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Marijuana Use and Its Association with Participation, Navigation and Enrollment in Health Research among African Americans

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BACKGROUND

In 1993, the National Institutes of Health (NIH) mandated that research include racial/ethnic minorities and persons from culturally, economically, educationally or socially disadvantaged backgrounds (NIH, 2001). Including traditionally underrepresented groups in research is important to understand how interventions and treatments work in diverse populations, how to give everyone a voice in research, how to increase population impact of research findings, all of which could ultimately decrease health disparities (United States Department of Health and Human Services [US DHHS], 2013; Ford et. al., 2008). Despite this, the World Health Organization (2009) shows many groups remain underrepresented in research because they know nothing about research, they know but they choose not to join, or they are excluded by study teams. In fact, only 3 to 5% of the adult population participates in 80,000+ clinical trials in the United States (US) annually with ethnic/racial, rural and female populations remaining the most underrepresented (Jones, 2014; Rabin, 2014; UC Davis Health System, 2014).

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Prevalence of Drug Use

The exclusion of drug users, including marijuana (Mj) users (National Institute on Drug Abuse [NIDA], 2013) reduces the diversity of participating populations. Reasons for excluding drug users have included the need to avoid real drug interactions, the need to have additional monitoring, and the need to conduct additional assessments to document past, prior and current drug use (NIDA, 2006) while some investigators perceived Mj users would not attend follow-up appointments (Striley et. al., 2008).

While some studies may justifiably exclude Mj users for scientific reasons and that excluding Mj users is not always unethical or scientifically non-meritorious, it is important to include Mj users since the Substance Abuse and Mental Health Services Administration [SAMHSA] (2013) reports that in 2012, 18.9 million persons 12+ used Mj. SAMHSA (2010; 2013) reports that the percent of Americans using Mj has increased from 5.8% in 2007 to 7.3% in 2012 with overall Mj use among African American (AA) adolescents increasing nearly 2% between 2008 and 2010. Excluding AA Mj users without medical reason could significantly hinder generalizability of findings from youth, males, persons living in poverty, the unemployed and divorced — risk factors prevalent among users (DiNitto & Choi, 2011).

Marijuana Users and Research Participation

In the recent past, Mj users have been excluded from research because such use was classified as “illicit” and investigators have felt that users would not be compliant with protocols. However, the degree of Mj use did not prevent participation in randomized clinical trials among current Mj users. Specifically, Frewen and colleagues (2009) found that issues like severity of marijuana use, co-occurring mental health conditions and other medical issues did not serve as barriers to be enrolled, or take part in randomized trials. Furthermore, Cottler and colleague’s seminal study (1996) found little difference in retention by drug use.

One of the main impediments to the inclusion of Mj users in research, or to even investigate Mj use itself is that the substance is still classified as a Schedule I drug under federal law, similar to the same classification as heroin and LSD. However, the national movement to legalize marijuana moves it from a traditional exclusion criterion, and supports the inclusion of Mj users in research (Lee & Gelles, 2014; Karimi, 2014; Wing, 2014). To our knowledge, this is the first study or one of the first studies to evaluate these issues in African Americans. We hypothesized that current Mj users would be less likely to have been in a study and to be less likely to be enrolled in a study. We thought that Mj users would be as willing to take part in research as non-Mj users.

METHODS

Founded and developed by Dr. Linda B. Cottler, HealthStreet’s community-engagement model seeks to reduce disparities in health research by directly engaging community members through Community Health Workers (CHWs). Fully described elsewhere, the HealthStreet model, funded by the NIH NIDA and the Clinical Translational Science Award

(CTSA) at the University of Florida (UF) assesses health needs and concerns, refers individuals to medical and social services, as well as refers community members to health research studies based on their needs and concerns (Cottler, O’Leary, Striley, 2011).

