPs’ clinical practice or
the age of the NPs. Additionally, awareness of GINA in NPs was not associated with any of the adopter categories of the NP: an innovator, an early adopter, in the early or late majority of adopters or a traditionalist/laggard. NPs who were aware of GINA scored in the early adopter, early majority and late majority categories. The communication channels that NPs used to gain clinical information also did not statistically indicate a relationship between awareness of GINA and the type of communication channels used by the NP participants. Effect size analysis did show that NPs who are aware and not aware of GINA use similar communication channels to gain information. This information can be used to effectively diffuse information about GINA using these communication channels. Further investigation into awareness of GINA in NPs, including antecedent, innovation, and adoption factors that contribute to the awareness of GINA among NPs is warranted. Additionally, further research with a different, larger sample of NPs in South Carolina may indicate statistically significant results between awareness of GINA and the study variables.

**Implications for Practice**

Advanced practice nurses may have witnessed discrimination, against their patients and families with pre-existing genetic diseases, from either health insurers or employers. GINA offers protections from discrimination based on their genetic information to these individuals. To protect their patients and their families, NPs should be aware of the provisions and limitations of GINA. Education strategies to increase awareness of GINA could incorporate factors identified from Rogers’ Diffusion of Innovation theory to, not only meet the essential genetic and genomic competencies for
nurses with graduate degrees, but also to facilitate the diffusion and adoption of GINA by NPs.

**Background**

Genetic testing for highly penetrant disorders with clinical action ability is used to predict risk for future disease, to detect mutations associated with genetic conditions, and to guide treatment decisions (Genetics & Public Policy Center [GPPC], 2008, Green et al, 2013). Genetic test results may not only reveal genetic information to symptomatic and asymptomatic individuals, but it is possible that genetic test results may lead to discrimination by health insurers and employers (Chapman & Smith, 2002). Since the Genetic Information Nondiscrimination Act of 2008 (GINA) was enacted in 2009, health care professionals need to be aware of GINA’s provisions and limitations to assist their patients and families in making informed decisions regarding genetic testing (International Society of Nurses in Genetics (ISONG), 2010). Recent legislation, the passage and enactment of the Patient Protection and Affordable Care Act (PPACA), does not amend GINA’s provisions and limitations, but rather serves the complementary purpose to guarantee health insurance for all individuals who request it, in particular, those patients with a pre-existing genetic condition (Sarata, DeBergh, & Staman, 2011; NHGRI, 2014).

Advance practice registered nurses (APRNs) such as nurse practitioners (NPs), are well-positioned to integrate GINA’s protections into their clinical practice. APRNs conduct comprehensive health assessments, diagnose, and treat individuals and their families possessing actual or potential genetic health problems. As facilitators/change
agents, APRNs transmit new knowledge to nurses at the bedside as well as to patients and their families (Doran, 2007).

Historically, genetics and genomic content has not been routinely integrated into master’s level nursing education curricula. Since GINA became enacted in 2009, genetics and genomic content, including didactic knowledge and skills, are required to be incorporated in graduate nursing curricula, so future APRNs will be stronger advocates for their clients and families possessing genetic disease risks (Consensus Panel on Genetics/Genomic Nursing Competencies, 2009). NPs need to possess awareness and knowledge of GINA and its applicability to clinical nursing practice. Therefore, the purpose of this research study is to empirically assess the extent to which NPs possess this awareness and knowledge of GINA.

A review of the literature supports the need for this research study. Three unpublished master’s theses measured awareness of GINA among consumers, genetic counselors and primary care physicians (Fusina, 2009; Garrison, 2010; Pamarti, 2011) Two published articles and two abstracts of articles pending publication surveyed consumers and physicians about their awareness and attitudes about GINA (Allain, Friedman & Senter, 2012; Laedtke, O’Neill, Rubinstein & Vogel, 2011; Huang, Huston, & Perri, 2013; Qurehi, Warda, Rahaghi, Ferrer, Ramirez, Oliveria. . . Rahaghi, 2010). Table 4.1 describes the research studies conducted to study awareness and knowledge of GINA in consumers and healthcare personnel. No studies were identified that utilized a theoretical framework to conduct their study. More importantly, no study was identified that assessed awareness of GINA in the nursing profession.
### Table 4.1

**Research Studies Assessing Awareness of GINA**

<table>
<thead>
<tr>
<th><strong>Author &amp; Date</strong></th>
<th><strong>Population</strong></th>
<th><strong>Instrument/Method</strong></th>
<th><strong>Study Purpose</strong></th>
<th><strong>Findings</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Allain, Friedman, &amp; Senter 2012</td>
<td>1,699 members of a Hereditary Breast and Ovarian Cancer Syndrome advocacy group</td>
<td>Anonymous online questionnaire, 34 items</td>
<td>Examine awareness and attitudes about GINA</td>
<td>45.7% were aware of GINA before taking the survey, p&lt;0.0001</td>
</tr>
<tr>
<td>Fusina 2009</td>
<td>56 physicians affiliated with Mount Sinai School of Medicine</td>
<td>Anonymous online survey, 19 closed-ended questions and one open-ended question</td>
<td>Examine awareness of GINA by physicians</td>
<td>42.9% were aware of GINA, p=0.0004</td>
</tr>
<tr>
<td>Garrison 2010</td>
<td>1,076 members of FORCE, (Facing Our Risk of Cancer Empowered) advocacy group and clients of Ohio State’s Clinical Cancer Genetics Program</td>
<td>Anonymous online survey, 33 multiple-choice questions</td>
<td>Evaluate consumer knowledge and attitudes of GINA</td>
<td>52.1% of respondents were aware of GINA before the study, p&lt;0.02</td>
</tr>
<tr>
<td>Laedtke, O’Neill, Rubinstein &amp; Vogel 2011</td>
<td>401 members of American Academy of Family Physicians</td>
<td>Mailed/online survey. Number of items on survey not reported</td>
<td>Evaluate physician’s awareness/knowledge of GINA</td>
<td>45.5% aware of GINA, 10.3% self-reported knowledge of GINA, p&lt;0.001</td>
</tr>
<tr>
<td>Huang, Huston, &amp; Perri 2013</td>
<td>295 general population panel of U.S. citizens, ages 18-64</td>
<td>17-item survey, included 2 questions to measure awareness/knowledge of GINA</td>
<td>Evaluate consumer awareness of genetic discrimination and GINA</td>
<td>8.8% were aware of GINA, 3.4% knew GINA prohibits improper use of genetic information, p value not reported</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Methodology</td>
<td>Findings</td>
<td></td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------------</td>
<td>--------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Pamarti 2011</td>
<td>257 genetic counselors from National Society of Genetic Counselors</td>
<td>32-item online survey, adapted from previous surveys</td>
<td>Assess knowledge about the scope of GINA and genetic discrimination in clients</td>
<td></td>
</tr>
<tr>
<td>Qurehi, Warda, Rahaghi, Ferrer, Ramirez, Rahaghi 2010</td>
<td>41 physicians at Cleveland Clinic/Florida</td>
<td>Questionnaire - number of items and type not reported</td>
<td>Evaluate personal practice of ordering lab tests and awareness of GINA</td>
<td></td>
</tr>
</tbody>
</table>
**Purpose of the Study**

The overall purpose of this pilot study was to assess the awareness of GINA among NPs. Research questions that guided this study are:

1. Is there a relationship between terminal academic degrees (Master versus PhD and DNP) and awareness of GINA?
2. Does awareness of GINA differ among NPs in clinical specialties where germline genetic testing is common versus those NPs in clinical specialties where germline genetic testing is uncommon?
3. Is there a difference in awareness of GINA depending on years of NP clinical practice?
4. Is there a difference in awareness of GINA depending on the age of the NP?
5. Is there a relationship between awareness of GINA and the adopter category of the NP?
6. What communication channels do NPs, who are aware of GINA, use to find information related to their clinical practice?

**Theoretical Framework**

Everett Rogers’ Diffusion of Innovations theory (DOI) guided this pilot study (Rogers, 2003). The DOI theory has been applied in education, public health, communication, economics and marketing disciplines. Most recently this theory was used as the framework to establish essential genetic and genomic nursing competencies for nurses seeking baccalaureate degrees (Consensus Panel on Genetic/Genomic Nursing Competencies, 2009; Jenkins & Calzone, 2007).
Rogers’ theory is based on diffusion, a special type of communication where messages that concern a new idea, or innovation, are conveyed between individuals. Diffusion of an innovation is defined as, “the process by which an innovation is communicated through certain channels over time among the members of a social system” (Rogers, 2003, p. 475). To diffuse an innovation, the potential adopter must first possess “awareness-knowledge” of the innovation; however, awareness alone does not lead to the adoption or rejection of the innovation. Rogers’ identified five concepts; relative advantage, complexity, compatibility, trialability and observability of the innovation that may influence the rate of diffusion of the innovation. Also, the time frame that an individual takes to adopt an innovation, as compared to time taken by other members in their social system, affects diffusion of the innovation.

Five constructs were identified from the theory that may affect the diffusion of GINA among NPs. These five constructs, included in Rogers’ definition of diffusion of an innovation, include:

- Awareness-Knowledge
- Innovation
- Communication
- Time
- Social System

Constructs and their concepts, derived from the DOI theory, used in this study are summarized in Table 4.2. Constructs are identified in bold type with their unbolded concepts identified below the construct.
Table 4.2

*Constructs and Concepts Derived from DOI Theory*

<table>
<thead>
<tr>
<th>Awareness-Knowledge</th>
<th>Innovation</th>
<th>Communication</th>
<th>Time</th>
<th>Social System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognition</td>
<td>Relative Advantage</td>
<td>Mass media</td>
<td>Innovators</td>
<td>Demographics</td>
</tr>
<tr>
<td>How-to knowledge</td>
<td>Complexity</td>
<td>Interpersonal</td>
<td>Early adopters</td>
<td>Practice setting</td>
</tr>
<tr>
<td>Principles knowledge</td>
<td>Compatibility</td>
<td></td>
<td>Early majority</td>
<td>Clinical specialty</td>
</tr>
<tr>
<td></td>
<td>Trialability</td>
<td></td>
<td>Late majority</td>
<td>Highest nursing degree attained</td>
</tr>
<tr>
<td></td>
<td>Observability</td>
<td></td>
<td>Laggards/Traditionalists</td>
<td>Year highest nursing degree attained</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Genetic education included in most recent nursing curriculum</td>
</tr>
</tbody>
</table>
Methods

Design and study sample

This cross-sectional descriptive pilot research study employed a web-based questionnaire, using selected constructs and concepts from Rogers’ Diffusion of Innovation Theory that play roles in the awareness of GINA among nurse practitioners (NPs). The independent variable used was “awareness” under the Awareness-Knowledge construct and the dependent variables were under the Social System construct: NP terminal academic degree, NP specialized clinical practice setting, years of NP clinical practice, age of the NP and adopter category of the NP as well as type of communication channels NPs use to find information related to their clinical practice.

