# Primary Care Physicians' Awareness, Experience and Opinions of Direct-to-Consumer Genetic Testing

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## Abstract:

The purpose of this study was to assess primary care physicians' awareness, experience, opinions and preparedness to answer patients' questions regarding direct-to-consumer (DTC) genetic testing. An anonymous survey was mailed to 2,402 family and internal medicine providers in North Carolina. Of the 382 respondents, 38.7% ($n = 148$) were aware of and 15% ($n = 59$) felt prepared to answer questions about DTC genetic tests. Respondents aged 50 or older were more likely to be aware of DTC genetic testing than those less than 40 years old ($OR = 2.42$). Male providers were more likely to feel prepared to answer questions than female providers ($OR = 2.65$). Among respondents who reportedly were aware, family practitioners were more likely than internists ($OR = 3.30$) to think DTC testing was clinically useful, and 18.9% had patients ask questions or bring in test results. The small percent of physicians who were aware of DTC genetic testing or felt prepared to answer questions about it suggests that education of providers will be necessary if testing becomes more widespread.

**Keywords:** Direct-to-consumer | Genetic testing | Primary care providers | Genetic susceptibility Personalized medicine | Genetics in primary care

## Article:

### Introduction

Personal genome tests that use variants identified by genome wide association studies (GWAS) to assess risk for disease have been offered directly to the consumer over the internet since 2007 (Offit *2008*). There have been discussions within the medical community concerning personal genome testing including: 1) the questionable clinical utility of GWAS tests, 2) the inability to

determine absolute disease risk from GWAS data, 3) the absence of specific health recommendations based on the genotypic results of these tests, 4) inadequate informed consent prior to testing, 5) limited explanation of test results, and 6) whether personal genome tests are valid and reliable in comparison to genetic tests that are administered and regulated under the supervision of healthcare providers (Evans and Green *2009*; Gross et al. *2009*; Kutz *2010*; Swan *2010*).

Personal genome testing companies screen for risks of serious diseases such as heart disease, cancer and diabetes. By offering tests directly to the public, healthcare providers are bypassed by people who are ordering and receiving test results. Without proper explanation and informed consent, there is an increased chance that lay individuals will misunderstand their test results (Gollust et al. *2003*). The companies state that they do not provide medical advice based on their test results (23andMe *2011*; deCODEme *2011*; Pathway Genomics *2011*). One area where companies differ is the extent to which they offer genetic counseling and whether it is performed by a board certified/eligible genetic counselor. While companies with genetic counselors may provide genetic counseling to individuals purchasing tests, the companies without genetic counselors direct patients back to their personal physician, who may not have the knowledge or time to interpret the test results (Baars et al. *2005*; Caulfield *2001*; Evans et al. *2010*; Greendale and Pyeritz *2001*; Swan *2010*; Williams-Jones *2003*).

Currently, there is a dearth of information about healthcare providers' awareness, experience and perceptions of personal genome testing. Ohata and colleagues (*2009*) assessed general practitioners' awareness of, and opinions about direct-to-consumer (DTC) genetic tests that can predict an individual's susceptibility to certain adult onset diseases. These researchers found that 38% of general practitioners were aware of DTC genetic testing, primarily from the media, scientific meetings/journals, and the Internet. Less than 1% had ordered a DTC genetic test on a patient. Physicians listed several benefits and some concerns regarding the testing. Noted benefits included convenience, promotion of preventive medicine, providing personalized services, and confidentiality of information. Concerns regarding DTC genetic testing included the reliability of test results, provision of adequate information/counseling, potential misunderstanding of results, inappropriateness of advertising, discrimination in employment and insurance, the possible spread of beliefs such as genetic determinism, and the inappropriate disclosure of patients' genetic information.

Kolor and colleagues (*2009*) reported results from the 2008 DocStyles survey which was sent to internists, family physicians, pediatricians, obstetricians/gynecologists, dermatologists and registered dieticians in the US. These researchers found that less than half (42%) of respondents were aware of personal genome tests offered directly to consumers. Practitioners most often cited the media and the Internet as their source of information about personal genome tests, with medical or scientific journals being a secondary source of information. Less than half of their healthcare provider respondents who were aware of personal genome testing had discussed test

results with their patients within the last year or interacted with a patient who had questions about personal genome tests.

Both of these studies surveyed a broad range of healthcare providers at the national level, which could obscure regional differences in attitudes, awareness, and the use of personal genome testing.

### Purpose of the Present Study

In this study, North Carolina primary care physicians (PCP) were surveyed to assess their awareness, experience and opinions regarding personal genome testing. Participating PCPs were limited to family physicians and internists because personal genome tests are marketed to healthy adults and generally screen for common diseases seen most frequently in these practice settings. The aims of this study were to assess North Carolina PCPs': 1) awareness, 2) experience, 3) preparedness to answer patient questions, and 4) opinions regarding the perceived clinical usefulness of personal genome testing.

## Methods

### Participants

A convenience sample of family physicians and internists who were members of the North Carolina Medical Society (NCMS) were recruited to participate. The NCMS is the state's largest physician organization with more than 12,000 members (North Carolina Medical Society *2011*). Members include medical students, residents, practicing physicians, retired physicians, and physician assistants. A publically available list containing physician names, medical practice and office addresses was obtained from the NCMS website. Of the 12,000 NCMS members, 1,349 are family medicine providers, and 1,301 are internal medicine providers. Addresses were confirmed and/or updated through a Google search using the physician's name, medical practice, and/or the city in which the practice was located. Of the 2,650 family and internal medicine providers mentioned above, 2,402 addresses were confirmed.

### Instrumentation

A novel survey consisting of 30 questions was created by the investigators to meet the goal of this project (Appendix A). Eighteen questions were multiple-choice, seven were dichotomous items (yes/no), three were fill-in-the-blank, and two were in the form of a Likert-type rating scale. Six questions were drawn, with permission, from the 2008 DocStyles survey developed by the Centers for Disease Control and Prevention (CDC). A description of personal genome testing was adapted from the DocStyles survey, and provided in the introduction. It read: "Genetic tests that scan a person's entire genetic makeup for potential health risks are currently being marketed directly to consumers by several different companies (e.g., 23andMe, deCODEme, Navigenics)."

