Race and Nicotine Replacement Treatment Outcomes Among Low-Income Smokers

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Background: Prior research suggests that racial/ethnic minority smokers experience more difficulty with cessation than white smokers and access formal treatment less often. Minority smokers may respond differently to treatment interventions than white smokers. This prospective, observational cohort study compared long-term cessation outcomes among four racial/ethnic groups after an aided quit attempt using nicotine replacement therapy (NRT).

Methods: A random cohort of smokers (N=1782) who recently filled a prescription for NRT was selected, stratified by race, using Minnesota Health Care Programs (e.g., Medicaid) pharmacy claims databases between July 2005 and September 2006. The primary outcome was 7-day point prevalence abstinence, which was assessed about 8 months after the NRT index prescription fill date using a mixed-mode survey protocol.

Results: The overall survey response was 58.2%. Overall, abstinence outcomes did not significantly vary by race. Unadjusted comparisons show that among survey respondents, at 8 months, 7-day point prevalence abstinence was 13.8% among whites, 13.6% among blacks, 14.1% among American Indians/Alaska Natives, and 20.7% among Asians (p=0.42). Similarly, the 30-day duration abstinence was 10.0% among whites, 11.5% among blacks, 8.9% among American Indians/Alaska Natives, and 18.3% among Asians (p=0.14). In multivariate analysis using propensity adjustment for potential confounding and response bias, there was no evidence that the effectiveness of NRT was lower for racial/ethnic minority smokers compared to white smokers.

Conclusions: These findings indicate that racial/ethnic minorities are as likely to quit smoking at a level similar to whites when using cessation treatment that includes NRT. Given documented disparities in the use of evidence-based cessation treatments such as NRT, interventions are sorely needed to improve access and utilization of these treatments in racial/ethnic minority groups.

(Am J Prev Med 2008;35(6S):S442–S448) Published by Elsevier Inc. on behalf of American Journal of Preventive Medicine.

Introduction

Racial/ethnic disparities in smoking cessation have been consistently documented in epidemiologic studies.[1–4] Although racial/ethnic minority smokers are more likely to attempt cessation than white smokers, they are less successful. In 2000, the quit ratio (i.e., percentage of lifetime smokers who have quit smoking) was lower among blacks (37.5%) compared to whites (50.4%).[3] In a secondary analysis of the Lung Health Study, a randomized trial of a behavioral group smoking intervention with adjunct nicotine gum compared to usual care among individuals with asymptomatic airway obstruction, black participants had a lower treatment effect with adjusted odds ratios of quitting at 1 year of 1.48 compared to 5.99 among whites.[5] There are also racial/ethnic variations in smoking prevalence. In 2005, smoking prevalence was highest among American Indians/Alaska Natives (32.0%), intermediate among blacks (21.5%) and whites (21.9%) and lowest among Asians (13.3%).[6]

Evidence suggests multiple causes for observed racial/ethnic differences in quit rates and response to treatment. From a biological perspective, there is speculation that treatment may yield varying results due to racial/ethnic differences in nicotine metabolism[7–9] or differences in dopamine-related genetic polymorphisms (e.g., DRD2 receptor and transporter SLC6A3).[10,11] At a cultural level, these differences may be due to variations in smoking patterns. For example, racial/ethnic minori-

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Published by Elsevier Inc. on behalf of American Journal of Preventive Medicine
0749-3797/08/$–see front matter
doi:10.1016/j.amepre.2008.09.009