According to a Kaiser Family Foundation report (2011), there are 3,687 licensed nurse practitioners in South Carolina. E-mail addresses for NPs in South Carolina were unavailable from the SC State Board of Nursing and the SC American Nurses Association, so the memberships of nurse practitioner associations in South Carolina were used to obtain the convenience sample for this study. Eligible participants consisted of South Carolina licensed NPs from the NP memberships of two South Carolina nurse practitioner associations that responded to the researcher’s query for participants. The volunteer NP participants learned of the study by an e-mail communication from their association president a few days before receiving the email invitation which contained a link to the online questionnaire from the author.
Instruments

To meet the overall purpose for this exploratory study, a new questionnaire was developed, using the DOI theory (Rogers, 2003). The process of development of this online questionnaire, including field testing and pilot testing, was based on DeVellis’s guidelines for scale development (DeVellis, 2003) and will be discussed in a future manuscript. All items in the final questionnaire were distributed to nine genetic content experts for clarification and for scoring content validity. After content validity scoring by the nine genetic content experts, follow-up with each expert was done to establish face validity. Questionnaire item content validity was 0.78 with overall questionnaire content validity of 0.64. Inter-rater reliability was scored only for the first three constructs (Awareness-Knowledge, Innovation and Communication) with a score of 0.64. The Time construct was measured using the Individual Innovativeness Scale with an established Cronbach’s alpha of 0.94, used with permission (Hurt, et.al. 197). Additionally, the final questionnaire version was field-tested by ten Clemson University NPs, in order to determine the questionnaire logistics; readability, item burden and ease of administration.

The questionnaire consisted of 72 questions, divided into five parts, each part reflecting the identified constructs and concepts used from the DOI theory to create the questionnaire. The Awareness-Knowledge construct was measured with 12 questions, the Innovation construct with 16 questions and the Communication construct was measured with six questions. The Time construct consisted of 20 questions and the Social System construct consisted of 18 demographic questions describing the characteristics of the NPs who volunteered to participate in the study.
Questions included in the questionnaire were mainly true/false and 5-point Likert-type scales, ranging from “strongly agree” to “strongly disagree”. Some revised questions with the same item stem had answers that were collapsed in multiple choice options that included “all of the above” and “none of the above” to lessen item burden and redundancy. Participants were encouraged to complete the entire questionnaire in the invitation to participate portion of the questionnaire. Table 4.3 shows the breakdown of questionnaire items according to constructs and concepts operationalized from the DOI theory.
Table 4.3

*Questionnaire Items*

<table>
<thead>
<tr>
<th>Construct</th>
<th>Concept</th>
<th># of Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awareness-Knowledge</td>
<td>Awareness cognition</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>How-to-knowledge</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Principles knowledge</td>
<td>3</td>
</tr>
<tr>
<td>Innovation</td>
<td>Relative Advantage</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Complexity</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Compatibility</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Trialability</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Observability</td>
<td>5</td>
</tr>
<tr>
<td>Communication</td>
<td>Communication Channels</td>
<td>6</td>
</tr>
<tr>
<td>Time</td>
<td>Innovativeness Inventory</td>
<td>20</td>
</tr>
<tr>
<td>Social System</td>
<td>Demographics</td>
<td>18</td>
</tr>
</tbody>
</table>
**Human subjects and research approval procedures**

Prior to each step of the questionnaire development and data collection, the study protocol received approval from the Clemson University Institutional Review Board (IRB). Before beginning the online questionnaire, participants were informed, by e-mail invitation, of the study’s purpose. The invitation also included an informed consent stating that no identifying information would accompany their questionnaire submission. The ten Clemson University NPs who field-tested the questionnaire were excluded from participation in this pilot study.

**Data collection procedures**

A convenience sample of 239 nurse practitioners, taken from the two nurse practitioner associations’ membership, was invited by e-mail to participate in the pilot study. Informed consent preceded the online, self-administered questionnaire; activated using Qualtrics® survey software. No individual incentives were offered for participation; however, NPs who completed the questionnaire were entered into a drawing where four members of each NP association would have their 2014 annual dues paid.

The data collection spanned from October 28, 2013 to November 18, 2013, before the holiday season commenced and after receiving IRB approval for the pilot study. E-mail reminders were sent to the sample population weekly for two weeks. Additionally, postcards that contained the study’s purpose and Qualtrics® link were distributed during the data collection time period at the two NP associations’ monthly
meetings, both held on November 12, 2013. Data were collected and stored in a password-protected file only accessible to study personnel.

Data Analysis

Data were exported from the Qualtrics® questionnaire into Microsoft® Excel 2013 and SPSS® 21 software. A biostatistician was consulted about the appropriate statistical analyses. Fisher exact and chi-square analyses assessed NP’s awareness of GINA with the study variables of interest to answer the research questions. Demographic statistics for categorical and continuous data included means, standard deviations, and frequencies. Missing data occurred for a few demographic questions, such as gender (N=2) and for the specialized practice setting question (N=9). The missing data did not affect the statistical results. All p values are two-tailed and presented without adjustment. Statistical significance of comparison was set at p < .05.

Results

The final sample consisted of 65 NP participants who submitted completed questionnaires for a 27.20% response rate. The participants were 97 % female and 3% male. The mean age of the participants was 43.2 years with a standard deviation of 16.2 years. Mean years as an NP was 8.51 years with a standard deviation of 2.57 years. Participant demographic and clinical setting characteristics are presented in Table 4.4
Table 4.4

Participant Demographics of the Study Sample (N=65)

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>2</td>
<td>3%</td>
</tr>
<tr>
<td>Female</td>
<td>61</td>
<td>97%</td>
</tr>
<tr>
<td>Age (categories)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26-35 years</td>
<td>11</td>
<td>17%</td>
</tr>
<tr>
<td>36-45 years</td>
<td>12</td>
<td>18%</td>
</tr>
<tr>
<td>46-55 years</td>
<td>23</td>
<td>35%</td>
</tr>
<tr>
<td>56-65+ years</td>
<td>19</td>
<td>30%</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian American</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Black, not Hispanic</td>
<td>2</td>
<td>3%</td>
</tr>
<tr>
<td>White, not Hispanic</td>
<td>61</td>
<td>94%</td>
</tr>
<tr>
<td>Other-not specified</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Years of experience as an NP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-5 years</td>
<td>25</td>
<td>38%</td>
</tr>
<tr>
<td>6-10 years</td>
<td>8</td>
<td>12%</td>
</tr>
<tr>
<td>11-15 years</td>
<td>16</td>
<td>25%</td>
</tr>
<tr>
<td>16-20+ years</td>
<td>16</td>
<td>26%</td>
</tr>
<tr>
<td>Employment Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full time (&gt;40 hrs./week)</td>
<td>13</td>
<td>20%</td>
</tr>
<tr>
<td>Part time (≤40 hrs./week)</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Retired</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Seeking employment</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Not seeking employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employment Setting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambulatory/outpatient/primary care office</td>
<td>4</td>
<td>6%</td>
</tr>
<tr>
<td>Retail clinic (e.g., Walgreen’s, CVS)</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>OB clinic</td>
<td>4</td>
<td>6%</td>
</tr>
<tr>
<td>Emergency Department</td>
<td>2</td>
<td>3%</td>
</tr>
<tr>
<td>Employee health clinic</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Setting</td>
<td>Count</td>
<td>Percentage</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------</td>
<td>------------</td>
</tr>
<tr>
<td>Extended/long-term care facility</td>
<td>2</td>
<td>3%</td>
</tr>
<tr>
<td>Skilled nursing facility</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Intensive care/acute care</td>
<td>7</td>
<td>11%</td>
</tr>
<tr>
<td>In-patient hospital unit/hospitalist</td>
<td>3</td>
<td>5%</td>
</tr>
<tr>
<td>Occupational health</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Educational</td>
<td>2</td>
<td>3%</td>
</tr>
<tr>
<td>Non-traditional setting</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td>Other setting</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Site</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urban area (&gt;50,000 population)</td>
<td>15</td>
<td>23%</td>
</tr>
<tr>
<td>Urban cluster (2,500 to &lt;50,000 population)</td>
<td>2</td>
<td>3%</td>
</tr>
<tr>
<td>Rural (&lt;2,500 population)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Awareness of GINA and NP Education Preparation

NPs’ awareness of GINA was compared to NP terminal education preparation, using Fisher’s exact test, since the sample was of sufficient size for a more accurate comparison. Of the 22 participants who were aware of GINA, 19 possessed a master’s degree in nursing as their terminal nursing preparation as compared with three of the respondents who possessed either a PhD or DNP degree. There was no participant that held an EdD degree. One NP participant had a NP certificate as a terminal nursing degree but was not aware of GINA, so that participant was excluded from the cross tabulations of statistics. Although percentages indicate that NPs with a PhD or DNP included a higher percentage of NPs aware of GINA, the Fisher’s exact test yielded a p-value = 0.6837. Thus there was not a statistically significant relationship between awareness of GINA and NP terminal academic preparation (Table 4.5).
Table 4.5

Comparison of Awareness of GINA and NP Terminal Academic Preparation (N=64*)

<table>
<thead>
<tr>
<th>Awareness of GINA</th>
<th>Master</th>
<th>PhD or DNP</th>
<th>Total</th>
<th>Fisher’s Exact p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>19</td>
<td>3</td>
<td>22</td>
<td>0.6837</td>
</tr>
<tr>
<td>No</td>
<td>38</td>
<td>4</td>
<td>42</td>
<td></td>
</tr>
</tbody>
</table>

*n=1 missing, certificate education preparation excluded
Awareness of GINA and Clinical Specialty Practice

Responses to the question asking about “specialized practice setting” were divided into two groups by the researcher and a genetic epidemiologist: those specialized practice settings where germline genetic testing is common, compared with settings where germline testing is uncommon.

