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The impact of HIPAA authorization on willingness to participate in clinical research

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Abstract

Purpose—This study systematically examines the impact of inclusion of HIPAA authorization on the willingness of African Americans of diverse sociodemographic characteristics to participate in a clinical research study and explores reasons for non-participation.

Methods—For a purposive sample of 384 African American outpatients at 4 metropolitan primary care clinics from August 2005 through May 2006, willingness to participate in a hypothetical clinical research study of an antihypertensive medication under one of two experimental conditions was compared. Interviewees were randomly assigned to undergo informed consent alone (control group) or informed consent with HIPAA authorization (HIPAA group). They were asked whether they would participate and reasons for their decision.

Results—A smaller proportion of interviewees in the HIPAA group were willing to enroll in the study (27% vs. 39%; p=.02), with an adjusted odds ratio = 0.56 (95% confidence interval: 0.36 – 0.91). Those in the HIPAA group were more likely to give reasons related to privacy (p<.001), poor understanding of the form (p=.01), and mistrust or fear of research (p=0.04) for non-participation.

Conclusions—The inclusion of HIPAA authorization within the informed consent process may adversely affect the willingness of African Americans to participate in clinical research and may raise concerns about privacy, understanding the forms, and mistrust or fear of research.

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Introduction

To increase the representation of minorities in clinical research studies is a national goal.\(^1\) Despite this goal, the participation of African Americans in clinical research is low.\(^2\)\(^-\)\(^7\) Numerous barriers to the participation of African Americans’ in clinical research have been identified, including mistrust of medicine and research; time and financial constraints; and less opportunity for participation due to exclusions based on disease severity and co-morbid conditions and failure to be invited.\(^8\)\(^,\)\(^9\)

In 1999, a systematic review concluded that the language and information within the consent form is a potential barrier to research participation.\(^10\) Focus groups with low-income, urban African Americans specifically identified the informed consent process, and misunderstanding of that process, as a barrier to research participation.\(^11\)

Prior to the implementation of the Standards for Privacy of Individually Identifiable Health Information (i.e., the Privacy Rule) under the Health Insurance Portability and Accountability Act (HIPAA) in April, 2003,\(^12\) the Common Rule alone governed the protections of privacy of research participants. The Common Rule requires institutional review boards to determine whether a research protocol adequately protects study participants from breaches of confidentiality, and requires participants to sign an informed consent form describing privacy protections and those who have access to study-related data.\(^13\)

Under the HIPAA Privacy Rule, researchers must obtain participants’ explicit written authorization to use or disclose protected health information as part of the informed consent process. The HIPAA authorization must address a number of specific elements\(^12\) including a list of all permissible uses or disclosures of identifiable health information by those entities covered by HIPAA, and a statement that not all individuals who receive the identifiable health information may be required by HIPAA to protect the health information.

A recent comparative analysis demonstrates that consent forms satisfying federal regulations for human subjects research need only minimal additional text to satisfy the requirements of the HIPAA Privacy Rule.\(^14\) However, many research institutions require the addition of lengthy, complex language to comply with the HIPAA rule.\(^14\) As such, consent forms have increased in length, complexity, and reading level since implementation of the HIPAA Privacy Rule.\(^15\)

Federal research administrators propose that requiring research participants to give their explicit authorization to use protected health information will enhance research participation since the risks of breach of participants’ privacy is lower.\(^16\) Conversely, researchers have expressed that HIPAA authorization may detract from other important study information and engender concerns that privacy is less protected given the expanded disclosures.\(^15\),\(^17\),\(^18\)
Surveyed investigators report that the addition of language to satisfy the HIPAA Privacy Rule often confuses research participants and undermines recruitment.\textsuperscript{19}

Few published studies have investigated the role of the HIPAA Privacy Rule on participation in clinical research studies. A case study examining the consent process finds that technically complicated consent and privacy protection forms were a main factor preventing research participation.\textsuperscript{20} Two published studies that compared the proportion of eligible individuals who consented to enroll in a research pre- and post-implementation of privacy legislation found a significant decrease in recruitment and an effect upon generalizability.\textsuperscript{21,22} Neither of these studies examined individuals’ reasons for declining to participate.