ties, especially blacks, are more likely than whites to smoke menthol cigarettes[12] that may be more addictive than plain cigarettes.[13–15] In addition, recent evidence from health services research suggests that racial/ethnic disparities in quit rates may be due to minorities' lower utilization of evidence-based cessation treatments such as nicotine replacement therapy (NRT),[16–19] and lower levels of physician advice and assistance to quit smoking.[20–22] To date, there are very little data about the efficacy of guideline-recommended pharmacotherapies for smoking cessation among racial/ethnic minority populations. For example, in preparing for the 2000 Public Heath Service Treating Tobacco Use and Dependence Clinical Practice Guidelines, none of the 192 studies available for meta-analysis reported smoking abstinence by racial/ethnic status.[23] To our knowledge, there have been only three randomized, placebo-controlled clinical trials of smoking-cessation pharmacotherapies (one for nicotine patch, one for nicotine gum, and one for bupropion) conducted specifically in African Americans[24–26] and none among American Indians/Alaska Natives, Asian Americans, or Native Hawaiians/Pacific Islanders. Even though data are lacking, current 2008 national clinical practice guidelines recommend the use smoking-cessation pharmacotherapies such as NRT or bupropion for racial/ethnic minority smokers.[27,28]

The purpose of this prospective cohort study was to compare long-term smoking-cessation outcomes among four racial/ethnic groups following a quit attempt using NRT. NRT products are the most common FDA-approved treatments used by smokers to aid cessation attempts. The nicotine patch, nicotine gum, and nicotine lozenge are available over-the-counter, while the nicotine inhaler and nicotine nasal spray are available by prescription. Many insurance carriers, including Medicaid in most states, provide coverage for NRT as a prescription benefit.[29] This study tested the hypothesis that racial/ethnic minority smokers would have lower levels of long-term smoking cessation than white smokers after a quit attempt using NRT.

Methods

Study Design and Setting

This study used a prospective, observational cohort design. A cohort of low-income smokers was identified who filled an NRT prescription from the Minnesota Health Care Programs (MHCP), which include three major publicly subsidized healthcare assistance programs (Medical Assistance, MinnesotaCare, and General Assistance Medical Care) administered by the Minnesota Department of Human Services (DHS). MHCP provides insurance coverage for all recommended first-line nicotine replacement products (patch, gum, lozenge, inhaler, and nasal spray). Using DHS pharmacy claims, a list was generated of all individuals who filled an NRT prescription from July 1, 2005 through September 30, 2006. The routes to obtaining an NRT prescription are not known. This database also does not include over-the-counter NRT products purchased out-of-pocket. Bupropion was excluded because the reason for the prescription could not be determined, whether for smoking cessation or for depression.

Minnesota residents who were MHCP clients (aged ≥18 years) were eligible for study participation. Subjects were randomly selected from the list using a stratified random sampling plan with strata defined by race for the four largest groups enrolled in MHCP (white, black, American Indian/Alaska Native, and Asian). Individuals with missing/unknown race or Hispanic ethnicity were excluded. In this study, the specific focus was on the use of commercial tobacco. The cover letter describing the study to American Indian subjects stated that the sacred use of tobacco for spiritual practice was respected and the purpose of the survey was to learn about their every-day tobacco use.

Data Sources

Two primary sources of individual-level data were used: (1) follow-up questionnaire and (2) baseline administrative data on healthcare utilization extracted from the Medicaid Management Information System (MMIS). MMIS is the largest healthcare payment system in Minnesota. The Minnesota DHS uses MMIS to pay the medical bills and managed care payments for over 525,000 Minnesotans enrolled in the Minnesota Health Care Programs.

Follow-up Survey Procedures

About 8 months on average, after the first identified prescription fill date for NRT, participants were mailed a self-administered questionnaire. A modified Dillman mixed-mode survey protocol was used to maximize response and data quality.[30,31] All selected subjects were first sent a mailing that included a personalized cover letter describing the study, a $2 cash incentive, the survey instrument, and a postage-paid return envelope. Two weeks later a reminder postcard was sent. Subjects who did not respond to the first survey mailing were sent a second survey mailing 2 weeks later (or 4 weeks after the first mailing), which also included a pen (material incentive). Three weeks later (7 weeks after the first mailing), subjects who did not return a mailed survey were contacted for telephone administration of the survey. A maximum number of 12 calls were attempted per individual at varying times during the week.