Specialized NP clinical practice settings where germline genetic testing is common included: genetics, neonatal, pulmonary, cardiovascular (including cardio-thoracic), gastroenterology, and psychiatric, internal medicine, oncology (including surgical and hematological oncology). Uncommon NP clinical specialty practice settings included renal, family practice, adult/gerontology, neurosurgery, infectious disease, orthopedics, urology, hospice, retail outpatient, clinical trials, emergency room, young adult, college, and military practice settings.

Percentages for NPs in specialty clinical practice awareness of GINA versus those NPs in specialty clinical practice not aware of GINA were similar. Chi-square analysis for this comparison resulted in $\chi^2 = 0.1275$ with an associated $p$-value $= 0.7211$ indicating no statistical significance between awareness of GINA and their clinical specialty area (germline genetic testing common versus uncommon) (Table 4.6).
Table 4.6

Comparison of Awareness of GINA and NP Clinical Specialty Practice with Common vs. Uncommon Use of Germline Genetic Testing (N=56*)

NP Clinical Specialty Practice with Common vs. Uncommon Use of Germline Genetic Testing

<table>
<thead>
<tr>
<th>Awareness of GINA</th>
<th>Common</th>
<th>Uncommon</th>
<th>Total</th>
<th>x²</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>6</td>
<td>13</td>
<td>19</td>
<td>0.1275</td>
<td>0.7211</td>
</tr>
<tr>
<td>No</td>
<td>10</td>
<td>27</td>
<td>37</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* n=9 missing
Comparison of Awareness of GINA and Years of NP Clinical Practice

Since GINA was signed into legislation in 2008 and enacted in 2009, this study explored whether NPs who started clinical practice as an NP in the last five years might have an increased awareness of GINA than their peers who have been in NP clinical practice six or more years. The results indicated that 7 out of the 22 participants (28%) who were aware of GINA had been in NP clinical practice less than 5 years. However, those in NP clinical practice six or more years, 15 out of 22 participants (37.5%) were more aware of GINA. However, the results from this comparison were not statistically significant with an $x^2=0.6201$ with $p=.4310$ (Table 4.7).
Table 4.7

Comparison of Awareness of GINA and Years of NP Clinical Practice (N=65)

*Years of NP Clinical Practice*

<table>
<thead>
<tr>
<th>Awareness of GINA</th>
<th>≤5 years</th>
<th>≥6 years</th>
<th>Total</th>
<th>$x^2$</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>7</td>
<td>15</td>
<td>22</td>
<td>0.6201</td>
<td>0.4310</td>
</tr>
<tr>
<td>No</td>
<td>18</td>
<td>25</td>
<td>43</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Comparison of Awareness of GINA and Age of the NP

Age of the NP participants was measured in age intervals. There were no participants who were younger than 26 who participated in the study. There was one participant who was older than 65 and was collapsed in the 56-65+ interval range. The results indicated that the 36-45 years of age interval had the highest percentage of NPs aware of GINA (50%) and also held the lowest percentage of NPs (50%) not aware of GINA. However, there was not statistical significance that age of the NP played a role in the NP’s awareness of GINA, since $x^2 = 2.101$ and $p = 0.552$ (Table 4.8).
Table 4.8

*Comparison of Awareness of GINA and Age of the NP (N=65)*

*Age of the NP in Years*

<table>
<thead>
<tr>
<th>Awareness of GINA</th>
<th>26-35</th>
<th>36-45</th>
<th>46-55</th>
<th>56-65+</th>
<th>Total</th>
<th>$x^2$</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>3</td>
<td>6</td>
<td>8</td>
<td>5</td>
<td>22</td>
<td>2.101</td>
<td>0.552</td>
</tr>
<tr>
<td>No</td>
<td>8</td>
<td>6</td>
<td>15</td>
<td>14</td>
<td>43</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Comparison of Awareness of GINA and Time (Adopter Category of the NP)

Based on Rogers’ Diffusion of Innovations Theory, the Time construct concerns itself with innovativeness, operationalized as the degree to which a NP in South Carolina is relatively earlier in awareness of GINA than other NPs in South Carolina. New innovations can be diffused either in a planned or spontaneous manner and then, are either adopted or rejected by individuals (Rogers, 2003, p. 6) Diffusion is bound, not by the innovation, but by the potential adopters of the innovation and their social system (Rogers, 2003, p. 475). This willingness of an individual, within a social system to adopt a new idea over time, can be categorized into five adopter categories or groups: innovators, early adopters, early majority, late majority and laggards or traditionalists (Rogers, 2003, p 283-284).

According to the DOI theory, innovators are typically adventurous and like trying out new ideas. Early adopters follow the innovator’s decision to reject or adopt the innovation. The early majority, usually the largest adoption section, is followed by the late majority and the last group, laggards or traditionalists (Rogers, 2003, pp. 283-284.)

These five different adopter groups of an innovation over time have historically been represented graphically as bell-shaped curve, while the overall process of diffusion of an innovation may be represented by an S-shaped curve distribution (Rogers, 2003, p.12). Variations in “S” slopes have been shown to be dependent on the length of time it takes members of a social system to fully adopt an innovation (Rogers, 2003, p. 12). The S-shaped diffusion curve increases dramatically, when 10-20 percent of an innovation is
diffused and adopted by a social system. This typically occurs when communication channels of a social system are fully activated (Rogers, 2003, p. 12) (Figure 4.1).
Figure 4.1

Adopter of Innovation Category with Diffusion of Innovation over Time

Adopter Category, percent of population (blue line)
Diffusion of Innovation over Time (yellow line)
Adapted from Rogers, 2003.
The Time construct for this study was measured using the Individual Innovativeness Scale with an established Cronbach’s $\alpha = 0.94$ (Hurt, et al., 1977). The adopter category was scored for each NP participant who was aware of GINA, per the scales’ guidelines (Hurt et al., 1977). Interestingly, the results from this pilot study results identified a similar reliability measure with a Cronbach’s $\alpha = 0.86$.

Of the 22 NPs who are aware of GINA, results indicated that eight NPs scored in the “early adopters” or in the “early majority” (36% each), while six NPs scored in the “late majority” category (24%). There were no NPs who scored in the “innovator” or “laggard” category. The “early adopters” and “early majority” categories were collapsed into one category that represents the left half of a bell curve, while the “late majority” category represented the right half of the bell curve based on Rogers’ DOI theory. Although not statistically significant with an $x^2 = 1.759$ for a $p = 0.185$, the adoption of the innovation curve by this small sample of NPs aware of GINA, may be more similar to the DOI theory’s adoption of the innovation curve, presented earlier in this chapter, if a larger sample of NPs had participated in the study (Figure 4.2) (Table 4.9).
Table 4.9

Comparison of Awareness of GINA and Time (Adopter Category of the NP) (N=65)

*Adopter Category of the NP*

<table>
<thead>
<tr>
<th>Awareness of GINA</th>
<th>Early</th>
<th>Late</th>
<th>Total</th>
<th>$x^2$</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>16</td>
<td>6</td>
<td>22</td>
<td>1.759</td>
<td>0.185</td>
</tr>
<tr>
<td>No</td>
<td>24</td>
<td>19</td>
<td>43</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Figure 4.2

Time: Awareness of GINA among NPs

<table>
<thead>
<tr>
<th>Time: Awareness of GINA in NPs</th>
<th>Early Adopter 36%</th>
<th>Early Majority 36%</th>
<th>Late Majority 23%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8</td>
<td>8</td>
<td>6</td>
</tr>
</tbody>
</table>
Communication Channels Used to Gain More Information about their Clinical Practice

Which mass and interpersonal communication channels all NP participants, those who are aware and those who are not aware of GINA, would use to find more information about their clinical practice, are useful to developing educational avenues to diffuse GINA to NPs, and eventually into their clinical practice. These same communication channels could also be the same communication channels that NPs could use to find out information concerning GINA. Rogers’ DOI theory implies that information that increases awareness of GINA rarely comes from a communication channel they actively seek; that information about GINA may be actively sought after NPs are aware of GINA existence, that NPs would know which communication channels to utilize to provide information about GINA to them (Rogers, 2003, pp. 202-203).

Concerning mass media communication channels, the Internet and online website/search engine were the most favored forms of mass communication channels used by all participants aware of GINA (N=15 or 68.2% of aware participants), followed by a peer-reviewed journal (N=13 or 59% of aware participants). The favored mass communication channels for NPs not aware of GINA were the same mass communication channels of the aware participants: Internet (N=29 or 69%), online website/search engine (N=27 or 64.3%) and peer-reviewed journal (N=20 or 46.7%).

The two interpersonal communication channels selected by the NPs of both the aware and unaware groups to find more information about GINA included attendance at
professional meetings (N=52 or 81.3% of all participants) followed by face-to-face workshops or lectures (N=45 or 70.3% of all participants).