The purpose of this study was to investigate the impact of inclusion of HIPAA authorization on the willingness of African Americans to participate in a clinical research study. This study focuses on African Americans as they are under-represented in clinical research studies,\textsuperscript{2-7} increasing minority enrollment is a national goal,\textsuperscript{1} and the informed consent process is identified as a potential barrier to research participation among African Americans.\textsuperscript{11}

\section*{Methods}

\subsection*{Study design}

This cross-sectional survey assessed willingness to participate in a hypothetical clinical research study under one of two experimental conditions. Interviewees were randomly assigned to undergo informed consent alone (control group) or in conjunction with HIPAA authorization (HIPAA group). To gain insight into underlying reasons for inter-group differences in willingness to participate, reasons for declining to participate were compared. The study was approved by the Institutional Review Board of Emory University.

\subsection*{Setting/Participants}

Study participants were recruited from two private and two public primary care clinics affiliated with an academic medical center in metropolitan Atlanta. Eligible participants were African American (self-identified) outpatients $\geq$ 18 years of age, who spoke English, and were able to consent. The target sample size was 384 African American participants (192 in each group). A purposive quota sampling strategy was used to systematically construct the sample along three critical axes of diversity: age (< 40 yrs, $\geq$ 40 yrs), gender (male, female), and educational level (< high school diploma/GED, high school diploma/GED, some college, $\geq$ college diploma), resulting in 16 cells with 12 individuals per cell in each group. The goal of sampling was to include a range of important demographic characteristics with sufficient power to detect inter-group differences by age, gender, and education categories. Data collection took place at the clinic sites from August 2005 through May 2006.

Participants were allocated to either the HIPAA or control group in a stratified random manner. Each participant was demographically categorized and then randomized within the particular category. Random assignment was achieved via a computerized random number
generator with a block size of two to pre-assign the order in which consecutive participants in each category would be allocated.

**Intervention**

Participants in the HIPAA group reviewed with the study interviewer the same informed consent document as those in the control group. The informed consent document described a Phase III clinical research study comparing an experimental antihypertensive medication to an established medication. In addition, participants in the HIPAA group reviewed a HIPAA authorization form with the study interviewer.

The consent and HIPAA authorization documents were prepared according to recommended templates available from the Emory University Institutional Review Board (www.emory.edu/IRB/consent_sample.php; www.emory.edu/IRB/hipaa_forms.php). The “additive” approach of including all language required for authorization into the consent process was used because this is the process required by many institutional review boards.

**Data Collection**

Potential participants were approached by the study interviewer (an African American female) while in the waiting room. The interviewer explained we were conducting a research study to better understand why people do and do not choose to take part in medical research, and that if s/he chose to take part in this research study s/he would review with the interviewer an informed consent form for a study that is being planned at a later time. Potential participants were asked to give verbal consent because no identifying information was collected as part of this minimal risk study, and we did not want to influence participant responses to the hypothetical informed consent documents.

Consenting participants first answered questions to elicit age, level of education, gender, household income (above or below the federal poverty level), and whether the participant or anyone close to them had hypertension. Control group participants reviewed with the interviewer the informed consent form for the hypothetical Phase III trial. The interviewer initiated review of the forms by reading them to all participants, although many participants took over reading the forms for themselves. Upon having reviewed the informed consent form and having any questions answered, the participant was asked whether s/he would or would not be willing to participate in such a study, and was asked to explain why s/he would or would not be willing to participate.

HIPAA group participants reviewed the same informed consent form in addition to a HIPAA authorization form, and were asked the same questions as above. In addition, they were asked whether they would or would not release their information for participation in the study, and were asked to explain why they would or would not be willing to do so.

Participants could give multiple reasons for their decision. The interviewer asked probe questions, as necessary, to elicit a response (“What thoughts or concerns do you have?”, “Any additional thoughts or concerns?”) and to clarify participants’ reasons for their answer (“What do you mean by that?”).
All interviews took place in a private area of the outpatient clinic sites. Responses were audio-recorded and transcribed into text files. If participants refused audio-recording, the interviewer transcribed participant responses verbatim. A random sample of audio cassettes was reviewed independently to check for accuracy.

Data Analysis

Participant responses to whether they would participate were dichotomized: ‘willing to participate’ for those who responded they would participate (‘yes’) or consider participating (‘maybe’); ‘unwilling to participate’ for those who responded they would not participate (‘no’). For univariate analyses, the proportion of interviewees in each group ‘willing to participate’ in the hypothetical clinical research study was compared using Pearson Chi-square tests; crude odds ratios and 95% confidence intervals were calculated using binary logistic regression.

