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Differences in Diffusion of FDA Antidepressant Risk Warnings Across Racial-Ethnic Groups

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Abstract

Objective: Numerous articles have identified that medical technologies diffuse more rapidly among non-Latino whites compared with other racial-ethnic groups. However, whether health risk warnings also diffuse differentially across racial-ethnic minority groups is uncertain. This study assessed racial-ethnic variation in children's antidepressant use before and after the 2004 black-box warning concerning risks of antidepressants for youths. **Methods:** Data consisted of responses for white, black, and Latino youths ages five through 17 from the 2002–2008 Medical Expenditure Panel Survey (N = 44,422). The dependent variable was any antidepressant use in the prior year. Independent variables were race-ethnicity, year, psychological impairment, income, insurance status, region, and parents' education level. Logistic regression models were used to assess antidepressant use conditional on race-ethnicity, time, interaction between race-ethnicity and time, need, socioeconomic status, and Institute of Medicine–concordant estimates of disparities in predicted antidepressant use before and after the warning. **Results:** The warnings affected antidepressant use differentially for whites, blacks, and Latinos. Usage rates among whites decreased from 3.3 to 2.1 percentage points between prewarning and postwarning, whereas usage rates remained steady among Latinos and increased among blacks. Findings were significant in multiple regression analyses, in which predictions were adjusted for need. **Conclusions:** The findings indicate that health safety information on antidepressant usage among children diffused faster among whites than nonwhites, suggesting the need to improve infrastructure for delivering important health messages to racial-ethnic minority populations.

Disparities in mental health care between whites and nonwhites are well documented, with blacks and Latinos receiving unequal access to health services and appropriate prescription psychotropic medications compared with whites (1–9). These disparities extend to black and Latino children, who are slower to receive novel medical technology and prescription medication (10,11), particularly psychotropic drugs (12,13) and antidepressants (14,15). It is unknown whether differences in diffusion of health-related warnings follow the same pattern.

The diffusion of health care safety information

In this article we use the term “diffusion” to refer to the process through which an innovation is both communicated and adopted by a community, through a social network, and over time (16). We broaden the concept of diffusion to include the communication and adoption of information about health risks.

There are three potential mechanisms by which health risk information may diffuse later to black and Latino youths than to whites. First, blacks may be more likely to seek mental health care from a general medical physician rather than from a mental health specialist (17), possibly because they are more likely to live in counties with a smaller supply of specialists (18). These differences may lead to a disparity in diffusion if mental health risk warnings reach mental health care specialists before general practitioners. Second, compared with white children, black and Latino children are more likely to be uninsured (19–21) and without a usual source of care (21), both factors that may contribute to slower receipt of up-to-date health risk information. Third, physicians treating people from minority groups are less likely to be board certified, are more likely to report that they were unable to provide high-quality care to their patients, and have more difficulty connecting their patients with high-quality specialty care (22). These factors may decrease the likelihood that youths from racial-ethnic minority groups will encounter physicians who access networks where health-related information is rapidly disseminated.

Black-box antidepressant warnings

Between May 2003 and March 2004, the U.S. Food and Drug Administration (FDA) released a series of public health advisories regarding the potential link between pediatric and adolescent suicidality and usage of selective serotonin reuptake inhibitors (23–27). In October 2004, the FDA directed pharmaceutical companies to issue black-box warning labels on antidepressant packages, the most severe action that the FDA can take short of a product ban. This ruling was finalized in January 2005 (23), underscoring the risks and need for monitoring of younger consumers of these medications. In 2007, the FDA extended the warning to include young adults through age 24 (28).

Notable declines in adolescent anti-depressant prescriptions, use (25,26,29), and diagnoses of pediatric depression followed the issuing of these health warnings (30). The proportion of visits in which an antidepressant was prescribed remained stable, indicating that children with major depressive disorder continued to receive appropriate pharmacological treatment while those with a less severe form of depression were not prescribed anti-depressants at the same rate (25). Research identified a shift in the prescribers of adolescent psychiatric medication from generalist physicians to psychiatric specialists (24).