Effect size was determined for all communication channels used by NPs as a way of quantifying the size difference between the utilization of mass media and interpersonal communication channels by the aware and unaware NP groups. The type of effect size statistic used for these study results was the phi coefficient (\( \varphi \)), which serves as a function of both the chi-square (\( x^2 \)) and the total sample size (N=65). The effect size statistics for communication channels between aware and not aware NP groups range from -0.311 to 0.115, (with a phi coefficient (\( \varphi \)) = 0 indicating independence) between communication channels used and awareness of GINA by NPs (Cohen, 2001, p. 653). Thus the effect size for both the mass media and interpersonal communication channels used by NPs who were aware of GINA versus NPs who were not aware of GINA is not statistically significant (See Table 4.10).
Table 4.10

Communication Channels Used by NPs to Gain More Information about their Clinical Practice

Communication Channels Used by NPs to Gain Information

<table>
<thead>
<tr>
<th>Channel</th>
<th>NPs Aware of GINA</th>
<th>NPs Not Aware of GINA</th>
<th>Effect Size (Phi coefficient)</th>
<th>Total # of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (N/Total N)</td>
<td>N (N/Total N)</td>
<td>φ</td>
<td>N           %</td>
</tr>
<tr>
<td><strong>Mass Media</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internet</td>
<td>15 (68.2)</td>
<td>29 (69.0)</td>
<td>-0.009</td>
<td>44          68.8</td>
</tr>
<tr>
<td>On-line website/search engine</td>
<td>15 (68.2)</td>
<td>27 (64.3)</td>
<td>0.039</td>
<td>42          65.6</td>
</tr>
<tr>
<td>Peer-reviewed journal</td>
<td>13 (59.0)</td>
<td>20 (47.6)</td>
<td>0.109</td>
<td>33          51.6</td>
</tr>
<tr>
<td>Genetic association website</td>
<td>9 (40.9)</td>
<td>15 (35.7)</td>
<td>0.051</td>
<td>24          37.5</td>
</tr>
<tr>
<td>Association website/newsletter</td>
<td>5 (22.7)</td>
<td>6 (14.3)</td>
<td>0.115</td>
<td>11          17.2</td>
</tr>
<tr>
<td><strong>Interpersonal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional meeting</td>
<td>18 (81.8)</td>
<td>34 (81.0)</td>
<td>0.011</td>
<td>52          81.3</td>
</tr>
<tr>
<td>Workshop/lecture</td>
<td>17 (77.3)</td>
<td>28 (66.7)</td>
<td>0.110</td>
<td>45          70.3</td>
</tr>
<tr>
<td>Face-to-face communication</td>
<td>8 (36.4)</td>
<td>13 (31.0)</td>
<td>0.055</td>
<td>21          32.8</td>
</tr>
<tr>
<td>Formal education class</td>
<td>8 (36.4)</td>
<td>16 (38.1)</td>
<td>-0.017</td>
<td>24          37.5</td>
</tr>
<tr>
<td>Pharm/medical sales rep</td>
<td>0 (0)</td>
<td>10 (23.8)</td>
<td>-0.311</td>
<td>10          15.6</td>
</tr>
<tr>
<td>Texts from peers</td>
<td>0 (0)</td>
<td>2 (4.76)</td>
<td>-0.130</td>
<td>2           3.13</td>
</tr>
<tr>
<td>E-mail from peers</td>
<td>2 (9.09)</td>
<td>5 (11.9)</td>
<td>-0.043</td>
<td>7           10.9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>22 (42)</td>
<td></td>
<td>-0.313</td>
<td>64*</td>
</tr>
</tbody>
</table>

*N=1 data missing from non-aware participant
Limitations

Data collection from a small, self-selected, convenience sample size in a pilot study has inherent limitations. These limitations are not limited to: the small sample may not be representative of the NP population in South Carolina, the number of questions may have deterred some NPs from participating in the study and NPs may have felt intimidated by their lack of awareness of GINA, so they self-selected themselves from participation in the survey. Additionally, members of the volunteer sample were affiliated with one of two NP associations in South Carolina, located in the Southeast and Northwest corners of South Carolina. Therefore, this distribution may not reflect the awareness and knowledge of GINA by NPs in a clinical practice located in other parts of the state.

Implications for Practice and Conclusions

This pilot study possesses the following strengths:

- A new theory-based conceptual approach for examining the awareness of GINA in the nurse practitioners is introduced, using defined research questions.
- The created online questionnaire uses a well-known, well-researched theory, Rogers’ Diffusion of Innovations theory
- This empirical research study draws upon previous research assessing awareness of GINA in consumers, genetic counselors and physicians.
- The initial results data can be used to determine sample size calculations for subsequent studies assessing the awareness of GINA among NPs.
The pilot study did find that the majority of NPs composing the sample group in South Carolina are not aware of GINA. There may exist clinically and statistically significant relationships between awareness of GINA and recently graduated NPs with Master’s degrees and those NPs employed in specialized clinical settings; however, undue significance of the results cannot be placed without formal power calculations as the research sample population was too small to draw any conclusions.

Awareness of GINA was not shown to be statistically significant when compared to age of the NP and their adopter category. However, the data indicate that NPs in the 36-45 years of age interval were more aware of GINA than other age groups. Also, although no NPs who were aware of GINA scored in the “innovator” category, neither did any of the NPs score in the “laggard” or “traditionalist” category.

Lastly, NPs, both aware and unaware of GINA, indicated they use similar mass media and interpersonal communication channels to gain awareness about GINA. The effect sizes of these communication channels indicate that awareness of GINA is not dependent on which communication channel the NPs chose to utilize. Thus, in planning to disseminate information of and about GINA to NPs, the mass communication channels of the Internet, online website/search engines and peer-reviewed journals should include information about GINA. Interpersonal channels NPs use the most, professional meetings and workshops/lectures are the best way to diffuse information about GINA.

**Future Research**

Future research opportunities are identifiable. These opportunities include to conduct additional pilot studies, expanding on Roger’s DOI theory using antecedents of
the knowledge stage and determining if there are statistically significant relationships between the antecedents of knowing and awareness-knowledge of GINA. Results of this subsequent study could then determine if a larger research study, first utilizing NPs and then expanding to other nurses with advanced degrees (certified registered nurse anesthetist, clinical nurse specialist and certified nurse midwife) could be studies concerning awareness of GINA. Also, a NPs’ knowledge of essential genetic and genomic competencies that may be studied to see if knowledge of these competencies play a critical role in the diffusion of GINA. The current questionnaire needs to be validated and shown to be reliable, which would require more rigorous methods of measurements. The ultimate goal of this researcher is to use a reliable and validated online questionnaire to assess awareness of GINA in NPs nation-wide.

Summary

This pilot study contributes to the general body of knowledge concerning awareness of GINA in healthcare professionals. In particular, this pilot study is the first known research to study awareness of GINA in NPs. Study findings suggest that awareness of GINA was not statistically associated with a NP’s terminal nursing education, their clinical specialty, their years of clinical practice, their age, their adopter category or which communication channels NPs use to find information. However the descriptive statistics did indicate that NPs in clinical practice longer may have more awareness of GINA, particularly in the 36-45 age range. The adopter category indicated that NPs who were aware of GINA did not score in the “innovator” or “laggard” category, however since the questionnaire was self-selective and self-administered, the
findings might be different if that NP was evaluated by a peer. Finally, this research indicated what mass and interpersonal communication channels NPs use to find information about GINA. This information can and will be used to further disseminate GINA information to NPs, so they can, in turn, further disseminate that information to their patients and families.
References


CHAPTER FIVE

SYNTHESIS

The three manuscripts that make up this dissertation focus on awareness of discrimination based on genetic information. Nurses have a critical role in educating, counseling and advocating for their patients and families as they make genetic and genomic-based healthcare decisions. The patients’ personal genetic information challenge nurses to not only understand the ethical issues associated with protecting and maintaining confidentiality of a patient’s health information, but also the legal issues in order to prevent discrimination based on genetic information (Cassells, Jenkins, Lea, Calzone, & Johnson, 2003).

The first manuscript takes a critical look at the application of GINA for nursing professionals in oncology who work with cancer patients and their families with a system specific diagnosis of these inherited genetic-based malignancies. The manuscript is specifically written for the nursing profession; advising oncology nurses to be “aware and beware of GINA” as they integrate GINA into their clinical practice. Also included is a discussion on how GINA amends previously passed and current federal anti-discrimination health laws. The manuscript concludes with a discussion concerning the awareness of GINA by healthcare professionals since GINA’s provisions were enacted in 2009, under a new presidential administration. Since then, the Obama/Biden Plan (2009) has been introduced, which prohibited private insurance companies from denying individuals healthcare coverage based on pre-existing health conditions, including pre-existing genetic disease, such as cancer.
The need for the usefulness of awareness of GINA is exemplified by publication of the first manuscript by the *Clinical Journal of Oncology Nursing (CJON)*. The manuscript was selected as the continuing education article of the month for *CJON*, recorded as an Oncology Nursing Society podcast interviewing the author about the need to be aware of GINA, and was picked up by *Breast Cancer Network News*, which includes news on “current breast cancer research, treatment, symptoms, causes and risk factors to educate the public and healthcare providers (Breast Cancer News Network, 2011). The five citations from this publication, including one of the research studies in the review of literature for the pilot study, imply the importance other scholars have credited to this article as a pinnacle of GINA awareness. Even with professional and lay support of the importance of awareness of GINA, this researcher wanted to further examine the concept of “awareness of discrimination based on genetic information”, utilizing a concept analysis method.

The second manuscript analyzes the “awareness of discrimination based on genetic information” concept by utilizing and adding to Roy’s Adaptation model and Wilson’s method of concept analysis, defining the concept for use in nursing with a model case, contrary case and borderline case as examples of discrimination based on a patient’s genetic make-up (Hupcey, Morse, Lenz, & Tason, 1996; Phillips, 2010). The resultant operational definition, “to know differences against people or distinguish between people based on their ancestral, heritable, communicated facts or knowledge” for the concept utilizes terms, key words and concepts that are also found in Rogers’ Diffusion of Innovation theory (see Table 4.2). The DOI theory also guided the
development and direction of the pilot questionnaire in the third manuscript, the research portion for this dissertation (Steck, 2012).

The third manuscript begins with a literature review to justify the need to assess the awareness of GINA among NPs; that NPs have been overlooked as a significant group of healthcare professionals who may use GINA’s provisions and limitations when providing patient care. The creation of a questionnaire based on the operational definition of the awareness concept in addition to elements from Rogers’ DOI theory was necessary in to empirically assess NPs’ awareness of GINA. A 72 item online questionnaire was thus created and tested for item and questionnaire content validity and inter-rater reliability, guided by Rogers’ DOI theory. Because the DOI theory was previously used as a guide to establish the genetic and genomic competencies for nurses with undergraduate degrees, and associated with the American Nurses Association (ANA) “Essential Genetic and Genomic Competencies for Nurses with Graduate Degrees, the elements of ethics and policy in these competencies was used as the ethical framework for this dissertation (Consensus Panel of Genetic/Genomic Competencies, 2009).