Outcome Measures

The primary outcome was quit rates approximately 8 months after the initial prescription fill date. The primary measure was self-reported 7-day point prevalence abstinence because it is the principal outcome that has been used in most smoking-cessation RCTs.[27,28,32] Participants were categorized as successful quitters if they had not smoked a single cigarette in the previous 7 days. As a secondary measure, 30-day duration of abstinence was assessed.

Independent Measures

The main independent variable was race, obtained from baseline administrative data and from the follow-up questionnaire. Data on administrative race are collected on the MHCP application, which could be completed by the enrollee or by

a family member/friend or caseworker. The MHCP application includes five check boxes for race (Asian, black or African American, white, American Indian or Alaska Native, and Pacific Islander or Native Hawaiian), and there is no option for multiple races. A previous study of race data from MMIS indicates that administrative data correctly classifies 94% of cases.[33] On the follow-up questionnaire, participants were asked: *Which of the following best describes you* with options of white/Caucasian, black/African American, Asian, Native Hawaiian or Pacific Islander, American Indian/Alaska Native, or other. Participants were instructed to check all that apply. About 13% of the respondents indicated multiple races and were primarily American Indian/Alaska Native (AI/AN) and white, or black and white. Participants who indicated multiple races on the follow-up survey were categorized as belonging to the minority race group. Eight participants reported being Pacific Islanders and they were grouped together with Asians.

For the purpose of this analysis, the gold standard was the self-reported measure of race from the survey. About 4% of participants did not indicate their race on the survey and for these participants their administrative race designation was used. Agreement between administrative race and self-reported race was assessed; the weighted kappa was 0.89 (95% CI=0.86, 0.92).

Measures obtained from MMIS administrative data included demographic variables such as age, gender, and marital status, and information on clinical characteristics such as the presence of smoking-related medical conditions and psychiatric co-morbid conditions, ascertained from participants' clinical diagnoses (ICD-9 codes) in the 12 months prior to the index prescription. Survey items assessed education, income, and smoking history variables (e.g., age of smoking initiation and nicotine dependence).

Statistical Analysis

Two sets of analyses were performed to assess the effect of race: (1) a set of complete case analyses and (2) a series of analyses after augmenting the complete case to include cases with imputed missing items for those missing data on covariates. We did not impute for missing outcomes because there were very few missing data for the outcome measures. In both sets of analyses, methodologies were applied to adjust for possible effect of confounders and a possible bias due to survey nonresponse.

Propensity Methods to Control for Confounding and Response Bias

A propensity vector method was used to control for potential confounding and response bias on the estimate of the effect of race on the specified smoking abstinence outcomes. First, in order to take into account the potential response bias, the propensity of being a survey responder was calculated for each randomly selected subject using baseline MMIS administrative data. These propensities were ranked to create three equal-sized strata. Within each of these strata, responders and nonresponders would have the same distribution for the observed covariates and provide response bias adjusted estimates. Second, using a generalized logit model, probabilities of being in each of the four race categories were calculated. To maximally control the variations of the three-dimensional propensity vectors, principal components analyses (PCA) were conducted on three of the four propensities. Then the first principal component was ranked within each of the strata described above to create three more equal-sized strata where within each stratum the distributions of the unbalanced baseline covariates were now approximately the same independent of race. Within each of nine strata that were constructed, separate regression analyses were conducted and combined using stratified logistic analyses.

Survey logistic procedure as implemented in SAS 9.1 was used to perform the final stratified logistic modeling. The weight for each subject in a stratum was the total number of subjects divided by the number of subjects in the stratum. A race effect was assessed by using the type-III Wald chi-square results. Odds ratios between each nonwhite race group to whites were estimated. In addition, multiple imputation (m=10) Marcov Chain Monte Carlo methods were used for missing administrative and survey items (except the outcome measures) using the baseline MMIS administrative variables. Then the above procedure in assessing the effect of race was conducted, which adjusted for confounders, unbalanced covariates, and response bias. The F test for multivariate inference with multiple imputations was used to assess for a race effect. Odds ratios between each nonwhite race group to whites were again estimated.