Respondents were told that the term “DTC genetic test” would be used as a shorthand way to describe this service.

The survey was divided into six sections. Questions from the DocStyles survey were placed in four sections that assessed the PCP’s 1) awareness of DTC genetic testing, 2) experience with patients discussing/bringing in results from DTC genetic tests, 3) opinions about DTC genetic testing, including “perceived clinical usefulness,” and 4) medical management (follow-up) after DTC genetic testing. The remaining sections assessed the PCPs’ preparedness to answer questions about DTC genetic testing, and participant demographics. Each section consisted of 2–8 questions, and contained a skip pattern that would allow respondents to skip over questions that were not applicable. The survey was piloted with 10 family medicine and internal medicine physicians practicing in Greensboro, NC. No modifications were made.

This study was approved by The University of North Carolina at Greensboro’s Institutional Review Board.

## Procedures

The physicians and surveys were numbered and a unique ID was created. Cover letters, surveys, informed consent, and a self-addressed stamped envelope (SASE) were mailed to all family practitioners and internists with confirmed addresses. Several tactics were used in the cover letter, to help increase participation in the survey. They included: 1) provision of information about the survey, 2) a request for help or advice, 3) showing positive regard by personalizing the salutation (e.g., Dear Dr. Smith), and 4) saying thank you (Dillman et al. *2009*). While no compensation was provided to respondents, they were offered a copy of the results once the survey was completed (Dillman et al. *2009*; Lydeard *1996*). Other tactics used to maximize survey response included providing alternative ways to return the survey such as a fax number and a link to an online version of the survey housed on Zoomerang, an online survey tool. Physicians completing the survey online were asked to enter their survey number to avoid duplication. When a survey was returned, the physician’s name and address were deleted from the key.

Two reminders were sent to non-responders at three-week intervals. The first reminder was a postcard which referenced the online link. The second reminder contained a cover letter, survey and SASE. Data collection occurred between January and May, 2010.

## Data Analysis

Information from the returned surveys was entered into Zoomerang. Data analysis was conducted using PASW Statistics version 18.0 (Chicago, IL). The respondents’ personal characteristics and survey responses relating to self-reported awareness, self-reported experience with patients, physician opinion of DTC genetic testing, and preparedness to answer questions about DTC genetic testing were described with frequencies and percentages. The ages of

participants was collected within five categories: ≤30, 31–40, 41–50, 51–60, and >60. The age variable was collapsed into three categories. The variable ≤30 and 31–40 was collapsed to ≤40 (younger and less experienced PCPs), the variable 41–50 (middle-aged and moderately experienced PCPs) and 51–60 and >60 was collapsed to ≥51 (older and more experienced PCPs). Board specialty was dichotomized into "family medicine" and "internal medicine" and work setting was dichotomized into "private practice" and "other." Responses to all dependent variables (physician awareness, physician preparedness, and perceived usefulness of DTC genetic testing) were categorized yes and no.

Bivariate associations between each physician's personal characteristic variables and physician awareness, preparedness, and perceived usefulness of DTC genetic testing were calculated using cross-tabulations. Odds ratios were calculated along with a 95% confidence interval in order to explore the strength of the association between the individual predictors and the three outcome variables.

The dichotomous outcome variables of physician awareness, physician preparedness, and clinical usefulness were modeled as a function of independent variables for specific respondent personal characteristics. For all outcome variables, the initial model was formulated by including all of the covariates provided in Table 1. In order to reduce the initial model to the final reduced model, odds ratio (OR) estimates were used for all personal characteristics that were shown to be predictors of awareness, preparedness, and clinical usefulness. Covariates that were not statistically significant predictors of awareness, preparedness, and clinical usefulness were eliminated from the full model using a step-wise forward regression procedure in a manner that subtraction of the covariates from the model did not alter the odds ratio between any of the predictors and the outcome variable by more than 20%. Based on analysis, age and years in practice were found to be significantly correlated (Pearson $r = 0.487$, $p = 0.00$). Age has a stronger correlation to years in practice, therefore years in practice was eliminated from the model. The aim of this methodology is to identify the strongest simplified model of respondents' personal characteristics associated with the three identified outcome variables. Multivariate adjusted ORs and their 95% confidence interval (CI) were determined by exploring log ORs from the multivariate logistic regression using a forward stepwise likelihood ratio model.

**Table 1** Personal characteristics of respondents ($N = 382$)

| **Personal characteristics** | **Total** | |
|---|---|---|
| | ***n*** | **%** |
| Gender | | |
| Male | 263 | 69.6 |
| Female | 115 | 30.4 |
| Age | | |
| ≤40 years old | 157 | 41.5 |
| 41–50 years old | 147 | 38.9 |

| | | |
|---|---|---|
| ≥51 years old | 74 | 19.6 |
| Board specialty[a] | | |
| Family medicine | 205 | 54.7 |
| Internal medicine | 123 | 32.8 |
| Other | 47 | 12.5 |
| Work setting | | |
| Private practice | 211 | 70.3 |
| Other | 34 | 11.3 |
| Academic medical center or medical school | 28 | 9.3 |
| Community hospital | 19 | 6.3 |
| Medical center not affiliated with university | 8 | 2.7 |
| Years in practice | | |
| ≤10 years | 62 | 20.7 |
| More than 10 years | 237 | 79.3 |

[a] *n*'s do not sum to the total sample size due to missing data

**Results**

Survey Characteristics

As per the eligibility criteria, surveys were sent to 2,402 PCPs in North Carolina. Fifty surveys were "returned to sender," resulting in 2,352 eligible respondents. In total, 397 surveys were returned to the researchers. Surveys were excluded from the final analysis if they were returned blank ($n = 10$) or the PCP was retired ($n = 5$), resulting in 382 completed surveys. The usable response rate for this study was 16.2% (382/2,352).