Originally, it was believed the pilot study, using the DOI theory to formulate this questionnaire and guide the study, outcomes would contribute to understanding what variables influence the diffusion of GINA among NPs in South Carolina. The research questions in this study, utilized three of the four constructs taken from Rogers’ Diffusion of Innovations (DOI) Theory: time, communication and social system. The innovation construct, developed using the DOI theory, incorporated the perceived attributes or concepts of relative frequency, compatibility, complexity, triability, and observability,
were included in questionnaire items asking about NPs’ attitudes toward the use or potential use of GINA in their clinical practice. Since the DOI theory indicates that the characteristics of innovations, as perceived by individuals, helps to explain the different rates of adoption of an innovation, the collected data can be used to answer research questions in follow-up studies that explore how NPs perceive the attributes of GINA in relationship to their adoption of this law.

Six specific variables used to answer the research questions in the pilot study to determine awareness of GINA among the NP participants, have been discussed: 1) the NP’s terminal academic degree, 2) the NP’s specialty practice, 3) years of the NP clinical practice, 4) age of the NP, 5) adopter category of the NP and 6) the communication channels NPs would use to obtain information concerning GINA. To re-emphasize, these research questions were built based on the four main elements of the DOI theory (Rogers, 2003, p.11).

To answer the first four research questions, the data were cross-tabulated to analyze if awareness of GINA by the NPs in the sample had any statistically significant relationships with the NPs’ demographics under investigation. Rogers (2003) conceptually defined a social system as a “set of interrelated units that are engaged to a joint problem solving to accomplish a common goal” (p. 23). This conceptual definition was operationalized by the researcher for this study to define a social system as a ‘set of interrelated characteristics/demographics of NPs in South Carolina that possess awareness of GINA’. Collected data were analyzed to answer the following four research questions:
1. Is there a relationship between terminal academic degrees (Master versus PhD and DNP) and awareness of GINA?

2. Does awareness of GINA differ among clinical specialties where germline genetic testing is common versus clinical specialties where germline genetic testing is not common?

3. Is there a difference in awareness of GINA depending on years of NP clinical practice?

4. Is there a difference in awareness of GINA depending on the age of the NP?

Fisher’s exact and chi-square analyses did not find any statistically significant relationships between awareness of GINA among NPs with the demographic questions that queried the NP’s terminal academic degree, years of NP practice, age of the NP or the NP’s clinical specialty practice. However, the demographic statistics using frequencies indicated that NPs with a PhD or DNP had a higher percentage of awareness of GINA than NPs with terminal master’s degrees. NPs who had been practicing for more than 6 years, indicated they had greater awareness of GINA than newly-graduated NPs in the last 5 years who may have had the 2009 essential competencies for nurses with advanced degrees incorporated in their nursing curricula. NPs in the 36-45 age range also had the highest percentage of awareness in any NP age interval. No interrelated characteristic could be found in the data concerning NP clinical specialties where germline genetic testing is common versus the NP clinical specialties where germline genetic testing is not common. The data indicated this question, if used in subsequent studies, needs further clarification regarding what is intended to be measured.
When examining the research question that correlates awareness of GINA with NP adopter category (the Time construct), Rogers’ DOI theory states that “the units in a social system are not all identical in the behavior”, that the structure of a social system, in this case, the patterned arrangement of NPs in the system gives regularity and stability, allowing the researcher to predict behavior in the social system with some degree of accuracy (Rogers, 2003, p. 24). Although there was not a statistically significant relationship between the adopter category of the NP and awareness of GINA, the data indicates that 16 out of 22 NPs who were aware of GINA scored either as early adopters, the second fastest category of individuals who have awareness of GINA (behind innovators) or the third category, early majority, individuals who have awareness of GINA, the average member of the NP sample social system. Only six out of 22 in the aware NP group scored in the late majority category, made up of individuals who are aware of GINA after the average NP in the sample (Rogers, 2003, p.22). Although time has historically been used an independent variable in the DOI theory, the measurement of this dimension has been under scrutiny in dissertation research, since adopter category is scored, based self-report by the participant. However, this construct would be important to be included in subsequent studies concerning the innovation-decision process where a NP passes from awareness of GINA to the adoption or rejection of usage in clinical practice. In addition, the inclusion of time (adopter category) could assist in the determination of GINA’s rate of adoption among NPs and measured as the number of NPs who adopt GINA in a given time period (Rogers, 2003, p. 20).
The research question that explores if a relationship exists between an NP’s awareness of GINA and the communication channels (mass media and interpersonal) they use to search for information about clinical practice issues, though not yielding statistically significant analysis for such a relationship and not statistically significant for effect size, still provides valuable information to this researcher for future diffusion of GINA awareness in NPs. Rogers defines a communication channel as “the means by which messages get from one individual to another.” (Rogers, 2003, p. 18). In the beginning, communication channels for this study were operationalized to be ‘means by which awareness of GINA is shared from one individual to an NP’. This transfer of information occurs most frequently between two individuals who are homophilous in certain attributes such as education and a mutual language, like the NPs in this sample. Thus, the transfer of information about GINA’s existence potentially has a greater effect in attaining awareness, knowledge and adoption or rejection of GINA in clinical practice of a NP (Rogers, 2003, p.19).

The effect size and frequencies indicated that NP groups in the sample, those aware of or unaware of GINA, used the Internet, online website/search engines and peer-reviewed journals as the top three mass media communication channels and also used the same top two interpersonal channels, workshops, formal meetings and lectures to gain information used in their clinical practice. Before subsequent research is performed, using a different sample of NPs, this researcher plans to effectively diffuse information about GINA through these mass media and interpersonal communication channels as identified in the pilot study results.
In addition to the use of Rogers’ DOI theory to guide development of the questionnaire and to guide the research portion of this dissertation, these three manuscripts used the essential competencies as a guiding ethical framework to utilize evidence-based research to guide other research and clinical practice. The use of “The Essentials” demonstrate how the incorporation of the genetic and genomic competencies for nurses with graduate degrees can be accomplished in the education, clinical practice and research arenas (Consensus Panel on Genetic/Genomic Nursing Competencies, 2009).

The first manuscript describes a mechanism to address the important essential competency, “All nurses with graduate degrees in nursing inform health care and research policy related to ELSI issues in genetics/genomics” (Greco, Tinley, & Siebert, 2011). In the second manuscript, the author develops a concept analysis as a solid and meaningful foundation to explain “awareness of discrimination based on genetic information” as it related to GINA, meeting the competency that nurses with graduate degrees need to develop a solid foundation in genetic/genomics in order to provide quality care to their clients (Greco, Tinley, & Siebert, 2011). Using information derived from the first two manuscripts as a foundation, the third manuscript describes the development, implementation, and analysis of a questionnaire that collects data to determine if NPs are aware of GINA, an initial step in meeting the competency that nurses at the doctoral level are expected to provide leadership in the conduct of research and translate genetic findings into clinical practice (Greco, Tinley & Siebert, 2011). Adding to the rigor of this pilot study, the questionnaire developed for this study used
selected appropriate constructs from terms in the concept analysis that also served as main elements in the DOI theory, the same theory used to develop the essential competencies in genetics/genomics for nurse with graduate degrees (Greco, Tinley & Siebert, 2011).

As this research study was being developed, enforcement of GINA’s provisions and limitations was examined in the legal arena. Two recent cases of enforcement of GINA’s employment provisions have been brought to trial. One of the employers was found guilty and paid a $50,000 fine and agreed to provide anti-discrimination training to human resource employees. The employer in the other case was not found guilty of discrimination based on genetic information (Trottman, 2013). The Wall Street Journal also reported in July, 2013 that 170 GINA claims are currently being reviewed by EEOC regulators (Trottman, 2013). While the research data were being analyzed, an NP from the South Carolina Upstate area phoned the researcher to discuss a case where the insurance company was demanding genetic testing results from a young patient with no cancer diagnosis, but a positive BRCA mutation, placing the patient at highest risk for the development of breast cancer (J.A. Eggert, personal communication, December 11, 2013). As these cases concerning the enforcement of GINA’s provisions and limitations are publically reported, as well as presented in the local healthcare arena, the awareness and knowledge of GINA may be enhanced not only by all consumers, but also consumers of health care and their professionals. It also documents the researcher is viewed as an expert in awareness and knowledge about GINA when specific information is needed to enhance the long-term health and well-being of patients.
The overall outcome of this pilot study indicated that among NPs in the sample, the majority are not aware of GINA’s existence. Awareness of GINA among these NPs was not statistically correlated with NP’s terminal nursing degree, the NP’s years of clinical practice or the clinical specialty where they are practicing. Additionally, the awareness of GINA was not statistically correlated with the NP’s age and adopter category. The communication channels that NPs who were aware of GINA would use to find more information about GINA did not indicate a statistical relationship with the communication channels that NPs that are not aware of GINA would use. The top three mass media and top two interpersonal communication channels used by both the aware and not aware group were similar. Finally, these study results can guide diffusion of GINA’s provisions and limitations using targeted communication channels that NPs use to gain information relevant to their clinical practice.

This pilot study was not only designed to collect and analyze data about awareness of GINA among NPs in South Carolina, but it also tested the logistics of using a newly-created online questionnaire to assess awareness of GINA among NPs. The results of this pilot study should be interpreted cautiously as the sample may not be representative of the general population of NPs in clinical practice in South Carolina. However, this pilot study provides a foundation on which to build the next steps to further assess the pilot questionnaire. Results obtained from this study will also be used to refine and redesign the study method prior to conducting another research study, with a larger sample of different NPs first in other areas of South Carolina, then regionally,
moving towards, based on the results, the final goal of a national study assessing the awareness of GINA among NPs.