Results

Over the time period July 1, 2005, through September 30, 2006, there were 13,316 unique individuals who filled a prescription for NRT. To identify the cohort (Figure 1), 1973 subjects were randomly selected within race strata (600 whites, 600 African Americans, 575 AI/AN, and 198 Asians). Given their smaller numbers, all AI/AN and Asians were selected. The final cohort

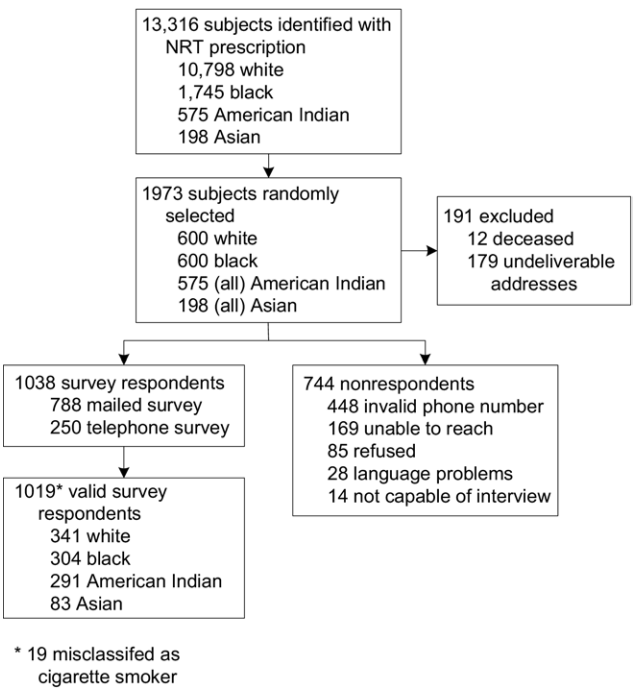

Figure 1. Subject flow diagram

sample size was N=1782 after 191 subjects were excluded due to death or undeliverable mailing addresses. The overall response was 58.2% with 788 respondents for the mailed survey and 250 respondents for the phone survey. Overall response to the survey varied significantly by race and was 65.0% for whites, 58.1% for blacks, 55.4% for AI/AN, and 47.6% for Asians (Pearson $\chi^2=20.4$, df=3, $p=0.0001$). There were 19 participants who were misclassified as cigarette smokers leaving $n=1019$ valid survey respondents for this analysis. The mean time from the NRT prescription index fill date to survey completion was 242 days (or about 8 months), and there were no significant differences by race.

Baseline characteristics of the survey respondents are presented by race in Table 1. There were a number of significant race differences in demographic variables as well as smoking history and clinical characteristics (e.g., co-morbidity). For example, Asian smokers in this cohort sample were younger on average and more likely to be men. American Indian smokers reported the earliest age on average of smoking initiation, had

Table 1. Baseline demographic characteristics and smoking history by race ($n=1019$; % unless otherwise indicated)