Multivariate logistic modeling was performed by first using a model containing all covariates (group, age, gender, education, poverty, presence of hypertension) as main effects and all 2-way interaction terms, with the subsequent elimination of all interaction terms as none were found to be significant. Further model selection was done by performing a stepwise backward elimination procedure, resulting in the elimination of the presence or absence of hypertension for self or others as covariates in the final model. The Hosmer-Lemeshow test was performed to examine the goodness of fit of the final logistic model. Quantitative analyses were performed using SPSS for Windows (version 14.0).

A qualitative descriptive content analysis approach, in which code development was guided by the literature and interview content, was used to analyze textual data related to participants’ reasons for not participating. A priori topics for the coding scheme, as guided by the literature and investigators’ experience, included mistrust of medicine and research, perceived lack of benefit, fear of adverse reactions, fear of medical procedures, and socio-structural barriers (e.g., time lost from work, lack of transportation or child care).

Text files containing qualitative data were reviewed independently by the study team, and the initial coding scheme was refined based on content of responses. The study team then collaborated to develop a final data coding scheme, which was applied to all textual data by two coders independently. Key foci of the final coding scheme included: mistrust or fear of research, researchers, or research institutions; perceived lack of benefit to self; fear of side effects or unknown reactions; fear of pain or medical procedures; socio-structural barriers; poor understanding of forms or procedures; concerns about privacy; concerns about health insurance.

Participants whose responses could not be coded (e.g., “just not interested”, “can’t say why”, “just wouldn’t”) despite interviewer probes were coded as ‘no reason given’.

A complete description of all qualitative analyses and findings is beyond the scope of this paper. For this paper, the qualitative codes assigned to each participants’ reason for non-participation were analyzed as a quantitative binary variable according to whether the participant mentioned a given topic or not, as described previously. Fisher’s exact test was
used to compare the proportion of participants in each group assigned specific codes for declining enrollment.

The qualitative analyses were performed using MaxQDA for Windows (version 2.0). Discrepancies in coding between the two coders were resolved by a majority decision rule with a third researcher serving as a tie-breaker. Inter-coder agreement was assessed for each code applied to participant responses using Cohen’s kappa.\textsuperscript{25}

**Results**

To achieve the target sample size of 384 participants for this study, 417 individuals were invited to participate (92.1% participation rate). Of the 384 participants, 34 (8.9%) refused to be audio-recorded. Twenty-six (76.5%) of those who refused audio-recording were 40 years of age or older, and 28 (82.5%) had high school education or less.

A similar proportion of participants in HIPAA and control groups reported hypertension [119/192 (61.9%) and 121/192 (63%) , respectively; p=0.92] or someone close to them having hypertension [154/192 (80.2%) and 156/192 (81.3%) , respectively; p=0.91]. A similar proportion of participants in HIPAA and control groups reported a household income less than the federal poverty level [77/192 (40.1%) and 86/192 (44.8%) , respectively; p=0.41].

For the study population overall, a statistically significant smaller proportion of those in the HIPAA vs. control group indicated willingness to enroll in the clinical research study (27% vs. 39%), with crude odds ratio = 0.58 (95% confidence interval: 0.38 – 0.89). For every demographic category, a smaller proportion of those in the HIPAA group was willing to enroll in the clinical research study with statistically significant differences observed for those 40 years or older, with high school education or less, and males (Table1).

Using multivariable logistic regression, the adjusted odds ratio for willingness to participate for those in the HIPAA vs. control group was 0.56 (95% confidence interval: 0.36 – 0.91), controlling for gender, age, education, and poverty status (Table 2). The adjusted odds ratios associated with the covariates age ≥ 40 years, ≤ high school diploma/GED, male gender, and household income < federal poverty level also significantly negatively impacted willingness to participate (Table 2). The Hosmer-Lemeshow goodness-of-fit statistic for the logistic model demonstrated a good fit (p=0.957).