Future researchers could also utilize the work in this dissertation, to incorporate concurrent research to investigate if graduate nursing faculties have fully integrated genetics and genomics, including information about GINA, into NP curriculums nationwide. A recent article by Mardiegue, Edwards and Seibert (2013) revealed there are education gaps in genetic/genomic content taught to advance practice NP students; approximately 70% of faculty in 2010 felt comfortable teaching basic genetic/genomic concepts. Related to this dissertation topic, it is not known if information concerning GINA is included in graduate nursing curricula. Currently, the Genetics Literacy Assessment Instrument (GLIA) for undergraduate nursing students, does incorporate one GINA-related question, “Which of the following is a consequence of federal legislation enacted in 2008 entitled “Genetic Information Nondiscrimination Act (GINA)?” This inclusion can increase awareness of GINA among undergraduate nursing students, however, there is not a comparable instrument to measure genetics literacy in graduate nursing students (Bowling, Acra, Wan, Myers, Dean …Huether, 2008).

The body of work in this dissertation represents not only the intellectual, physical and mental work of the researcher but also epistemological work, regarding how to conduct a concept analysis of a timely concept in healthcare, as well as the derivation of a questionnaire and subsequent pilot study using that questionnaire, based on selective parts of a well-known diffusion theory. However, this researcher has only begun to examine the diffusion of GINA in the nursing discipline. Ideas to add to this knowledge
base include conducting another concept analysis, for the awareness of discrimination based on genetic information, using either the Walker or Avant concept analysis methods. These other concept analysis methods identify antecedents related to the concept, some the same antecedents used in the DOI theory (Walker & Avant, p. 144). These antecedents could be incorporated in additional, more rigorous research study, utilizing a different, larger sample of NPs, with a reliable and valid questionnaire, assessing awareness of other innovations among nurses.

Figure 5.1 reflects this researcher’s perspective of how programs of study on this topic evolve; as the personal awareness of GINA and personal genetic medicine evolves, the collecting and management of a patient’s genetic information has increased in importance. Being able to predict what disease will most likely affect a patient, anticipate the monitoring of either the non-progression or progression of a patient’s genetically-derived disease, and being able to determine the most appropriate treatment for that patient based on their genetic make-up contribute to the advent of personalized genetic/genomic medicine (Feldman, 2012). By incorporating information about GINA in graduate nursing programs and NPs’ clinical practices, using the ethical framework provided by the essential competencies for genetics and genomics for nurses with graduate degrees, and by using the domains from Rogers’ DOI theory to evaluate those competencies, it is anticipated that awareness of GINA will continually evolve (Jenkins & Calzone, 2007) (see Figure 5.1).
Figure 5.1

Evolving Awareness of GINA
Summary

No human possesses a perfect set of genes. Every human may develop between 5 to 50 health disorders due to their genetic make-up and these may also be potentially lethal (Slaughter, 2008). Though lethal germline mutations may never be expressed in an individual, they may be passed onto the individual’s children (Slaughter, 2008). Approximately 13 million Americans are affected by at least 16,000 recognized genetic disorders (Slaughter, 2008; Tan, 2009). Consequently, every American possesses various degrees of risk to develop genetically linked disorders in their lifetime and is at risk to experience discrimination based on their inherited genetic information (Slaughter, 2008).

The Genetic Information Nondiscrimination Act of 2008 (GINA) required 13 years to pass both houses of Congress before it was signed into law, the same time span that was used to sequence the entire human genome (Tan, 2009). GINA is considered preemptive legislation; it anticipated that problems would arise as new discoveries were made in genetic science. Additionally, GINA’s provisions may have helped accelerate the rate of genetic science discoveries by addressing individuals’ fears of discrimination based on their genetic information when they enroll in clinical research trials (Tan, 2009).

Even though the recently implemented Affordable Care Act of 2010 prohibits denial of health insurance coverage based on an individual’s genetic information, it only acts as a complement to GINA’s provisions. GINA as a law is more stringent, since it prohibits health insurers from collecting genetic information and/or using it to establish individuals’ premiums (Feldman, 2012; National Human Genome Research Institute, 2014).
However, healthcare providers should continue to collect genetic information as it can lead to a higher quality of patient care. NPs, as healthcare providers in particular, need to be aware and knowledgeable about GINA as they translate genomics into clinical practice. By understanding GINA’s provisions and limitations the NPs can better assist patients and their families to understand their personalized genomic-based health care. Awareness and knowledge of and about GINA will help NPs provide the complex, appropriate and equitable genetic health care that patients and their families deserve (Badzek, Henaghan, Turner, & Monsen, 2013)


Appendix A

Copyright Letters for Manuscripts I and II

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Appendix B

Final Questionnaire for Pilot Study

Awareness of the Genetic Information Nondiscrimination Act of 2008 (GINA) in South Carolina Nurse Practitioners.

1. I am aware that The Genetic Information Nondiscrimination Act of 2008 (GINA) is current law.
   ○ Yes
   ○ No

2. I know how to use the definitions of genetic information found in GINA.
   ○ Strongly Disagree
   ○ Disagree
   ○ Neither Agree nor Disagree
   ○ Agree
   ○ Strongly Agree

3. I know how to use the provisions included in GINA.
   ○ Strongly Disagree
   ○ Disagree
   ○ Neither Agree nor Disagree
   ○ Agree
   ○ Strongly Agree

4. I know how to use the limitations included in GINA.
   ○ Strongly Disagree
   ○ Disagree
   ○ Neither Agree nor Disagree
   ○ Agree
   ○ Strongly Agree
5. Protected genetic tests in GINA include: (choose any that apply)
- mutations associated with hereditary cancers.
- properties of an existing tumor that could help determine therapy for the tumor.
- the Huntington disease mutation.
- carrier screening for cystic fibrosis, sickle cell anemia, spinal muscular atrophy and Fragile X Syndrome.
- all of the above.
- none of the above.
- I do not know

6. GINA prohibits: (choose any that apply)
- health insurers and employers from requesting that an individual take a genetic test.
- employers from using genetic information in employment decisions.
- employers from obtaining genetic information about an individual's family members.
- health insurers and employers from using fetal genetic tests of a pregnant family member to make health insurance and employment decisions.
- employers from acquiring genetic information inadvertently through conversations or electronic health records.
- all of the above.
- none of the above.
- I do not know

7. GINA does not apply to: (choose any that apply)
- employers with less than 15 employees.
- members of the United States (U.S.) military.
- veterans of the U.S. military, obtaining service through the Veterans' Administration.
- healthcare services through the U.S. Indian Health Service.
- all of the above.
- none of the above.
- I do not know

8. GINA provides protection when qualifying for life insurance coverage, disability and long-term care insurance.
- Yes
- No
- I do not know
9. GINA’s definitions of genetic information includes: (choose any that apply)
- an individual's of family member's genetic test results
- occurrence of genetic disease in an individual's family members.
- an individual or family member's genetic tests results, while participating in a research study.
- genetic counseling an individual or family member receives while participating in a clinical research study.
- genetic education an individual or family member receives while participating in a research study.
- all of the above.
- none of the above.
- I do not know

10. The addition of GINA prohibits all health insurance issuers from denying coverage to an individual based on their genetic information.
- Yes
- No
- I do not know

11. GINA states that genetic information be treated the same as other private health information under Health Insurance Portability and Accountability Act of 1996 (HIPPA).
- Yes
- No
- I do not know

12. Violation of GINA's provisions is considered a federal offense.
- Yes
- No
- I do not know

13. The advantages of GINA far outweigh the disadvantages.
- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree
14. GINA is an easy law to understand.
- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

15. GINA can be difficult to use in my practice.
- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

16. GINA requires little genetic background knowledge to understand its provisions.
- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

17. GINA requires little legal and/or regulatory knowledge to understand its provisions.
- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

18. GINA is applicable to patients in general clinical settings.
- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree
19. GINA is applicable to patients in specialized clinical settings.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

20. GINA is compatible with all aspects of my work as a nurse practitioner.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

21. GINA is compatible with only a few aspects of my work as a nurse practitioner.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

22. I have had a great deal of opportunity to apply GINA's provisions in my clinical practice.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

23. I have not used GINA in my clinical practice.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

24.
   - Yes
   - No
25. Employment protections of GINA are applied in my workplace.
   ☐ Yes
   ☐ No

26. GINA's health insurance protections are applied to my personal healthcare.
   ☐ Yes
   ☐ No

27. Information about GINA is displayed in my practice setting.
   ☐ Yes
   ☐ No

28. I have observed other healthcare professionals in my clinical practice using GINA.
   ☐ Yes
   ☐ No

29. Which of the following mass-media channel(s) did you use to gain information about GINA? (Check all that apply)
   ☐ Internet
   ☐ radio/television
   ☐ newspaper/magazine
   ☐ peer-reviewed journal
   ☐ on-line website/search engine (e.g. WebMD, Medscape, MayoClinic)
   ☐ genetic websites (e.g Genetic Alliance)
   ☐ association website/newsletter (e.g. NpAlert, AANP)
   ☐ social networks (e.g. Twitter, Facebook, blogs, Wikis, discussion boards)
   ☐ on-line continuing education courses/webinars
   ☐ electronic health records (EHRs)
   ☐ apps (e.g. Gene Screen, Gene Wall, Genetics4M)
   ☐ other ____________________
   ☐ I have never looked for information about GINA
30. Which of the following mass media channel(s) do you use the most to gain information useful to your current clinical setting? (Check all that apply)
- Internet
- radio/television
- newspaper/magazine
- peer-reviewed journal
- on-line website/search engine (e.g. WebMD, Medscape, MayoClinic)
- genetic websites (e.g. Genetic Alliance)
- association website/newsletter (e.g. NPAlert, AANP)
- social networks (e.g. Twitter, Facebook, blogs, Wikis, discussion boards)
- on-line continuing education courses/webinars
- electronic health records (EHRs)
- apps
- other ____________________

31. Which of the following interpersonal channel(s) did you use to gain information about GINA? (Check all that apply)
- face-to-face workshops/lectures
- professional meetings
- face-to-face communication (chats, consultations, reading notes in EHRs)
- formal education classes
- pharmaceutical/medical sales representatives
- texts from peers
- e-mail from peers
- other ____________________
- I have never looked for information about GINA