Respondents had the option of returning the survey by mail, fax, or completing it on-line. Of the surveys completed, 95.3% were returned by mail ($n = 364$) and 4.7% were completed on-line ($n = 18$). No respondents returned the survey by fax. Respondent demographics are summarized in Table 1. A total of 382 respondents who completed and returned the survey were included in the final analysis. A post-hoc analysis was conducted to determine statistical power given the sample size of 382 which was 0.80.

Sample Demographics

Approximately two-thirds of the respondents were males (69.6%, $n = 263$). More than half were 41 years of age or older (58.5%, $n = 221$). Similarly, 54.7% ($n = 205$) of the respondents were boarded in family medicine, 32.8% ($n = 123$) were boarded in internal medicine and 12.5% ($n = 47$) were boarded in other specialties such as pediatrics, geriatrics, etc. Most of the respondents (70.3%, $n = 211$) worked in a private practice setting, and the majority (79.3%, $n = 237$) had been in practice more than 10 years (Table 1). The average number of years in practice as a physician was 21.8 (SD = 11.7).

PCP Awareness of DTC Genetic Testing

Most of the respondents (61.3% $n = 234$) had never heard or read about DTC genetic testing (Table 2). Of those who had heard or read about DTC genetic testing ($n = 148$), the most common sources of information were medical or scientific journals (35.1%, $n = 52$), television (33.1%, $n = 49$), a newspaper article (28.4%, $n = 42$) and the Internet (27.0%, $n = 40$) (Table 2). Respondents could indicate more than one answer, and a majority (64.2%, $n = 95$) marked at least two sources of information. There was a strong positive association between respondent age and awareness of DTC genetic testing. Respondents 41–50 years old and 51 years of age and older were almost twice as likely to be aware of DTC genetic testing compared to those who were 40 years of age and younger (Table 3). Bivariate association was examined between work setting and awareness but no statistically significant associations were found. A multivariate logistic regression analysis using a forward stepwise likelihood ratio model indicates that only the PCPs' age was a significant predictor ($p = .01$) of respondent awareness of DTC genetic testing; this finding is similar to bivariate analysis results (Table 4).

**Table 2** Primary care providers' awareness, concerns and preparedness regarding DTC genetic testing ($N = 382$)

| | ***n*** | **%** |
|---|---|---|
| *Self-reported awareness of PCPs* | | |
| Heard or read about DTC genetic testing | | |
| Yes | 148 | 38.7 |
| No | 234 | 61.3 |
| Sources PCPs are exposed to for DTC genetic testing | | |
| Not exposed to any source | 235 | 61.5 |
| Exposed to one or more sources | 147 | 38.5 |
| Medical or scientific journal | 52 | 35.1 |
| Television | 49 | 33.1 |
| Newspaper article | 42 | 28.4 |
| Internet | 40 | 27.0 |
| Magazine article | 34 | 23.0 |
| Patients | 32 | 21.6 |
| Professional or scientific meeting | 26 | 17.6 |
| Professional organization | 25 | 16.9 |
| Directly from a company selling DTC genetic testing | 20 | 13.5 |
| Radio | 17 | 11.5 |
| Health professional | 12 | 8.1 |
| Other | 8 | 5.4 |
| *Concerns about DTC testing* | | |
| Patient anxiety | 129 | 87.1 |
| Patients incorrect interpretation of results | 126 | 85.1 |
| Misleading advertisements | 126 | 85.1 |
| Clinical utility questionable | 121 | 81.8 |
| Health insurance discrimination | 115 | 77.7 |
| Employment discrimination | 95 | 64.2 |

| | | |
|---|---|---|
| Obligation to refer to a specialist (unnecessarily) | 90 | 60.8 |
| Obligation to refer for follow-up procedures (unnecessarily) | 90 | 60.8 |
| Inadequate counseling | 75 | 50.7 |
| Analytical validity/accuracy questionable | 74 | 50.0 |
| Confidentiality of genetic information | 67 | 45.3 |
| Other | 8 | 5.4 |
| *Preparedness about DTC genetic testing* [a] | | |
| PCP preparedness about genetic testing | | |
| Yes | 57 | 15.0 |
| No | 323 | 85.0 |

[a] *n*'s do not sum to the total sample size due to missing data

**Table 3** Bivariate analysis (unadjusted odds ratios) of primary care providers' personal/professional characteristics with awareness, feeling of preparedness, and ratings of clinical usefulness of DTC genetic testing

| **Physician personal/professional characteristics** | **Awareness (*n* = 378)** | | **Preparedness (*n* = 376)** | | **Clinical usefulness (*n* = 148)** | |
|---|---|---|---|---|---|---|
| | **Odds ratio** | **95% CI** | **Odds ratio** | **95% CI** | **Odds ratio** | **95% CI** |
| Gender | | | | | | |
| Female (reference) | – | – | – | – | – | – |
| Male | 1.11 | 0.71, 1.75 | 2.65[a] | 1.26, 5.61 | 0.54 | 0.26, 1.10 |
| Age | | | | | | |
| ≤40 years old (reference) | – | – | – | – | – | – |
| 41–50 years old | 1.96[a] | 1.22, 3.14 | 1.29 | 0.66, 2.53 | 1.43 | 0.67, 3.04 |
| ≥51 years old | 1.99[a] | 1.12, 3.52 | 2.46[a] | 1.20, 5.08 | 0.71 | 0.28, 1.78 |
| Board specialty | | | | | | |
| Internal medicine (reference) | – | – | – | – | – | – |
| Family medicine | 0.81 | 0.51, 1.28 | 0.80 | 0.42, 1.52 | 3.30[a] | 1.52, 7.13 |
| Work setting | | | | | | |
| Other (reference) | – | – | – | – | – | – |
| Private practice | 1.01 | 0.61, 1.68 | 0.59 | 0.30, 1.13 | 1.76 | 0.76, 4.08 |