One of the main aims of the model is to understand needs and concerns of the community; in addition, we ask community members about their research perceptions and about their lifetime and past 30 day drug use. Thus, data can address the important question about the willingness of African Americans with a Mj use history to participate in health research, whether navigation to health research studies varies by Mj status, and whether actual enrollment in health research varies by Mj status.

After explaining the purposes of HealthStreet and obtaining informed consent, CHWs conduct brief Health Assessments with community members identified from a variety of community settings. The CHW-administered Health Assessment includes 94 items designed to be administered in approximately 20 minutes. The HealthStreet assessment measures individual health concerns, neighborhood concerns, interest in research studies, socio-demographic information, health status, social media use, medications, and history of drug use (further explained below). CHWs are also trained to assess where they initially contacted each community member, by using global positioning system coordinates. CHWs record the date and time of contact and the location’s zip code.

Marijuana Use Status

Marijuana (Mj) use status is measured from the Health Assessment by asking respondents “Have you ever used marijuana?” Respondents answering ‘no’ were classified as never users. If respondents answered yes, they are then asked “Have you used marijuana in the last 30 days?” Respondents answering no to using Mj within the last 30 days were classified as past users. Respondents answering ‘yes’ were classified as current MJ users.

Research Participation and Interests

Prior research participation is elicited by asking “Have you ever been in a health research study?” Responses were grouped as ‘Yes’ and ‘No/Not Sure’. The Health Assessment also includes questions to assess current willingness to participate in various kinds of research studies. All questions begin with the lead statement of: “Would you volunteer for a health research study...” followed by: “that only asked questions about your health?”; “If researchers wanted to see your medical records?”; “If you had to give a blood sample?”; “If you were asked to give a sample for genetic studies?”; “If you might have to take medicine?”; “If you were asked to stay overnight in a hospital or clinic?”; “If you might have to use medical equipment?”; and “Would you participate in a study if you didn’t get paid?” Respondents were also asked how much money they consider is a fair amount for participation in a study that includes an hour and a half interview and a blood test. Research interest is collected by asking “How interested are you in being in a research study?” where responses are either ‘Definitely’, ‘Maybe’, or ‘Not at All.’

Illicit Drug Use Comorbid Use

Participants self-report illicit drug use, such as ever used, and if so, used in the last 30 days. In efforts to control for prior and current drug use which may be associated with Mj status, a score of illicit drug use was also created using each 'yes' response to have ever used: ecstasy; cocaine or crack; heroin; speed or amphetamines; prescription pain medication like Vicodin, Oxycodone, Codeine, Demerol, Morphine, Percocet, Darvon, Hydrocodone; Adderall or Ritalin; prescription medications for anxiety or sleep like Valium, Xanax or Ambien; inhalants like glue, paint or gasoline; hallucinogens; or cigarettes. This newly created measure ranged from 0 to 11, and was included in modeling analysis.

Socio-Demographic Information

All information is obtained from the participant, including age, gender, race/ethnicity, highest education, employment status and marital status.

Study Navigation after HealthStreet Assessment

Navigation status is recorded by the HealthStreet navigator after three steps are completed: (1) providing information to a community member about a study that s/he may be potentially eligible to be enrolled in, (2) having the community member decide that s/he is interested, and then, (3) calling the study coordinator to provide information about the potential participant. Those for whom all 3 steps were completed were coded as navigated to a health study [1].

Study Enrollment after HealthStreet Navigation

Enrollment status is also recorded by the HealthStreet navigator. Dispositions are recorded after they confirm with a study coordinator that a specific community member, who is part of HealthStreet, has been enrolled in a health study.

Sample

From November 2011 through July 14, 2014, 2,426 community members from HealthStreet Gainesville who reported their race as 'African American/Black' provided informed consent to have their needs and concerns assessed by a CHW. Excluded from this sample were 825 individuals who were specifically navigated to the NIH NIDA RO1 (5R01DA027951; PI: Linda B. Cottler, PhD, MPH) study titled "Transformative Approaches to Reduce Research Disparities Towards Drug Users" designed specifically to increase drug users' involvement in health research studies, and 105 individuals whose Mj status was unknown. Thus, the total sample used in this analysis is 1,496.