32. Which of the following interpersonal channel(s) do you use the most to gain information useful to your current clinical setting? (check all that apply)
- face-to-face workshops/lectures
- professional meetings
- face-to-face communication (chats, consultations, reading notes in EHRs)
- formal education classes
- pharmaceutical /medical sales representatives
- texts from peers
- email from peers
- other ____________________
33. If I wanted to learn more about GINA I would use the following mass media channel(s). (check all that apply)
- Internet
- radio/television
- newspaper/magazine
- peer-reviewed journal
- on-line website/search engine
- genetic association website
- association website/newsletter
- social networks
- EHRs
- apps
- other ____________________

34. If I wanted to learn more about GINA I would use the following interpersonal channel(s) (check all that apply)
- face-to-face workshop/lecture
- professional meeting
- face-to-face communication
- formal education class
- pharmaceutical/medical sales representative
- texts from peers
- e-mail from peers
- other ____________________

35. My peers often ask me for advice or information
- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree

36. I enjoy trying new ideas.
- Strongly Disagree
- Disagree
- Neither Agree nor Disagree
- Agree
- Strongly Agree
37. I seek out new ways to do things.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

38. I am generally cautious about accepting new ideas.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

39. I frequently improvise methods for solving a problem when an answer is not apparent.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

40. I am suspicious of new inventions and new ways of thinking.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

41. I rarely trust new ideas until I can see whether the vast majority of people around me accept them.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree
42. I feel that I am an influential member of my peer group.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

43. I consider myself to be creative and original in my thinking and behavior.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

44. I am aware that I am usually one of the last people in my group to accept something new.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

45. I am an inventive kind of person.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

46. I enjoy taking part in the leadership responsibilities of the group I belong to.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree
47. I am reluctant about adopting new ways of doing things until I see them working for people around me.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

48. I find it stimulating to be original in my thinking and behavior.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

49. I tend to feel that the old way of living and doing things is the best way.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

50. I am challenged by ambiguities and unsolved problems.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree

51. I must see other people using new innovations before I will consider them.
   - Strongly Disagree
   - Disagree
   - Neither Agree nor Disagree
   - Agree
   - Strongly Agree
52. I am receptive to new ideas.
   ☐ Strongly Disagree
   ☐ Disagree
   ☐ Neither Agree nor Disagree
   ☐ Agree
   ☐ Strongly Agree

53. I am challenged by unanswered questions.
   ☐ Strongly Disagree
   ☐ Disagree
   ☐ Neither Agree nor Disagree
   ☐ Agree
   ☐ Strongly Agree

54. I often find myself skeptical of new ideas.
   ☐ Strongly Disagree
   ☐ Disagree
   ☐ Neither Agree nor Disagree
   ☐ Agree
   ☐ Strongly Agree

55. What NP certification(s) (recognized in South Carolina) do you currently hold? (check all that apply)
   ☐ Adult
   ☐ Family
   ☐ Pediatric
   ☐ Acute care
   ☐ Gerontology
   ☐ Adult psychiatric and mental health
   ☐ Family psychiatric and mental health
   ☐ Women's health
   ☐ Neonatal
   ☐ Adult acute care
   ☐ Advanced oncology
56. Nurse practitioner education preparation (highest level achieved)
- Certificate
- Bachelors
- Masters
- Doctor of Nursing Practice (DNP)
- Doctor of Philosophy (PhD)
- Doctor of Education (EdD)

57. Highest degree, other than in nursing, achieved
- PhD
- EdD
- Masters
- Bachelors
- None

58. Years as a nurse practitioners
- 0-5 years
- 6-10 years
- 11-15 years
- 16-20 years
- 21-25 years
- 26-30 years
- 31-35 years
- 36-40 years
- > 40 years

59. Years since highest non-nursing degree awarded
- 0-5 years
- 6-10 years
- 11-15 years
- 16-20 years
- 21-25 years
- 26-30 years
- 31-35 years
- 36-40 years
- > 40 years
60. Current age
- 20-25 years
- 26-35 years
- 36-45 years
- 46-55 years
- 56-65 years
- > 66 years

61. Gender
- Male
- Female

62. Race/Ethnicity
- American Indian or Alaskan Native
- Asian American
- Black, not of Hispanic Origin
- Hispanic
- Native Hawaiian or Pacific Islander
- White, not of Hispanic Origin
- Other ____________________
63. Nurse Practitioner Employment Setting
- Ambulatory/outpatient/primary care office
- Public health
- Obstetric clinic
- Retail clinic (e.g., Walgreen's', CVS)
- Emergency department
- Employee health clinic
- Extended/long-term care facility
- Skilled nursing facility
- Home care, hospice, palliative care
- Intensive care unit
- In-patient hospital unit/hospitalist
- Occupational health
- Wellness center
- Educational (please specify if it is an associate, diploma, bachelor or higher degree program) ____________________
- Non-tradition setting (specify) ____________________
- Other setting (specify) ____________________

64. Specialized practice setting
- Vascular/cardiology
- Pulmonary
- Oncology
- Pediatric
- Family Practice
- Women Health/ OB/GYN
- Genetic/Genomic
- Dermatology
- Gastroenterology
- Renal
- Neonatal
- Psychiatry
- Adult/Gerontology
- other (specify) ____________________
65. Site
- Urban area (50,000 or more population)
- Urban cluster (suburban, 2,500 to less than 50,000 population)
- Rural (less than 2,500 population)
- Other (specify) ____________________

66. Employment status
- Full-time (40 or more hours/week)
- Part-time (less than 40 hours/week)
- Per diem
- Retired
- Disabled
- Seeking employment
- Not seeking employment

67. How many courses in your formal NP education integrated genetics/genomics in the course content?
- 0
- 1
- 2
- 3
- >3

68. How many courses in your non-nursing education integrated genetics/genomics in the course content?
- 0
- 1
- 2
- 3
- >3

69. Local South Carolina professional nurse practitioner association membership (check all that apply)
- Low Country Nurse Practitioner Association
- Upstate Nurse Practitioner Association
- None
- Other (specify)
70. South Carolina state nurse practitioner association membership (check all that apply)
- American Nursing Association chapter (SCANA)
- Other (specify) ____________________
- None

71. National nurse practitioner association membership (check all that apply)
- American Association of Nurse Practitioners (AANP)
- National Organization of Nurse Practitioner Faculties (NONPF)
- National Association of Nurse Practitioners in Women's Health (NPWH)
- National Association of Pediatric Nurse Practitioners (NAPNAP)
- National Conference of Gerontological Nurse Practitioners (NCGNP)
- Nurse Practitioner Associates of Continuing Education (NPACE)
- Uniformed Nurse Practitioner Association (UNPA)
- Other (specify) ____________________

72. Membership in a professional organization that has a special interest in genetics/genomics (check all that apply)
- International Society of Nurses in Genetics (ISONG)
- Oncology Nursing Society - Special Interest Group (ONS SIG)
- Other (specify) ____________________
Appendix C

Invitation to Take Questionnaire

Dear South Carolina Nurse Practitioner,

As a member of one of the South Carolina nurse practitioner associations, I am inviting nurse practitioners, who are members in a South Carolina nurse practitioner association, to pilot test my dissertation research online questionnaire, “Development of an Online Questionnaire to Assess Awareness of the Genetic Information Nondiscrimination Act of 2008 (GINA) in Nurse Practitioners”. E-mail addresses were received from the various nurse practitioner associations in South Carolina. Once the survey has been distributed, all e-mail addresses will be destroyed.

As compensation for your time to complete this questionnaire, your e-mail address will be entered for a chance to have your 2014 membership dues paid. Four members from each nurse practitioner association in South Carolina will be randomly chosen from questionnaire respondents to have their dues paid. Once the nurse practitioners who will receive the membership dues have been randomly chosen, the questionnaires will be de-identified so that all responses will be anonymous during review and data analyses.

Please read the attached informed consent. After reading the informed consent, please go to the link provided to complete the questionnaire. It is anticipated that questionnaire completion will take about 20 minutes of your time.

Thank you very much for your participation in this study.

Sincerely,
Mary Beth Steck, PhD (c), APRN, BC
Interdisciplinary PhD in Healthcare Genetics
Clemson University
Appendix D

IRB Approval Letter for Focus Group

Mary Beth Steck

From: "JULIA A EGGERT" <JAEGGER@clemson.edu>
To: "Laura Moll" <LMOLL@clemson.edu>
Cc: <MBSTEOCK@charter.net>
Sent: Tuesday, December 04, 2012 5:13 PM
Subject: Re: Approval of IRB2012-369: Development of an Online Questionnaire to Evaluate Awareness of Genetic Information Nondiscrimination Act of 2008 (GINA) Among Nurse Practitioners

On Dec 4, 2012, at 3:48 PM, "Laura Moll" <LMOLL@clemson.edu> wrote:

Dear Julie and Mary Beth,

The Clemson University IRB (Institutional Review Board) / ORC (Office of Research Compliance) reviewed the protocol identified above using Exempt review procedures and a determination was made on December 4, 2012 that the proposed activities involving human participants qualify as Exempt from continuing review under Category B2, based on the Federal Regulations (45 CFR 46). You may begin this study.

I made a few revisions to the Informed Consent Form because of the change from expedited to exempt review. These are:

- Protection of Privacy and Confidentiality: deletion of language from, "The researchers may be required..." to "...and your rights were protected during the study.
- Footer: deletion of "IRB stamp-of-approval" paragraph.
- Choosing to Be in the Study: deletion of second paragraph, about disposition of data upon withdrawal.
- Deletion of signature lines and initialing lines.

Additionally, I added the following language into the Choosing to Be in the Study section: "If you choose not to take part or to stop taking part in this study, it will not affect your grades or your relationship with the Clemson University Healthcare Genetics Interdisciplinary PhD Program in any way."

I've attached this revised informed consent form. Please use this form for your study since it is the approved informed consent form for this protocol. If you have any questions or concerns about the revisions I made, please feel free to contact me.

Please remember that no change in this research protocol can be initiated without prior review by the IRB / ORC. Any unanticipated problems involving risks to subjects, complications, and/or any adverse events must be reported to the IRB / ORC immediately. You are requested to notify the ORC when your study is completed or terminated.

Please review the Responsibilities of Principal Investigators (available at http://media.clemson.edu/research/compliance/irb/pl-responsibilities.doc) and the Responsibilities of Research Team Members (available at http://media.clemson.edu/research/compliance/irb/research-team-responsibilities.doc) and be sure these documents are distributed to all appropriate parties.