[a]Significant at $p < .05$

**Table 4** Logistic regression—predictors of awareness, clinical usefulness and preparedness of DTC genetic testing by participant characteristics

| **Participant characteristics** | ***β*** | **Odds ratio (95% CI)** | ***p*** |
|---|---|---|---|
| *Awareness* | | | |

| | | | |
|---|---|---|---|
| Age | | | |
| 40-years-old or less (reference) | – | – | |
| 41–50-years-old | 0.505 | 1.657 (0.922, 2.979) | 0.09 |
| 51 years-old and older | 0.852 | 2.344 (1.187, 4.630)[a] | 0.01 |
| *Clinical usefulness* | | | |
| Gender | | | |
| Female (reference) | – | | |
| Male | −1.016 | 0.362 (0.132, 0.993)[a] | 0.04 |
| Specialty | | | |
| Internal medicine (reference) | – | – | |
| Family Medicine | 0.963 | 2.618 (1.073, 6.389)[a] | 0.03 |
| *Preparedness* | | | |
| Age | | | |
| 40-years-old or less (reference) | – | – | |
| 41–50-years-old | −0.167 | 0.846 (0.344, 2.080) | 0.71 |
| 51 years-old and older | 1.032 | 2.806 (1.208, 6.515)[a] | 0.01 |

[a]Significant at $p < 0.05$

PCP Experience with Patients

A majority of the PCPs who were aware of DTC genetic testing (81.1%, $n = 120$) had never discussed DTC tests with a patient or had a patient bring in results of DTC genetic tests (Table 5). Only 18.9% ($n = 28$) of PCPs had at least one patient ask about DTC genetic testing (mean = 3 patients, SD = 2.4) and only five PCPs had at least one patient bring in test results (mean = 2 patients, SD = 0.713). Additionally, the number of patients asking questions or bringing in DTC genetic test results comprised significantly less than 10% of the PCPs' patient population. Respondents were given a list of types of patient questions and instructed to indicate which of these their patients have asked them. Frequencies of each category of questions that were asked of physicians are listed in Table 6.

**Table 5** Experience and perceived clinical utility of DTC genetic testing among those primary care providers who are aware of testing ($n = 148$)

| | ***n*** | **%** |
|---|---|---|
| *Self-reported experience with patients* | | |
| Had patients ask about and/or bring in results of DTC genetic testing | | |
| Yes | 28 | 18.9 |
| No | 120 | 81.1 |
| Number of patients who asked questions about or brought in results from DTC genetic testing in the past year[a] | | |
| ≤2 patients | 16 | 57.1 |
| More than 2 patients | 12 | 42.9 |
| *Clinical Utility DTC genetic testing* | | |
| Feel that DTC testing is clinically useful | | |
| Yes | 63 | 42.6 |

| | | |
|---|---|---|
| No | 85 | 57.4 |
| Rating of clinical usefulness of DTC Genetic Testing[b,c] | | |
| Very useful | 3 | 5.1 |
| Useful | 4 | 6.8 |
| Somewhat useful | 50 | 84.7 |
| Not useful | 2 | 3.4 |
| PCPs rating on likelihood that DTC test results would influence patient care[c] | | |
| Very likely | 7 | 4.8 |
| Likely | 50 | 34.0 |
| Unlikely | 70 | 47.6 |
| Very unlikely | 20 | 13.6 |

[a]Frequency is based on the number of patients who asked and/or brought results of DTC genetic testing [b]Frequency is based on the number of PCPs who feel that DTC testing is useful [c] *n*'s do not sum to the total sample size due to missing data

**Table 6** Categories of questions patients asked to respondents about DTC genetic testing

| **Question category** | ***n* (27)[a]** | **%** |
|---|---|---|
| What you know about the test(s) | 20 | 74.1 |
| Whether you think the patient is at risk for a particular disease | 14 | 51.8 |
| What you know about the benefits of testing | 14 | 51.8 |
| What you would do in their situation | 12 | 44.4 |
| How the test results may change your patient's care | 7 | 25.9 |
| What you know about the (company/companies) that are offering the test | 6 | 22.2 |
| Whether the cost is appropriate for the type of information they will obtain | 6 | 22.2 |
| Other | 1 | 3.7 |

[a]Number of respondents answering the question; total *n* >100 because respondents could endorse multiple questions

The most frequent conditions for which patients brought in DTC genetic test results to discuss with their physicians were cancer ($n = 4$), cardiac disease ($n = 3$), neurological diseases ($n = 3$), and single gene disorders ($n = 3$). No respondent remembered which DTC testing company the patients had used for testing.

Follow-up Activities by PCPs Who are Aware of DTC Testing

This section of the survey assessed PCPs follow-up medical management plans for patients who brought in DTC genetic test results. Four of the five PCPs who had patients bring in results reported they did not change their patient's medical management, while the remaining physician recommended lifestyle changes including changes in diet and supplements. Reasons given for choosing not to change patient care were that the test did not indicate the patient was at increased risk for developing the disease ($n = 1$) or that there were no evidence-based medical guidelines respondents could follow that would prevent the disease ($n = 3$). Respondents were asked to choose one answer.

PCP Opinions Regarding Clinical Usefulness

Almost half of the respondents who were aware of DTC genetic testing (42.6%, $n = 63$) thought that testing was clinically useful when formulating medical management plans. Among the PCPs who indicated DTC genetic testing was clinically useful at some level, the majority (84.7%, $n = 50$) thought it was somewhat useful (Table 5).

The 63 respondents who indicated DTC genetic testing was clinically useful were asked about its clinical benefits. The most frequently endorsed benefits were the ability to: 1) offer screening tests (e.g., mammograms, colonoscopies, EKG) *at an earlier age* to individuals at an increased risk (82.5%, $n = 52$), and 2) offer screening tests *more frequently* to individuals who are found to be at an increased risk (81.0%, $n = 51$).