Statistical Methods

Analyses were conducted using SAS software, version 9.2 for Windows (SAS, 2009). Age and education were separately analyzed as continuous variables. Only African Americans were included in these analyses; those of other ethnicities/races were eliminated due to the focus of this study. Gender was analyzed as a dichotomous variable. Marital status was analyzed as a categorical variable consisting of three groups: 'never married', 'married', and 'separated, divorced, or widowed'.

Logistic regression was conducted to determine whether Mj current, past or never users were more likely to be navigated (n=1,465) to research studies while controlling for covariates of age, education, gender, interest, marital status, prior participation and use of other illicit drugs. Among those navigated (n=576), logistic regression was conducted to determine whether Mj current, past or never users were more likely to be enrolled in research studies while controlling for covariates of age, education, gender, interest, marital status prior participation and use of other illicit drugs. Odds ratios (ORs) and 95% confidence intervals (95% CIs) were derived from multivariate logistic regression to assess associations between variables and data were analyzed only for those with no missing information for logistic regression.

The Hosmer and Lemeshow goodness-of-fit test statistic was used to determine model fit for predicting navigation to health research studies. The first multivariate logistic regression modeling navigation as the outcome to include Mj status along with covariates of age, marital status, education, employment status, gender, interest in participating in a health research study, past participation in a health research study and other illicit drug use produced an acceptable model fit: Hosmer and Lemeshow Goodness-of-Fit test chi-square [X^2] = 10.2, degrees of freedom [DF]=8, $p=.25$. Modeling enrollment status as the outcome, the first multivariate logistic regression model to include Mj status, age, education, employment status, gender, marital status, interest in participating in a health research study, past participation in a health research study and other illicit drug use showed an acceptable fit ($X^2 = 5.10$, DF=8, $p=.75$).

RESULTS

Descriptive Results

Among the sample of 1,496 African American community members, 120 (8.0%) were current marijuana (CMj) users, 453 (30.3%) were past marijuana (PMj) users and 923 (61.7%) reported never using marijuana (NMj). Table 1 shows demographic characteristics of respondents stratified by Mj status. Overall, the average age of respondents was 41.7 years with a mean education of 12.5 years. While 38.4% of respondents were employed, the majority were female (58.7%) and never married (52.6%). Compared to PMj and NMj users, CMj users were significantly more likely to be younger ($p<.05$), less educated ($p<.05$), male ($p<.0001$) and never married ($p=.003$). Compared to PMj and CMj, NMj users were significantly less likely to use other illicit drugs paint, glue or gasoline. There were no differences observed between Mj status for employment.

The Association between Marijuana Use and Past Participation and Willingness to Participate in Future Research Given Various Requirements

Table 2 shows past participation in a health study as well as willingness to participate in various future research studies. Interestingly, there was no difference in past health research participation by Mj status. Current Mj users were more likely than PMj and NMj users to be willing to volunteer for a research study that only wanted to see their medical records ($p=.007$). PMj users were significantly more likely than CMj and NMj users to be willing to volunteer for a research study that required an overnight stay in a hospital or clinic ($p=.02$),

or required using medical equipment ($p=0.05$). Trends show that CMj users were more willing to volunteer for a health research study that only asked questions about their health. Participants did not like the idea of participating in a study that required taking medication, regardless of Mj status. Though not statistically significant, it may be meaningful that CMj users report willingness to participate in a study lasting about 1 ½ hours that involved an interview and a blood test for \$13-\$25 less compared to NMj and PMj users, respectively.