Good luck with your study and please feel free to contact us if you have any questions. Please use
the IRB number and title in all communications regarding this study.

Best,

Laura :-)

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Laura A. Moll, M.A., CIP
IRB Administrator
Office of Research Compliance
223 Brackett Hall
Clemson University
Clemson, SC 29634-5704
lmoll@clemson.edu
Phone: 864-656-6460
Fax: 864-656-4475
www.clemson.edu/research/compliance/irb/

<Image001.png> SafeZone
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

<IRB2012_369_Eggert_informed_consent1.doc>

12/4/2012
Appendix E

IRB Approval Letter for Content Expert Group

Mary Beth Steck

From: "Mary Steck" <mbsleck@charter.net>
To: <mbsleck@charter.net>
Sent: Thursday, August 15, 2013 10:36 AM
Subject: FW: IRB2012-369 Amendment #1 Approval: Development of an Online Questionnaire to Evaluate Awareness of the GINA...

From: Nalinee Pattni
Sent: Thursday, August 15, 2013 9:00 AM
To: JULIA A EGGERT
Cc: Mary Steck
Subject: IRB2012-369 Amendment #1 Approval: Development of an Online Questionnaire to Evaluate Awareness of the GINA...

Dear Dr. Eggert,

Your amendment to conduct an online survey with content experts has been approved. You may begin to implement this amendment.

As of June 1, 2013, the Office of Research Compliance (ORC) started assign expiration dates to all IRB exempt protocols. Your protocol will expire on February 28, 2014. If an extension is necessary, the PI should submit an Exempt Protocol Extension Request at least three weeks before the expiration date. Please refer to our website for more information on the new procedures, http://www.clemson.edu/research/compliance/IRB/guidance/reviewprocess.html.

No change in this approved research protocol can be initiated without the IRB’s approval. This includes any proposed revisions or amendments to the protocol or consent form. Any unanticipated problems involving risk to subjects, any complications, and/or any adverse events must be reported to the Office of Research Compliance (ORC) immediately.

We also ask that you notify the ORC when your study is completed or terminated. Please let us know if you have any questions and use the IRB number and title in all communications regarding this study.

All the best,
Nalinee

Nalinee D. Pattni
IRB Coordinator
Clemson University
Office of Research Compliance
Institutional Review Board (IRB)
Voice: (864) 656-0636
Fax: (864) 656-4425
E-mail: research@clemson.edu
Web site: http://www.clemson.edu/research/compliance/irb/
IRB E-mail: irb@clemson.edu

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8/15/2013
Appendix F

IRB Approval Letter for Field Testing Questionnaire

Mary Steck

From: Nalinee Patin
Date: Monday, October 07, 2013 9:50 AM
To: JULIA A EGGERT
Cc: Mary Steck
Subject: IRB2012-369 Amendment #2 Approval: Development of an Online Questionnaire to Evaluate Awareness of the GINA...

Dear Dr. Eggert,

Your amendment to pilot the Qualtrics questionnaire to a subsample of ten nurse practitioner has been approved. You may begin to implement this amendment.

No change in this approved research protocol can be initiated without the IRB’s approval. This includes any proposed revisions or amendments to the protocol or consent form. Any unanticipated problems involving risk to subjects, any complications, and/or any adverse events must be reported to the Office of Research Compliance (ORC) immediately.

The Clemson University IRB is committed to facilitating ethical research and protecting the rights of human subjects. Please contact us if you have any questions and use the IRB number and title in all communications regarding this study.

All the best,
Nalinee

Nalinee D. Patin
IRB Coordinator
Clemson University
Office of Research Compliance
Institutional Review Board (IRB)
Voice: (864) 656-0636
Fax: (864) 656-4475
E-mail: readir@clemson.edu
Web site: http://www.clemson.edu/research/compliance/irb/
IRB E-mail: irb@clemson.edu

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Appendix G

IRB Approval Letter for Pilot Study

Mary Beth Steck

From: "Mary Beth Steck" <mbsteck@charter.net>
To: "Mary Beth Steck" <mbsteck@charter.net>
Sent: Friday, October 25, 2013 12:58 PM
Subject: Fw: IRB2012-369 Amendment #3 Approval: Development of an Online Questionnaire to Evaluate Awareness of the GINA...

----- Original Message -----  
From: Nalinee Patna
Cc: Mary Beth Steck (mbsteck@charter.net) ; Mary Steck
Sent: Friday, October 25, 2013 11:53 AM
Subject: IRB2012-369 Amendment #3 Approval: Development of an Online Questionnaire to Evaluate Awareness of the GINA...

Dear Dr. Eggert,

Your amendment to pilot the revised questionnaire to nurse practitioners in SC has been approved. You may begin to implement this amendment.

No change in this approved research protocol can be initiated without the IRB’s approval. This includes any proposed revisions or amendments to the protocol or consent form. Any unanticipated problems involving risk to subjects, any complications, and/or any adverse events must be reported to the Office of Research Compliance (ORC) immediately.

The Clemson University IRB is committed to facilitating ethical research and protecting the rights of human subjects. Please contact us if you have any questions and use the IRB number and title in all communications regarding this study.

All the best,

Nalinee

---Nalinee Patna
IRB Coordinator
Clemson University
Office of Research Compliance
Institutional Review Board (IRB)
Voice: (864) 656-5638
Fax: (864) 656-4475
E-mail: irb@clemson.edu
Web site: http://www.clemson.edu/research/compliance/IRB
E-mail: irb@clemson.edu

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10/23/2013
Appendix H

IRB Approval Letter for Extension

Exempt Protocol Extension Request
*Clemson University IRB Website*

<table>
<thead>
<tr>
<th>Office use only:</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Validated as continuing to meet the criteria for Exempt status</td>
</tr>
<tr>
<td>Exemption Category: ____________________________</td>
</tr>
<tr>
<td>□ Not validated as continuing to meet the criteria for Exempt status</td>
</tr>
<tr>
<td>Signature of IRB Chair/Designee: ____________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Protocol Number:</th>
<th>IRB2012-369</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Title:</td>
<td>Development of an Online Questionnaire to Evaluate Awareness of the Genetic Information Non-Discrimination Act of 2008 (GINA) Among Nurse Practitioners</td>
</tr>
<tr>
<td>Principal Investigator:</td>
<td>Julia A. Eggert, PhD</td>
</tr>
</tbody>
</table>

1. Type of Request:
   - [x] Extend protocol
     - 6 months: [ ] One year [ ] Two years [ ] Three years
     - Describe the reason for an extension: ______
   - [ ] Close protocol (Ship to question 3 if closing protocol)
     - Project completed
     - Data analysis continues - data include no identifiers and no master list exists to link data to participant identities

2. Status of the project:
   - [x] Protocol unchanged
     - Requesting changes (check all that apply):
       - [ ] Changes in personnel
       - [ ] Consent process/forms
       - [ ] Data collection tools/procedures
       - [ ] Funding source (include a copy of the proposal)
       - [ ] Project goals
       - [ ] Subject recruitment methods/selection criteria
       - [ ] Other (please specify): ______

   - Summary: Provide a brief description and rationale for each change. Indicate if any of these changes increase the risk to subjects (attach new or revised documents).
     - Description: ______

3. Have you received any complaints or experienced unanticipated problems with this project? [ ] yes [ ] no
   - Description: ______

- [ ] I am the principal investigator. I am submitting this form electronically and this submission constitutes my signature.

Principal investigator signature: J. Eggert, PhD Date: 2/7/2014
Appendix I

Innovativeness Scale Guidelines

An innovation is an idea, practice, or object that is perceived as new by an individual or other unit of adoption (like an organization). People and organizations vary a great deal in their "innovativeness." Innovativeness has to do with how early in the process of adoption of new ideas, practices, etc. that the individual or organization is likely to accept a change.

The individual innovativeness scale was designed to measure individuals' orientations toward change. Research has indicated that this orientation is associated with several communication variables. The II instrument has been found to be highly reliable and the predictive validity is good.

Directions: People respond to their environment in different ways. The statements below refer to some of the ways people can respond. Please indicate the degree to which each statement applies to you by marking whether you: Strongly Disagree = 1; Disagree = 2; are Neutral = 3; Agree= 4; Strongly Agree = 5 Please work quickly, there are no right or wrong answers, just record your first impression.

1. My peers often ask me for advice or information.
2. I enjoy trying new ideas.
3. I seek out new ways to do things.
4. I am generally cautious about accepting new ideas.
5. I frequently improvise methods for solving a problem when an answer is not apparent.
6. I am suspicious of new inventions and new ways of thinking.
7. I rarely trust new ideas until I can see whether the vast majority of people around me accept them.
8. I feel that I am an influential member of my peer group.
9. I consider myself to be creative and original in my thinking and behavior.
10. I am aware that I am usually one of the last people in my group to accept something new.

11. I am an inventive kind of person.

12. I enjoy taking part in the leadership responsibilities of the group I belong to.

13. I am reluctant about adopting new ways of doing things until I see them working for people around me.

14. I find it stimulating to be original in my thinking and behavior.

15. I tend to feel that the old way of living and doing things is the best way.

16. I am challenged by ambiguities and unsolved problems.

17. I must see other people using new innovations before I will consider them.

18. I am receptive to new ideas.

19. I am challenged by unanswered questions.

20. I often find myself skeptical of new ideas.

**Scoring:**

Step 1: Add the scores for items 4, 6, 7, 10, 13, 15, 17, and 20.
Step 2: Add the scores for items 1, 2, 3, 5, 8, 9, 11, 12, 14, 16, 18, and 19.
Step 3: Complete the following formula: II = 42 + total score for Step 2 - total score for Step 4.
Step 4: Scores above 80 are classified as Innovators. Scores between 69 and 80 are classified as Early Adopters. Scores between 57 and 68 are classified as Early Majority. Scores between 46 and 56 are classified as Late Majority. Scores below 46 are classified as Laggards/Traditionalists.

In general people who score above 68 and considered highly innovative, and people who score below 64 are considered low in innovativeness.

**Source:**