The 85 respondents who were aware of DTC genetic testing and indicated that it is *not* clinically useful endorsed these reasons: 1) no guidelines exist to reduce or alleviate the risk for many diseases (80.0%, $n = 68$), 2), it is too difficult to interpret what the results mean regarding patient care (58.8%, $n = 50$), 3), it will cause more patient anxiety (51.8%, $n = 44$), 4), they would not change a patient's management based on DTC testing (35.3%, $n = 30$), or 5) "Other" (18.8%, $n = 16$). "Other" reasons fell into the following categories: the lack of clinical usefulness of results ($n = 6$), the lack of accuracy of the test results ($n = 6$), and concerns about future insurance coverage for a patient who had DTC genetic testing ($n = 4$).

Of the five respondents who had a patient bring in results, four respondents indicated that DTC genetic testing was *not* clinically useful. These four endorsed the following reasons: no guidelines exist to reduce or alleviate the risk for many diseases ($n = 4$), it is too difficult to interpret what the results mean regarding patient care ($n = 3$), and it will cause more patient anxiety ($n = 2$). None of the four endorsed the comment "I would not change a patient's management based on DTC testing".

Primary care providers who were aware of DTC genetic testing were also asked what concerns they have about the testing. From a list of 12 concerns (Table 2), the most common concerns included that: results could increase patient anxiety (87.1%, $n = 129$), patients may interpret the results incorrectly (85.1%, $n = 126$), advertisements may mislead patients (85.1%, $n = 126$), and the clinical utility is questionable (81.8%,$n = 121$).

When asked how likely it was that a patient's DTC genetic test results would influence their care of a patient, those respondents who were aware of DTC genetic testing ($n = 148$, 38.8%) felt DTC genetic test results were likely (33.8%, $n = 50$) or very likely (4.7%, $n = 7$) to influence the care of patients in their practice (Table 5). A majority of the PCPs (74%, $n = 42$) who thought that DTC testing was likely or very likely to influence care also felt the results were clinically useful. A strong positive association was obtained between the PCP's specialty and their opinions about the clinical usefulness of DTC genetic testing. Primary care providers who were practicing family medicine were three times as likely to think DTC genetic testing is clinically

useful compared to PCPs who were practicing internal medicine (Table 3: *OR* = 3.3; *CI* = 1.52–7.13). In a multivariate logistic regression analysis, using a forward stepwise likelihood ratio model, PCP gender ($p = .04$) and specialty ($p = .03$) (Table 4) of the PCP were found to be of significant predictive value for determining respondent's opinion regarding the clinical usefulness of DTC genetic testing. Regression analysis results for gender were not similar to the bivariate analysis findings.

PCP Preparedness to Answer Questions About DTC Genetic Testing

A majority of the respondents (85%, $n = 323$) did not feel prepared to answer their patient's questions regarding DTC genetic testing (Table 2). A strong positive association was obtained between the PCP's gender and their sense of preparedness in answering questions about DTC genetic testing. Male PCPs were twice as likely to feel prepared to answer questions about DTC genetic testing compared to female PCPs (Table 3; *OR* = 2.65; *CI.* = 1.26–5.61). A strong positive association was detected between respondents' age and preparedness. Primary care providers ≥51 years of age were more than twice as likely to feel prepared to answer questions about DTC genetic testing compared to younger PCPs (Table 3; *OR* = 2.46; *CI* = 1.20–5.08). A positive correlation was found between a sense of preparedness and awareness about DTC genetic testing (Pearson $r = .259$, $p = .01$) and age (Pearson $r = .123$, $p = .01$). No significant findings were obtained associations for bivariate associations with work setting and preparedness. A multivariate logistic regression analysis using a forward stepwise likelihood ratio model was performed to determine predictors of preparedness. Only PCP age was found to be of a significant predictor ($p = .01$) (Table 4) of preparedness to answer questions about DTC genetic testing. Primary care providers who were ≥51 years of age were significantly more likely to say they were prepared to discuss DTC genetic testing than those who were ≤40 years of age.

## Discussion

This is the first regional survey in the United States of primary care physicians concerning their awareness and attitudes about DTC genetic testing. Primary care providers were specifically targeted because 1) it is anticipated that patients in adult primary care offices will increasingly ask questions, or bring in results from this type of genetic testing, 2) DTC genetic testing companies target their tests toward healthy adults, and 3) the conditions companies test for, with few exceptions, are common complex diseases that typically have an adult onset. The present results indicate that approximately 39% of respondents were aware of DTC genetic testing. Their awareness level and sources of information are similar to those reported previously in the literature (Kolor et al. *2009*; Ohata et al. *2009*).

While the overall awareness level of DTC genetic testing in this study was similar to other studies, the level of PCP experience with patients inquiring about DTC genetic testing was substantially lower. Only 18.9% ($n = 28$) of PCPs who were aware of DTC genetic testing had ever answered questions or discussed DTC test results with their patients compared to 42% of

providers in a national sample of US providers (Kolor et al.*2009*). When looking at how much first-hand experience PCPs in this study had, on average they answered questions from three patients or discussed DTC genetic testing from two patients. These results suggest that, at this time, a minority of North Carolinians may be pursuing DTC personal genome testing or, if they are pursuing testing, that they are not discussing the results with their primary care physicians. This is consistent with other reports indicating a low demand (an estimate of 20,000–30,000 tests purchased world wide from one of the three companies offering DTC genetic testing in 2009) for DTC genetic testing on a national level (*2009* by the numbers 2009; Pollack *2010*; Wright and Gregory-Jones *2010*). The low patient interest in DTC genetic testing may also reflect the fact that North Carolina has a relatively low household median income level (41st in the country) (U.S. Census Bureau *2009*). Therefore, since this testing is typically not covered by insurance, North Carolina residents may lack the disposable income to pay for this type of testing.