The proportion of coder agreement was high for each reason code for those ‘unwilling to participate’: access to health insurance (255/257; 99.2%), structural barriers (255/257; 99.2%), no perceived benefit to participation (254/257; 98.8%), fear of pain or procedures (254/257; 98.8%), privacy concern (253/257; 98.4%), fear of side effects or unknown effects (252/257; 98.1%), poor understanding of the form (250/257; 97.3%), and mistrust or fear of research (249/257; 96.8%). Cohen’s kappa coefficient was > 0.80 (range 0.842 – 0.965) for the application of each ‘reason code’, indicating satisfactory inter-coder agreement for each.

The coded reasons given by those ‘unwilling to participate’ in the clinical research study are given in Table 3. Compared to the control group, those in the HIPAA group were

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significantly more likely to report concerns related to mistrust or fear of research, researchers, or research institutions; privacy; and poor comprehension of the forms as reasons for declining participation (Table 3). Other reasons for declining enrollment did not significantly differ between groups.

There was variation in the proportion of participants giving specific reasons for declining participation according to demographic categorization (Table 4). Privacy concerns were reported by a significantly greater proportion in the HIPAA group for all demographic categorizations. Mistrust or fear of research was reported by a significantly greater proportion of those 40 years or older in the HIPAA vs. control group. Poor understanding of the forms was reported by a significantly greater proportion of those in the HIPAA group 40 years or older, with high school education or less, and males. Concerns about health insurance access and coverage were reported by a significantly greater proportion of those in the HIPAA group with greater than a high school education.

Discussion

In this study, fewer African Americans were willing to participate in a hypothetical clinical research study when the informed consent process included HIPAA authorization. Specific demographic groups for which there was a reduction in willingness to participate with inclusion of HIPAA authorization included those 40 years of age or older, with high school education or less, and males. Among African Americans who declined participation in the hypothetical clinical research study, more mentioned mistrust or fear of research, researchers, or research institutions; concerns about privacy; and poor understanding of the forms when the informed consent process included HIPAA authorization. For all sociodemographic categories, privacy concerns were mentioned more often as a reason for declining to participate when the informed consent process included HIPAA authorization.

This study contributes to a growing body of evidence that the “additive” approach to satisfying the HIPAA Privacy Rule may create additional barriers to research participation. The difference in rates of willingness to participate between those in the HIPAA and control groups was smaller in this study (12%) compared to others. A disease registry noted a reduction in enrollment of approximately 62% post-implementation of privacy legislation that required patients to return mailed consent forms, as compared to obtaining telephone verbal consent pre-implementation. An experimental study in Australia found a 20% difference in participation rates in a colorectal cancer study following implementation of privacy legislation. Differences among studies may be due to differences in the types and topics of research studies into which participants were asked to enroll.

The principal limitation of this study – the hypothetical nature of the clinical research study into which participants were asked to consider enrolling – may also contribute to the smaller intergroup difference. The overall proportion of African Americans who were ‘willing to participate’ for both HIPAA and control groups (39% and 27%, respectively) is within the upper range of previously published rates of participation of African Americans in clinical trials. The relatively high observed rates of participation, even among those with low educational attainment, suggests that self-reported rates of willingness may be higher than...
actual participation rates. In some cases, viewing the HIPAA authorization elements may have detracted from other important study items, which may have differentially biased self-report of willingness to participate relative to the control group.

Due to the hypothetical nature of the clinical study into which interviewees were asked to consider enrolling, we are not able to conclude whether modifying the HIPAA authorization process would enhance African Americans participation in research. Even with changes in the HIPAA authorization process, participants would face the numerous structural barriers, time demands, financial constraints, and mistrust of medicine and research that have previously been cited as reasons for low participation in clinical research.8,9 From this study we are unable to conclude how individuals of other races and ethnicities would respond to the inclusion of HIPAA authorization.

This study did not investigate the “integrative” approach14 to HIPAA authorization, which adds only minimal additional language to the consent form. It is possible that observed differences in willingness to participate for HIPAA vs. control groups would be less, or even eliminated, if an “integrative” approach to HIPAA authorization were used.

Professional organizations involved in clinical research have expressed doubt that HIPAA legislation can provide meaningful privacy protections.26,27 Alternative means of achieving meaningful protection of participant privacy in research have been proposed.18,20,28,29 The findings of this and other studies warrant further investigation of the impact of inclusion of HIPAA authorization in the informed consent process and evaluation of other means of achieving privacy protections. Given the present federal and institutional requirements to include HIPAA authorization as part of the informed consent process, these types of studies may be difficult to conduct, as has been described.30

Acknowledgments

The authors gratefully acknowledge the nursing and medical records staff at the Emory Family Medicine and Grady Neighborhood Health Centers who facilitated access to outpatients for performance of this study.