The Association between Marijuana Use and Navigation to and Enrollment in Health Research Studies

Table 3 shows odds ratios and 95% confidence intervals for navigation to a study, and enrollment in a health research study when adjusting for covariates. Of 1,465 individuals eligible to navigate, 576 were navigated to health research studies. While adjusting for covariates, CMj users were significantly less likely (CI: 0.21-0.58) to be navigated to a health research study compared to NMj users. Those who were significantly more likely to be navigated to a health research study: were slightly older (odds ratio [OR]: 1.02; CI: 1.01-1.03); were less likely to be male (OR: 0.78; CI: 0.62-0.98); were definitely (OR: 3.48; CI: 2.28-5.29) or maybe interested (OR: 2.07; CI: 1.36-3.16) in participating in a health research study; or had prior participation in a research study (OR: 1.60; CI: 1.18-2.18).

Table 3 also shows ORs and CIs for enrollment in a study when adjusting for covariates. Of the 576 individuals navigated to studies, 134 were enrolled. While adjusting for covariates, PMj users were 1.67 times (CI: 1.05-2.64) more likely to be enrolled in a health research study compared to NMj users. Those who had more education (OR: 1.11; CI: 1.01-1.21) and who had previously participated in a health research study (OR: 1.99; CI: 1.20-3.06) were significantly more likely to be enrolled in health research studies compared to their respective counterparts.

DISCUSSION

A major finding of this study is that interest to participate in health research studies is high (> 88%) for all kinds of research except for research requiring one to take medicine. Additionally, community members who used or formerly used marijuana tend to be more willing to participate in health research studies compared to community members who have never used marijuana. This is important given the prevalent use of marijuana coupled with the ethical need to include individuals with varying experiences and conditions in health research. If current or past drug use is an exclusionary criterion, then 92.4% of current Mj users and 90.4% of PMj users definitely and maybe interested in research studies, respectively would be excluded.

Navigation to and Enrollment in Health Research Studies

We also found that CMj users were significantly less likely to be navigated to a health research study than NMj users after controlling for several covariates. Our findings indicate that while African Americans who currently or previously use Mj are willing to volunteer for health research, only PMj users actually get enrolled compared to NMj users. These

findings seem to support our hypotheses that CMj and PMj users would be as willing to participate in research but less likely given the opportunity to do so.

Our results also indicate that past participation in a health research study is significant for determining navigation to, and subsequent enrollment in a study. It may be that those who have previously participated in a health research study are more confident and comfortable with the process; thus, they express a willingness to be navigated to, and subsequently enrolled in health research studies when invited.

HealthStreet, A Community Engagement Model

Our findings may be unique to the HealthStreet model, which pays close attention to increase social and health equity among underserved groups. Of the 3,715 community members in HealthStreet, 65% are Black/African American, 56% are female and 51% never married, which may reflect the increased efforts of CHWs to invite all community members in which they come into contact with. However, CHWs do not approach any community member with a knowledge of Mj status; thus, willingness to participate in research studies should not differentially affect (or be reported by) Mj status. Thus, we believe that willingness to participate in health research should be an unbiased report from participants.

Potential Study Limitations

While we believe our findings contribute new information to what is currently known, there are limitations. For example, one potential limitation includes the fact that all data are self-reported. However, Harrison and colleagues (2007) showed that Mj users accurately report their use and our estimates are consistent with state and national reports of Mj use (Blanco et. al., 2008). Another potential limitation is that there is no definitive time period for past Mj use beyond 30 days; thus, we are currently unable to determine whether PMj users are more similar to NMj users, or more similar to CMj users. However, PMj users may represent a group in *transition* and thus still provide insight regarding a possible temporal sequence between those who have formerly used Mj and those who currently use Mj.

Potential Reasons for Low Participation

Researchers may shy away from enrolling drug users in their studies since they are deemed 'vulnerable'. Blanco & colleagues' (2008) research showing that 50% of alcohol dependent individuals and 79% who sought treatment were excluded from participating in clinical trials supports this premise. DuBois, O'Leary & Cottler (2009) offer solutions to increase the protection of these groups. For example, they suggest researchers take extra measures to provide consent information as well as ensure potential participants understand relevant information and are not high when providing consent. As important, DuBois, O'Leary & Cottler (2009) found that participants wanted researchers themselves to assume the consenting responsibility to ensure that researchers maintain a "hands-on" approach when implementing their studies.