Almost half of the responding PCPs who were aware of DTC genetic testing felt that it was at least somewhat clinically useful for formulating medical management plans. Therefore, if a PCP feels the test is clinically useful then it is likely the results will influence medical management. Despite a lack of guidelines on how to manage patients based on DTC test results, the ability to offer screening tests more frequently and at earlier ages to those who test positive for adult onset diseases were often endorsed as benefits of the tests. Overall, family practice PCPs were significantly more likely to believe that this technology is clinically useful. One plausible explanation may be that family practice physicians focus on disease prevention and health promotion, which is one of the primary goals of genomic medicine, whereas internists tend to be skilled in the management of patients who have undifferentiated or multi-system disease processes (American Academy of Family Physicians *2006*).

Respondents' concerns about patient anxiety, the potential for misinterpretation, and misleading advertising are consistent with those reported in other studies (Ohata et al. *2009*), and by professional societies (American College of Medical Genetics (ACMG) *2008*; American Society of Human Genetics (ASHG) *2007*; National Society of Genetic Counselors (NSGC) *2007*), governmental agencies (Kutz *2010*; Secretary Advisory Committee on Genetic Testing *2008*) and advocacy groups (Genetic Alliance *2005*). National genetic organizations and advocacy groups have called for personal genome companies to provide relevant information about their tests in an easily accessible and understandable format. This includes providing information to the consumer on the clinical validity and utility of the tests, credentials of the laboratories performing the tests, how patient privacy is maintained and how to access a knowledgeable healthcare provider for interpretation of results (ACMG *2008*; ASHG *2007*; Genetic Alliance *2005*; NSGC *2007*).

Other concerns were also noted by survey respondents. Despite a lack of evidence of genetic discrimination (Billings et al. *1992*), and the fact that the Genetic Information Non-Discrimination Act went into effect in 2009 (Genetic Information Nondiscrimination Act of *2008*), most respondents were concerned about health insurance and employment

discrimination. Therefore, important discussion points to include in a PCP education program are the risks of insurance and employment discrimination as well as legislation currently in place to protect against genetic discrimination.

Studies have indicated that patients will seek out their primary care provider to discuss their genetic test results and obtain the appropriate follow-up care (Burke *2004*; Holtzman and Watson *1997*; Miller et al. *2010*; Morren et al. *2007*). Similarly, at least one study has suggested that individuals undergoing personal genome testing expect their physician to help interpret the results (McGuire et al. *2009*), and DTC companies direct patients to their physician to discuss the test results before acting upon the genetic testing information (23andMe *2011*; deCODEme *2011*; Pathway Genomics *2011*). Therefore, PCPs are most likely going to shoulder the responsibility for discussing this technology with their patients. However, the majority of respondents in this survey indicated they did not feel prepared to answer patient questions (e.g. preparedness) about DTC genetic testing. Similar findings are reported in the literature, as several studies have found that PCPs generally have a lack of knowledge about genetics, genetic testing and genetic counseling (Greendale and Pyeritz *2001*; Guttmacher et al. *2001*; Suther and Goodson *2003*). Since whole genome scanning is a newer technology, PCPs' knowledge of this topic may be low, resulting in a lack of confidence in assessing risk or managing care.

Study Limitations

Several aspects of this study may have limited generalizability of the findings. In particular, the fact that this is a convenience sample of PCPs, and there was a low response rate (16.2%), it cannot be determined how representative the survey respondents are of the general PCP population in North Carolina. However, this study does provide preliminary findings for a larger comprehensive study. The literature indicates that surveys of general practitioners generally achieve poor response rates (McAvoy and Kaner *1996*). Possible reasons for the low response rate include 1) lack of monetary incentives, 2) the mailed survey was four pages, printed front and back and appeared long, and/or 3) the topic was not of current clinical interest to the PCP population. The gender demographics of this survey resembles the gender distribution of the NCMS membership (i.e. 66% and 73% males in family practice and internal medicine, respectively); these are which is the only demographic characteristics we could compare as the NCMS did not respond to requests for information concerning other demographic characteristics of their members.

Another limitation is that we could not determine the extent to which respondents used a particular resource to obtain information about DTC testing. For instance, some respondents may have had multiple exposures to different sources of information while others had a single exposure. In addition, some may have had brief exposures while others may have researched the topic in more detail. Differences between the various resources may determine whether a PCP feels that explaining DTC genetic testing is easy or complicated. Therefore, one area of future

research is to compare and contrast the accuracy and depth of the messages within information sources.

Finally, survey respondents could have misunderstood the type of genetic testing that was the focus of this study. Efforts were made to indicate that the questions pertained to personal genome tests available directly to consumers. However, some questions only included the wording "DTC genetic testing" and respondents could have thought these items referred to any DTC genetic testing (e.g., nutrigenomic genetic testing) or genetic tests where DTC marketing is performed (e.g., Myriad's BRAC *Analysis*). This confusion could have influenced their responses, thereby raising questions about the validity of the data obtained.

## Clinical Implications

Despite the limitations of this study, the findings have implications for clinical practice. Should DTC genetic testing become more widely used, a comprehensive education program may be necessary to increase PCP awareness of DTC genetic testing and help PCPs discuss testing with their patients. Based on the concerns indicated by the respondents, topics to include in an education initiative are guidelines on how to manage patients at increased risk for common disease, information on how to communicate results without unnecessarily increasing patient anxiety, the clinical utility of DTC genetic testing, privacy issues, and patient concerns surrounding health insurance and employment discrimination. Access to genetic counseling may help alleviate some of these concerns. A genetic counselor, or other qualified health professional, can discuss the pros and cons of the test, thus assisting consumers in recognizing both the utility and limitations of personal genome tests (American Society of Human Genetics *2007*).

## Research Recommendations

This study focused solely on physicians. Other health care professionals, such as physician assistants and nurse practitioners who specialize in primary care, should be surveyed about DTC testing. These providers may see their own patients and may have awareness, experiences and opinions that are distinctly different from those of physicians. Additionally, investigations of the North Carolina consumer population to determine their attitudes and experience with DTC genetic testing may provide some insight into who is being tested in North Carolina and whether the numbers of individuals being tested is equivalent to those who are talking with their providers.