Characteristic	White ($n=341$)	Black ($n=304$)	American Indian ($n=291$)	Asian ($n=83$)	*p* value
Age (years), mean±SD	42.7±12.4	43.0±12.3	44.5±12.7	40.3±15.6	0.030
Age of smoking initiation (years), mean±SD	16.2±4.1	17.4±4.9	15.4±4.6	18.1±5.6	<0.0001
Gender, female	68	68	74	42	<0.0001
Marital status, married	21	8	15	33	<0.0001
Education					
Less than HS	19	27	26	46	<0.001
HS graduate	31	30	27	20	
Some college or more	50	43	47	34	
Employment status					
Currently employed for wages	41	31	25	34	<0.001
Not currently employed for wages	59	69	75	66	
Income ($)					<0.0001
<10,000	39	51	58	54	
10,000–19,999	27	28	27	28	
≥20,000	34	20	15	18	
Time to first cigarette					0.024
<5 minutes after waking	37	39	33	32	
6–30 minutes after waking	48	38	42	45	
>30 minutes after waking	15	23	24	12	
Cigarettes per day					<0.0001
≤10 or less	19	50	31	57	
11–20	50	37	45	30	
≥21	31	13	24	12	
Longest duration of prior quit attempt					0.310
<1 month	40	43	41	46	
1–6 months	23	26	28	31	
>6 months	37	32	31	23	
Smoking-related co-morbidity					
Cancer	2	1	1	0	n/a
Cardiovascular disease	21	22	22	13	0.368
Respiratory disease	28	34	36	19	0.007
Presence of psychiatric co-morbidity					0.294
None	38	40	33	45	
One	23	24	22	19	
Two or more	39	36	45	36	
Psychiatric co-morbidity					
Depression	45	40	48	37	0.159
Anxiety disorder	22	17	28	12	0.001
Post-traumatic stress disorder	6	8	10	12	0.088
Substance abuse/dependence	21	24	31	22	0.032
Serious mental illness (bipolar, schizophrenia, other psychoses)	20	19	20	24	0.797
Other psychiatric disorder	25	22	26	23	0.736
Anti-depressant medication use in 12 months prior to index prescription	51	42	52	36	0.008
Anti-anxiety medication use in 12 months prior to index prescription	27	19	32	12	<0.0001

HS, high school

Table 2. Index prescription and smoking abstinence outcomes by race (n=1019)

	White (n=341) (%)	Black (n=304) (%)	American Indian (n=291) (%)	Asian (n=83) (%)	p value
Index prescription					0.66
Nicotine patch	65	61	60	66	
Nicotine gum	11	10	13	14	
Nicotine inhaler or nasal spray	10	11	8	6	
Nicotine lozenge	4	3	5	1	
Unspecified nicotine product	5	6	7	4	
Multiple nicotine products	6	9	7	8	
Smoking abstinence					
7-day point prevalence abstinence	13.8	13.6	14.1	20.7	0.42
30-day duration of abstinence	10.0	11.5	8.9	18.3	0.14

the lowest levels of current employment, and were most likely to belong to the lowest-income group. White smokers demonstrated the highest smoking levels. The prevalence of psychiatric co-morbidity was high across all racial groups, and overall 22% had one psychiatric condition and 40% had multiple psychiatric disorders.

Smoking Abstinence Outcomes

Seven-day point prevalence smoking abstinence. Unadjusted comparisons indicated that smoking abstinence outcomes did not vary significantly by race (Table 2). At about 8 months of follow-up, 7-day point prevalence abstinence was 13.8% among whites, 13.6% among blacks, 14.1% among AI/AN, and 20.7% among Asians. The higher abstinence levels observed for Asians was not significant after a Bonferroni correction for multiple comparisons. Multiple logistic analyses with propensity adjustment assessed the effect of race on smoking abstinence, controlling for possible confounders and response bias (Table 3). A survey logistic regression model for 7-day point prevalence abstinence was estimated including race and the important baseline predictors of abstinence. These predictors were type of index NRT prescription, number of cigarettes smoked per day, time to first cigarette, age of smoking initiation, longest duration of prior abstinence, history of prior substance abuse, and history of smoking-related respiratory disease. The propensity-adjusted analyses showed no evidence that the effectiveness of NRT for smoking abstinence varied by race in the complete case model (Wald χ^2=2.35, df=3, p=0.503). In the multiple imputation model, the overall race effect was significant (F test=8.07, df=18, p=0.001); however, only Asians were significantly more likely to quit smoking compared to whites. There were no significant differences between blacks and American Indians compared to whites.