Regarding navigation to and enrollment into health research, barriers to enrolling drug users include increased study attrition and reluctance to pay participants who use drugs. Qualitative research conducted by Slomka et. al. (2008) found that, among minority drug

users, the primary motivation to participate in research was monetary compensation. However, our data show a trend that could refute the notion that drug users participate in order to get money since we found that CMj users reported a lower amount as fair for participation in a study that lasts about 1 ½ hours and involves an interview and a blood test compared to other Mj users. Additionally, Festinger et. al. (2005) found that a) offering cash or gift card incentives failed to present undue coercion or lead to new drug use among study participants and b) offering higher incentives (up to \$70) resulted in a greater percent of follow-up.

Importance for Inclusion & Future Research

Although enrolling and retaining vulnerable populations such as marijuana users into research studies may require additional safeguards and monitoring, this is fundamentally important for research to be ethically just and inclusive of all individuals. Moreover, populations that will eventually use the medication or intervention tested should contribute to studying efficacy and effects. Future research should continue to explore ways to increase participation of all individuals, specifically AA Mj users as health research participants.

Future research should examine what types of health research studies Mj users would be willing to participate in, and how health researchers could or would modify study criteria in order to include diverse groups while maintaining study fidelity. Future efforts should also focus on ensuring access for all groups to participate in health research, marijuana users who are African American, rather than focusing on how to change their perceptions or willingness to participate in health research.

CONCLUSIONS

These findings signify an important area of research to identify novel approaches to reduce research barriers for African American marijuana users. Individuals from minority groups are willing to participate in research and should be given the opportunity to do so, which increases justice for all. Navigating and enrolling marijuana users into studies could help decrease health disparities and increase health equity for the entire community since study findings would undoubtedly be more representative of the entire community rather than a select few.

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Sociodemographic characteristics of MJ users: data from HealthStreet 11/2011 through 7/14/2014

Table 1

Demographics	Total		Current MJ Use		Past MJ Use		Never Used MJ		p value
	N	%/yrs	N	%/yrs	N	%/yrs	N	%/yrs	
	1496	100	120	8.0	453	30.3	923	61.7	
Age (mean years)	1493	41.7	120	34.7	453	42.3	921	42.3	< .05
Education (mean years)	1495	12.5	120	11.9	453	12.4	922	12.6	< .05
Employed (Yes)	571	38.4	39	32.5	178	39.5	354	38.7	.37
Gender									
Female	876	58.7	43	35.8	229	50.6	604	65.4	< .0001
Marital Status									
Married	318	21.3	18	15.1	96	21.2	204	22.2	
Never Married	784	52.6	83	69.8	231	51.0	231	51.1	.003
Separated/Divorced/Widowed	390	26.1	18	15.1	126	27.8	246	26.7	
Ever Used Other Illicit Drug (Yes)									
Adderall or Ritalin	50	3.36	9	7.56	18	4.00	23	2.50	0.01
Amphetamines	33	2.21	5	4.17	27	5.96	1	0.11	< .0001
Cocaine/Crack	177	11.8	30	25.0	98	21.6	1	0.11	< .0001
Ecstasy	45	3.01	17	14.2	27	5.97	49	5.31	< .0001
Hallucinogens	18	1.20	3	2.50	14	3.10	1	0.11	< .0001
Heroin	18	1.20	3	2.50	14	3.10	1	0.11	< .0001
Paint, Glue or Gasoline	4	0.27	0	0	3	0.66	1	0.11	0.14
Prescription Medications									
Anxiety	167	11.2	16	13.3	66	14.6	85	9.22	0.009
Pain	612	40.9	54	45.0	206	45.5	352	38.1	0.02
Smoke Cigarettes	696	46.6	89	74.2	307	67.9	300	32.5	< .0001
Summative Drug Use (mean)	1488	1.21	119	1.87	449	1.72	920	0.88	< 0.05