Another area of research would be to identify all of the factors PCPs would take into consideration when preparing management plans based on DTC genetic testing. This study asked the question "*In general, do you think DTC genetic testing is currently clinically useful, meaning you would take a patient's test results into consideration when formulating your medical management plan (*e.g.*, when to refer for screening tests, when to refer to a specialist,* etc.*)?*". Since respondents were only able to answer yes or no, it is unknown what other factors they would consider.

A final area of research that arises from these findings involves the factors that make a PCP aware of, and feel prepared to answer questions about DTC genetic testing. In the present study, male respondents and those 51 years or older more were more likely to feel prepared to answer questions. Research in the area of gender differences indicates that men are encouraged to express more assertive and independent behaviors (Heilman *2001*), and at least one study has indicated the tendency for male physicians to overestimate their competence (Lind et al. *2002*). Additionally, the respondents in this study who were age 51 years or older (and typically in practice longer than younger respondents) were more likely to be aware of DTC genetic testing. Development and validation of measures that assess the importance of gender and other factors such as confidence gained through years of practice may help identify reasons for these findings.

## Conclusions

Primary care providers surveyed in a regional area reported similar awareness rates but less patient experience than findings of a national survey of providers (Kolor et al. *2009*). Additionally, most PCPs tended to be skeptical of the clinical utility of DTC genetic testing and did not feel prepared to answer patient questions on the subject. Knowledge of DTC genetic testing issues may increase PCPs' comfort and proficiency discussing such testing and deciding whether to make changes in a patient's care plan based on testing results. Education about clinical utility, privacy issues, and the pros and cons of testing is needed if DTC genetic testing becomes more widely used. Genetic counselors are positioned to play a key role in providing this education for PCPs and for consumers.

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## Appendix A: Survey Questions

Awareness

Genetic tests that scan a person's entire genetic makeup for potential health risks and are marketed directly to consumers are called direct-to-consumer (DTC) genetic tests. For the majority of this survey, we will use the term DTC genetic test to describe this service.

***1)*** Genetic tests that scan a person's entire genetic makeup for potential health risks are currently being marketed directly to consumers by several different companies (e.g., 23andMe, deCODEme, Navigenics). Have you heard or read about these genetic tests?

***a.*** Yes

***b.*** No → SKIP TO QUESTION 21

***2)*** From which of the following sources did you hear or read anything about genetic tests that scan a person's entire genetic makeup for potential health risks (e.g. tests marketed direct to consumers such as 23andMe, deCODEme, Navigenics)? Circle all that apply.

***a.*** Television

***b.*** Internet

***c.*** Professional organization

***d.*** Medical or scientific journal

***e.*** Patients

***f.*** Magazine article

***g.*** Newspaper article

***h.*** Health professional

***i.*** Radio

***j.*** Professional or scientific meeting

***k.*** Directly from a company selling DTC genetic testing

***l.*** Other, please specify:_____

Experiences with Patients

***3)*** Have any patients ever asked questions about or brought in results from DTC genetic tests?

***a.*** Yes

***b.*** No → SKIP TO QUESTION 15

***4)*** In the past year, how many of your patients *asked questions* about having a genetic test that scans a person's entire genetic makeup for potential health risks (e.g., 23andMe, deCODEMe, Navigenics)?

***a.*** None→ SKIP TO QUESTION 7

***b.*** Please put number of patients: _____

***5)*** What percentage of your total patient population does this make up? Please circle one.

***a.*** 1–10%

***b.*** 11–20%

***c.*** 21–30%

***d.*** 31–50%

***e.*** 51–75%

***f.*** >75%

***6)*** Into which of the following categories would you put the questions your patients have asked you about DTC genetic testing? Circle all that apply.

***a.*** I have not had a patient ask questions about DTC genetic testing

***b.*** What you know about the (company/companies) that are offering the test

***c.*** What you know about the test(s)

***d.*** Whether you think the patient is at risk for a particular disease

***e.*** What you know about the benefits of testing

***f.*** How the test results may change your patient's care

***g.*** What you would do in their situation

***h.*** Whether the cost is appropriate for the type of information they will obtain

***i.*** Other, please specify:_____

***7)*** In the past year, how many of your patients *brought results* from a genetic test that scans a person's entire genetic makeup for potential health risks (e.g., 23andMe, deCODEMe, Navigenics) to you for discussion? Please circle one.

***a.*** None→ SKIP TO QUESTION 15

***b.*** Please put number of patients: _____

***8)*** What percentage of your total patient population does this make up? Please circle one.

***a.*** 1–10%

***b.*** 11–20%

***c.*** 21–30%

***d.*** 31–50%

***e.*** 51–75%

***f.*** >75%

***9)*** What condition(s) have your patients been tested for when they had DTC genetic testing? Circle all that apply.

***a.*** Autoimmune (Graves disease, lupus, psoriasis, rheumatoid arthritis, sarcoidosis, inflammatory bowel)

***b.*** Bone (osteoarthritis)

***c.*** Cancer (breast, lung, colon, stomach, melanoma, prostate)

***d.*** Cardiac (atrial fibrulation, heart attack, coronary artery disease)

***e.*** Endocrine (type 2 diabetes, type 1 diabetes, obesity)

***f.*** Eye (macular degeneration, glaucoma)

***g.*** GI (hemochromatosis, Celiac disease, Crohn's disease, lactose intolerance)

***h.*** Neurologic (Alzheimer's, multiple sclerosis, restless leg syndrome)

***i.*** Pharmacogenomic testing (Genotyping for Warfarin response, Tamoxifen response, Oncotype Dx, Psychiatric drug response)

***j.*** Single gene disorder (familial hypercholesterolemia, cystic fibrosis)

***k.*** Vascular (abdominal aneurysm, brain aneurysm, DVT)

***l.*** Not sure/Cannot remember

***m.*** Other, please specify:_____

***10)*** What company/companies did your patient/patients use? Circle all that apply.

***a.*** 23 and Me

***b.*** DeCodeMe

***c.*** Navigenics

***d.*** DNA Direct

***e.*** I don't know/I cannot remember

***f.*** Other, please specify _____

Follow-up

***11)*** Did you ever change any aspect of a patient's care based solely on the results of his or her DTC genetic test? Please circle one.