Thirty-day duration of smoking abstinence. Similarly, the 30-day duration of smoking abstinence was 10.0% among whites, 11.5% among blacks, 8.9% among AI/AN, and 18.3% among Asians. Again, the higher abstinence levels observed for Asians were not significant after a Bonferroni correction. In multivariate propensity-adjusted analysis, there was no significant overall race effect in the complete case model (Wald χ^2=7.59, df=3, p=0.055). In the multiple imputation model, there was a significant overall race effect (F test=12.55, df=18, p<0.001), but again, only for Asians compared to whites.

Table 3. Smoking abstinence outcomes and race with adjustment for confounding and response bias

	Unadjusted model OR (95% CI)	Adjusted complete case model OR (95% CI)[a]	Adjusted multiple imputation model OR (95% CI)
7-day point prevalence	n=1015	n=858	n=1007
White	1.0	1.0	1.0
Black	0.98 (0.62, 1.54)	1.17 (0.66, 2.08)	1.26 (0.75, 2.14)
American Indian	1.022 (0.65, 1.61)	1.29 (0.74, 2.27)	1.25 (0.73, 2.11)
Asian	1.630 (0.88, 3.02)	1.92 (0.79, 4.62)	2.97 (1.40, 6.3)
p value for overall race effect	0.424	0.503	0.001
30-day duration abstinence	n=1017	n=857	n=1009
White	1.0	1.0	1.0
Black	1.17 (0.71, 1.93)	1.75 (0.91, 3.37)	1.75 (0.96, 3.18)
American Indian	0.88 (0.52, 1.51)	1.33 (0.68, 2.58)	1.22 (0.64, 2.30)
Asian	2.02 (1.04, 3.91)	3.61 (1.38, 9.44)	4.39 (1.88, 10.24)
p value for overall race effect	0.142	0.055	<0.001

[a]The complete case analysis does not include survey responders who were missing data on any of the survey variables that were in the model and administrative marital status. By race, the proportion of survey responders partially missing data on survey questions were 13% of whites, 16% of blacks, 15% of American Indians, and 24% of Asians.

Discussion

Contrary to the study hypothesis, we observed that the degree of smoking cessation is similar among all racial/ethnic groups, when compared to white smokers. These findings indicate that racial/ethnic minorities are as likely to quit smoking at a level similar to whites when using cessation treatment that includes NRT.

The current study is an observational study that uses a prospective cohort design, and hence is not able to directly evaluate the efficacy of NRT for smoking cessation. Numerous clinical trials have established the efficacy of NRT products for smoking cessation among whites. No clinical trials have been conducted among Asians or American Indians. Among blacks, there are only two randomized, placebo-controlled clinical trials have evaluated the efficacy of NRT. For example, Ahluwalia and colleagues[24] conducted a randomized, placebo-controlled trial of the nicotine patch among inner-city blacks and found significant differences in short-term (10 weeks) quit rates (21.5% with nicotine patch vs 13.7% with placebo patch, $p=0.03$). However, differences in long-term quit rates (6 months) were not significant (17.1% with nicotine patch vs 11.7% with placebo patch, $p=0.08$).

Some have observed that the long-term quit rates for blacks (14.2%–17.1%) in the previously-mentioned clinical trials are lower than the quit rates observed for whites in other clinical trials of NRT. For example, two meta-analyses of the nicotine patch report quit rates of 17.7%–21.8% for the nicotine patch compared to 9.4%–10.8% for placebo at 6 months.[27,34] A meta-analysis of the nicotine gum reported quit rates of 23.7% for active gum and 17.1% for placebo.[27] These trials, however, consisted primarily of white, middle-class participants. In addition, this observation is not based on a direct comparison between blacks and whites, and data are lacking from clinical RCTs regarding differences between whites and other racial/ethnic groups. The current study stands in contrast to this observation in indicating that racial/ethnic minorities are as likely as whites to achieve long-term smoking abstinence when using NRT.