Willingness of HealthStreet Respondents to Participate in Research, by Marijuana Status

Table 2

	Total		Current MJ Use		Past MJ Use		Never Used MJ		<i>p</i> value
	N	%	N	%	N	%	N	%	
Been in a health research study (Yes)	1496	100	120	8.0	453	30.3	923	61.7	
	225	15.2	15	12.6	71	15.7	139	15.2	.84
Interested in Being in a Research Study									
Definitely	677	45.5	55	46.2	223	49.4	399	43.4	
Maybe	642	43.1	55	46.2	187	41.5	400	43.5	.06
Not at All	170	11.4	9	7.6	41	9.1	120	13.1	
Volunteer for a health research study ...									
That only asked questions about your health	1366	91.4	114	95.0	415	91.6	837	90.8	.29
If researchers wanted to see your medical records	1247	83.4	109	90.8	389	85.9	749	81.2	.007
If you had to give a blood sample	1214	81.3	97	80.8	376	83.2	741	80.4	.45
If you were asked to give a sample for genetic studies	1208	80.9	102	85.0	365	80.8	741	80.4	.48
If you might have to take medicine	811	54.4	65	54.6	236	52.3	510	55.4	.55
If you were asked to stay overnight in a hospital or clinic	1003	67.3	84	70.0	325	71.9	594	64.6	.02
If you might have to use medical equipment	1157	77.6	97	80.8	371	82.3	689	74.8	.005
If you didn't get paid	1141	76.5	83	69.2	345	76.5	713	77.5	.13
How much money do you think is a fair amount for participation in a study that lasts about 1 ½ hours and involves an interview and a blood test? (\$)	1268	\$92.8	103	\$73.4	390	\$86.3	775	\$98.6	.18

Table 3

Multivariate logistic regression analysis predicting participation in health research

	Navigation to a Health Research Study n = 1465		Enrollment in a Health Research Study n = 576	
	Odds Ratio	95% Confidence Interval	Odds Ratio	95% Confidence Interval
Marijuana Status				
Marijuana Status				
CMj (past 30 days)	0.34	0.21 – 0.58	0.95	0.30 – 3.02
PMj (before past 30 days)	0.95	0.73 – 1.22	1.67	1.05 – 2.64
NMj (never used)	1.00		1.00	
Other Illicit Drug Use				
Summative Score	1.11	0.99 – 1.23	1.05	0.89 – 1.25
Sociodemographic Information				
Age (years)	1.02	1.01 – 1.03	1.01	0.99 – 1.02
Education (years)	0.99	0.95 – 1.05	1.11	1.01 – 1.21
Employment				
Employed (full/part time)	0.99	0.78 – 1.26	0.88	0.56 – 1.39
Unemployed	1.00		1.00	
Gender				
Male	0.78	0.62 – 0.98	0.68	0.44 – 1.06
Female	1.00		1.00	
Marital Status				
Never Married	0.82	0.61 – 1.13	0.81	0.47 – 1.39
Widowed/divorced/separated	0.88	0.64 – 1.21	0.69	0.40 – 1.18
Married	1.00		1.00	
Interest and Past Participation				

	Navigation to a Health Research Study n = 1465		Enrollment in a Health Research Study n = 576	
	Odds Ratio	95% Confidence Interval	Odds Ratio	95% Confidence Interval
Interest in Participating in a Health Research Study				
Definitely Interested	3.48	2.28 – 5.29	1.05	0.43 – 2.58
Maybe Interested	2.07	1.36 – 3.16	0.85	0.34 – 2.14
Not at all Interested	1.00		1.00	
Past Participation in a Health Research Study				
Yes	1.6	1.18 – 2.18	1.99	1.20 – 3.06