***a.*** Yes

***b.*** No, because none of the tests indicated that a patient was at increased risk for disease→ SKIP TO QUESTION 15

***c.*** No—even though tests indicated that a patient was at increased risk for disease, because there were no evidence-based medical management guidelines to follow that would reduce their risk or prevent the disease → SKIP TO QUESTION 15

***d.*** No—for reasons other than those specified above, please explain _____ → SKIP TO QUESTION 15

***12)*** For your patient(s) who brought the results from a genetic test that scanned the person's entire genetic makeup for potential health risks (e.g., 23andMe, deCODEme and Navigenics) to discuss with you during an office visit *during the past year*, which aspects of your patient's care did you change based on the results? Circle all that apply.

***a.*** Screening tests that you offered

***b.*** Medications or doses that you prescribed

***c.*** Lifestyle changes that you recommended

***d.*** Frequency of follow-up appointments scheduled

***e.*** Diagnoses that you made

***f.*** Not sure

***g.*** No aspects of patient care

***h.*** Other aspects of patient care, please specify: _____

***13)*** Did you refer any patient to a specialist based solely on the results of a DTC genetic test?

***a.*** Yes

***b.*** No → SKIP TO QUESTION 15

***14)*** To whom did you make a referral? Circle all that apply.

***a.*** Genetic counselor

***b.*** Geneticist

***c.*** Cardiologist

***d.*** Oncologist

***e.*** Neurologist

***f.*** Endocrinologist

***g.*** Gastroenterologist

***h.*** Dietician

***i.*** Other, please specify: _____

Opinions

***15)*** In general, do you think DTC genetic testing is currently clinically useful, meaning you would take a patient's test results into consideration when formulating your medical management plan (e.g. when to refer for screening tests, when to refer to a specialist, etc.)?

***a.*** Yes → SKIP TO QUESTION 17

***b.*** No

***16)*** If no, why do you feel DTC genetic testing is not clinically useful? Please, circle all that apply.

AFTER ANSWERING THIS QUESTION, PLEASE SKIP TO QUESTION 19.

***a.*** It is too difficult to interpret what the results mean regarding patient care

***b.*** I would not change a patient's management based on DTC testing

***c.*** It will cause more patient anxiety

***d.*** No guidelines exist to reduce or alleviate the risk for many diseases

***e.*** Other, please specify:_____

***17)*** If yes, how clinically useful do you feel DTC genetic testing currently is? Please circle one.

***a.*** Very useful

***b.*** Useful

***c.*** Somewhat useful

***d.*** Not useful

***18)*** Which of the following do you see as a clinical benefit of DTC genetic testing? Circle all that apply.

***a.*** Offering screening tests (e.g. mammograms, colonoscopies, EKG) more frequently to individuals who are found to be at increased risk

***b.*** Offering screening tests (e.g. mammograms, colonoscopies, EKG) at an earlier age to individuals who are found to be at increased risk

***c.*** Changing medication doses

***d.*** Prescribing medication

***e.*** Recommending lifestyle changes

***f.*** Changing the frequency of follow-up appointments

***g.*** Making a diagnosis

***h.*** Providing genetic testing in a more private, confidential manner

***i.*** None of the above

***j.*** Other, please specify: _____

***19)*** Which of the following concerns you about DTC genetic testing? Circle all that apply.

***a.*** I do not have any concerns about DTC genetic testing

***b.*** The analytical validity, or accuracy, of the test results is questionable

***c.*** The clinical utility, or ability to use the results in practice, is questionable

***d.*** Counseling provided by the companies following DTC genetic testing is nonexistent or inadequate

***e.*** Patients may interpret the results incorrectly

***f.*** Advertisements may mislead patients

***g.*** Results could lead to discrimination in employment

***h.*** Results could lead to discrimination in health insurance

***i.*** Genetic information may not be kept confidential by the DTC testing companies

***j.*** Results could increase patient anxiety

***k.*** Physicians may feel obligated to refer patients to specialists, perhaps unnecessarily

***l.*** Physicians may feel obligated to refer patients for follow-up procedures, perhaps unnecessarily

***m.*** Other, please specify: _____

***20)*** If a patient were to bring the results from a genetic test that scanned the person's entire genetic makeup for potential health risks (e.g., 23andMe, deCODEme and Navigenics) to discuss with you during an office visit today, how likely is it that the test results would influence your care of the patient? Please circle one.

***a.*** Very likely

***b.*** Likely

***c.*** Unlikely

***d.*** Very unlikely

Preparedness

***21)*** Would/do you feel prepared to answer a patient's questions about DTC genetic testing?

***a.*** Yes

***b.*** No

Background Information

***22)*** What is your gender?

***a.*** Male

***b.*** Female

***23)*** What is your age?

***a.*** <=30

***b.*** 31–40

***c.*** 41–50

***d.*** 51–60

***e.*** >60

***24)*** In which specialty were you boarded? Circle all that apply.

***a.*** Family medicine

***b.*** Internal medicine

***c.*** Pediatrics

***d.*** Geriatrics

***e.*** Other, please specify: _____

***25)*** How would you describe your work setting (if you have appointments at more than one setting, please answer these questions thinking of your primary institution)? Please circle one.

***a.*** Academic medical center or medical school

***b.*** Medical center not affiliated with a university

***c.*** Community hospital

***d.*** Private practice

***e.*** HMO

***f.*** Other, Please specify: _____

***26)*** How many years have you been practicing as a physician? (please specify in whole years, rounding up to the nearest year) _____ years

Thank you for taking this survey!

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