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List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
</tr>
<tr>
<td>GED</td>
<td>General Equivalency Diploma</td>
</tr>
</tbody>
</table>

References


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Table 1

Proportion of control (informed consent only) and experimental (HIPAA) groups willing to participate in the clinical research study.

<table>
<thead>
<tr>
<th>Demographic Categorization</th>
<th>Number (%) of interviewees indicating willingness to participate</th>
<th>Crude Odds Ratio * (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control Group</td>
<td>HIPAA Group</td>
</tr>
<tr>
<td>&lt; 40 years old (n=96)</td>
<td>40 (42%)</td>
<td>30 (31%)</td>
</tr>
<tr>
<td>≥40 years old (n=96)</td>
<td>35 (37%)</td>
<td>22 (23%)</td>
</tr>
<tr>
<td>≤High school diploma/GED (n=96)</td>
<td>29 (30%)</td>
<td>15 (16%)</td>
</tr>
<tr>
<td>&gt; High school diploma (n=96)</td>
<td>46 (50%)</td>
<td>37 (39%)</td>
</tr>
<tr>
<td>Males (n=96)</td>
<td>33 (34%)</td>
<td>19 (20%)</td>
</tr>
<tr>
<td>Females (n=96)</td>
<td>42 (44%)</td>
<td>33 (34%)</td>
</tr>
<tr>
<td>All (n=192)</td>
<td>75 (39%)</td>
<td>52 (27%)</td>
</tr>
</tbody>
</table>

* Odds of willingness to participate in the clinical research study for those in HIPAA vs. control group.

** Denotes statistically significant at the alpha = 0.05 level.
Table 2

Parameter estimates for covariates in the final logistic regression model for willingness to participate in the clinical research study.

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Adjusted*</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group status (HIPAA vs.Control)</td>
<td>0.58 **</td>
<td></td>
<td>0.36 – 0.91</td>
</tr>
<tr>
<td>≥40 years old</td>
<td>0.67</td>
<td></td>
<td>0.42 – 1.06</td>
</tr>
<tr>
<td>≤ High school diploma/GED</td>
<td>0.54 **</td>
<td></td>
<td>0.31 – 0.93</td>
</tr>
<tr>
<td>Male</td>
<td>0.48 **</td>
<td></td>
<td>0.30 – 0.78</td>
</tr>
<tr>
<td>Income &lt; federal poverty level</td>
<td>0.50 **</td>
<td></td>
<td>0.28 – 0.88</td>
</tr>
</tbody>
</table>

* Odds ratio for covariates in the logistic model specified by equation: \( \text{Logit} P(Y = 1) = \beta_0 + \beta_1(\text{Group}) + \beta_2(\text{Age}) + \beta_3(\text{Education}) + \beta_4(\text{Gender}) + \beta_5(\text{Income}) \); where \( P(Y = 1) \) is modeling the probability of willingness to participate in the clinical research study.

** Denotes statistically significant at the alpha = 0.05 level.
### Table 3

Reasons for not participating for control (informed consent only) and experimental (HIPAA) groups.

<table>
<thead>
<tr>
<th>Reason for not participating</th>
<th>Control Group (n = 117)</th>
<th>HIPAA Group (n = 140)</th>
<th>Fisher's exact p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mistrust or fear of research, researcher, or research institution</td>
<td>47 (40.2%)</td>
<td>74 (52.9%)</td>
<td>0.046 *</td>
</tr>
<tr>
<td>Fear of side effects or unknown effects</td>
<td>66 (56.4%)</td>
<td>61 (43.6%)</td>
<td>0.061</td>
</tr>
<tr>
<td>Privacy concern</td>
<td>3 (2.6%)</td>
<td>54 (38.6%)</td>
<td>&lt; 0.001 *</td>
</tr>
<tr>
<td>No perceived benefit to participation</td>
<td>46 (39.3%)</td>
<td>52 (37.1%)</td>
<td>0.797</td>
</tr>
<tr>
<td>Structural barriers</td>
<td>32 (27.4%)</td>
<td>30 (21.4%)</td>
<td>0.306</td>
</tr>
<tr>
<td>No reason given</td>
<td>10 (8.5%)</td>
<td>19 (13.6%)</td>
<td>0.238</td>
</tr>
<tr>
<td>Fear of pain or procedures</td>
<td>25 (21.4%)</td>
<td>18 (12.9%)</td>
<td>0.092</td>
</tr>
<tr>
<td>Poor understanding of forms</td>
<td>4 (3.4%)</td>
<td>18 (12.9%)</td>
<td>0.01 *</td>
</tr>
<tr>
<td>Health insurance concern</td>
<td>2 (1.7%)</td>
<td>10 (7.1%)</td>
<td>0.07</td>
</tr>
</tbody>
</table>