This study also stands in contrast to the findings of the Lung Health Study, but it was primarily an evaluation of a behavioral intervention and not pharmacotherapy. Future research is needed to examine the independent and combined effects of behavioral interventions along with pharmacotherapy on smoking abstinence outcomes in minority populations. Interestingly, in this study, Asians reported higher smoking abstinence levels, but this was not significant in unadjusted analyses. This finding was significant in the multiple imputation multivariate analysis with propensity adjustment for potential confounding and response bias.

However, caution should be exercised with the interpretation of this finding, particularly given the small sample of Asians included in this study. In addition, the Asian respondents likely have greater levels of acculturation as the survey included only participants who were proficient in English. One possible explanation for the observed higher cessation rate may be drawn from qualitative research previously conducted among Vietnamese and Hmong smokers.[35] In these Asian groups, physicians were viewed as trusted sources of information and could be helpful for cessation once a decision had been made to quit smoking. This might suggest that Asians may be particularly responsive to treatment with NRT that is prescribed by a physician once they have made a decision to quit smoking.

The strengths of this study include the prospective cohort design and the size and diversity of the sample, especially for blacks and American Indians; however, minorities in Minnesota may not necessarily be representative of minorities in the rest of the country. This research also compared racial/ethnic groups that were all low-income receiving subsidized/public insurance and allows the disentanglement of race and social class. Of note, nearly half of this sample had a history of a psychiatric disorder, which demonstrates the high proportion of psychiatric co-morbidity in low-income smokers. Psychiatric disorders were not related, in bivariate analyses, to smoking abstinence outcomes and were not entered into the regression analysis as independent covariates. However, to control for any potential confounding, psychiatric disorders were included in the propensity score for the propensity-adjusted analyses.

There are several noted limitations to the current study. For example, smoking abstinence outcomes were obtained by self-report from the follow-up survey and not biochemically verified. However, previous research indicates that misreporting is low in minimal-intensity studies such as those involving surveys.[32] The overall survey response was 58%, which is good for this low-income population. Nonetheless, there is potential for response bias, particularly as the level of response was significantly lower for minority groups compared to whites. Potential response bias was controlled using propensity methods; however, these methods assume that, within the same stratum, survey nonresponders have the same quitting behavior as the responders. These methods are also limited by the ability to model the response status of the subjects. A strength of this study was the availability of extensive baseline MMIS administrative data, which were used to model response status.

In conclusion, this study does not provide any evidence that treatment with NRT for smoking cessation is less effective for racial/ethnic minorities than for whites. Since the data on lower quit rates have raised the possibility that these treatments are less effective among minority smokers, this is a very important finding. Population-based

and epidemiologic studies consistently demonstrate overall lower smoking-cessation rates for racial/ethnic minorities than for whites, but this study would suggest that the reason is not lower treatment effectiveness of NRT. A more likely explanation for racial/ethnic disparities in smoking rates may be the limited utilization of evidence-based cessation treatments such as NRT. Indeed, racial/ethnic minorities are significantly less likely than whites to use NRT during attempts to quit smoking, even after controlling for SES and smoking-related characteristics.[16–19] Given documented racial/ethnic disparities in use of evidence-based cessation treatments, interventions are sorely needed to improve access and utilization of these treatments in racial/ethnic minority groups.

The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

Dr. Fu is supported by a Research Career Development Award from VA HSR&D; Dr. Burgess is supported by a Merit Review Entry Program Award from VA HSR&D.

The authors would like to gratefully acknowledge the support and assistance of Jeff Tenney and the Minnesota Department of Human Services.

This research was funded by Clearway Minnesota[SM] research program grant RC-2004-0017 to the University of Minnesota. The contents of this manuscript are solely the responsibility of the authors and do not necessarily reflect the official views of Clearway Minnesota[SM].

No financial disclosures were reported by the authors of this paper.

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