* Denotes statistically significant at the alpha = 0.05 level.
Table 4
Reasons for not participating for control (informed consent only) and experimental (HIPAA) groups, according to demographic categorization.

<table>
<thead>
<tr>
<th>Reason for not participating</th>
<th>Demographic categorization</th>
<th>Control group</th>
<th>HIPAA group</th>
<th>Fisher’s p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mistrust or fear of research</td>
<td>&lt; 40 years old</td>
<td>12/56 (21%)</td>
<td>16/66 (24%)</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td>≥40 years old</td>
<td>35/61 (57%)</td>
<td>58/74 (78%)</td>
<td>0.02*</td>
</tr>
<tr>
<td></td>
<td>≤ High school diploma</td>
<td>26/67 (39%)</td>
<td>45/81 (56%)</td>
<td>0.23</td>
</tr>
<tr>
<td></td>
<td>&gt; High school diploma</td>
<td>21/50 (42%)</td>
<td>29/59 (49%)</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td>Males</td>
<td>28/63 (44%)</td>
<td>43/77 (56%)</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>19/54 (35%)</td>
<td>31/63 (49%)</td>
<td>0.56</td>
</tr>
<tr>
<td>Privacy concern</td>
<td>&lt; 40 years old</td>
<td>2/56 (4%)</td>
<td>30/66 (46%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>≥40 years old</td>
<td>1/61 (2%)</td>
<td>24/74 (32%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>≤ High school diploma</td>
<td>0/67 (0%)</td>
<td>28/81 (35%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>&gt; High school diploma</td>
<td>3/50 (6%)</td>
<td>26/59 (44%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Males</td>
<td>1/63 (2%)</td>
<td>32/77 (42%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>2/54 (4%)</td>
<td>22/63 (35%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Poor understanding</td>
<td>&lt; 40 years old</td>
<td>3/56 (5%)</td>
<td>10/66 (15%)</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td>≥40 years old</td>
<td>1/61 (2%)</td>
<td>10/74 (14%)</td>
<td>0.01*</td>
</tr>
<tr>
<td></td>
<td>≤ High school diploma</td>
<td>4/67 (6%)</td>
<td>16/81 (20%)</td>
<td>0.02*</td>
</tr>
<tr>
<td></td>
<td>&gt; High school diploma</td>
<td>0/50 (0%)</td>
<td>4/59 (7%)</td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td>Males</td>
<td>0/63 (0%)</td>
<td>12/77 (16%)</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>4/54 (7%)</td>
<td>8/63 (13%)</td>
<td>0.38</td>
</tr>
<tr>
<td>Health insurance</td>
<td>&lt; 40 years old</td>
<td>1/56 (2%)</td>
<td>6/66 (9%)</td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td>≥40 years old</td>
<td>1/61 (2%)</td>
<td>4/74 (5%)</td>
<td>0.38</td>
</tr>
<tr>
<td></td>
<td>≤ High school diploma</td>
<td>2/67 (3%)</td>
<td>3/81 (4%)</td>
<td>0.99</td>
</tr>
<tr>
<td></td>
<td>&gt; High school diploma</td>
<td>0/50 (0%)</td>
<td>7/59 (12%)</td>
<td>0.02*</td>
</tr>
<tr>
<td></td>
<td>Males</td>
<td>2/63 (3%)</td>
<td>5/77 (7%)</td>
<td>0.46</td>
</tr>
<tr>
<td></td>
<td>Females</td>
<td>0/54 (0%)</td>
<td>5/63 (8%)</td>
<td>0.06</td>
</tr>
</tbody>
</table>

* Denotes statistically significant at the alpha = 0.05 level.