The IOM definition of racial-ethnic health care disparities

We adopted the Institute of Medicine (IOM) definition of a health care disparity, defined as differences in care that are not due to clinical appropriateness, need, or patient preferences (31). The IOM definition recognizes that racial-ethnic differences in clinical need and appropriateness should be equalized across racial-ethnic groups when measuring disparities. In regard to antidepressant use, prior studies with adult populations suggest that compared with whites, racial-ethnic minority groups have lower presumed rates of lifetime major depressive disorder and lower rates of other disorders (32,33) and thus have less need for antidepressant medication. Assuming the same patterns hold true for youths, we would not consider these differences, mediated through clinical need, to be a disparity, according to the IOM definition (34,35).

In this study, we assessed whether disparities found in the diffusion of innovative technologies and medications (10–15) also exist in the diffusion of health-related risk warnings. Specifically, we identified whether the release of the FDA black-box warning was associated with a change in racial-ethnic disparities in antidepressant use among youths.

Methods

Data

We analyzed interview responses to the Household Component and Prescription Drug File of the Medical Expenditure Panel Survey (MEPS). Our sample combined seven cross-sectional years of data (2002–2008) and included 44,422 children ages five through 17, including 18,932 non-Latino whites, 8,887 blacks, and 16,603 Latinos. The MEPS reflects responses of a nationally representative subsample of households and contains information regarding household demographic characteristics, health status, satisfaction with health care, health expenditures, insurance coverage, and so on. The prescription drug file identified each respondent's prescription drug events (including drug type, dose, and brand). The MEPS 2002–2008 surveys had response rates between 57.2% and 64.7%. Survey weights accounted for both the complex sampling design and nonresponse so that the MEPS remained nationally representative. This study was approved by the institutional review board at the Cambridge Health Alliance.

The dependent variable was a di-chotomous measure indicating the filling of an antidepressant prescription. Black and Latino group membership was categorized on the basis of U.S. Census definitions of race-ethnicity. To adjust for need for antidepressants, we equalized racial-ethnic groups on the existence of a probable mental illness using four variables, two of which measure mental health status: psychological impairment, indicated by a score ≥ 16 on the Columbia Impairment Scale (CIS), and parent-reported mental health of child as good, fair, or poor (as opposed to excellent or very good). The other two variables that we used to adjust for need were age (five through 17) and gender. Other covariates used in regression equations were income (poor, $< 100\%$ of the federal poverty level [FPL]; near poverty, 100% – 199% FPL; middle income, 200% – 399% FPL; and high income, $\geq 400\%$ FPL), region of the United States (Northeast, Midwest, South, and West), urbanicity (Metropolitan Statistical Area with population $\geq 250,000$), participation in a health maintenance organization plan, insurance category (private; State Children's Health Insurance Program or Medicaid; other public insurance, such as the Civilian Health and Medical Program of the Department of Veterans Affairs or other federal or public hospital and physician coverage; and uninsured), whether or not the parents' or parent's job offered health insurance and whether or not they completed high school.

The sample size of non-Latino white, black, and Latino children ages five through 17 in the 2002–2008 MEPS data was initially 46,288, but this total was trimmed to 44,422 due to exclusion of respondents with missing data on any of the variables used in regression modeling. To account for differential missingness and to maintain generalizability of the data to the white, black, and Latino youth population, we reweighted the included individuals to represent their propensity to be like individuals with missing values (36).

Estimation

We used chi square tests to identify significant differences in bivariate analyses comparing racial-ethnic groups on dependent and independent variables. We also tracked antidepressant use for each racial-ethnic group in overlapping two-year panels between 2002 and 2008.

We estimated a multivariate logit regression model of the dichotomous variable indicating any antidepressant use in the past year. To capture the change in racial-ethnic disparities over time, we entered the main effects and interactions of race-ethnicity (with the white group as referent) and time. In this analysis, we split time into three periods to track the diffusion of the black-box warning: 2002–2003 (pre-warning), 2004–2005 (soon after warning), and 2006–2008 (postwarning).

Measuring disparities

As in previous studies (35,37,38), we implemented the IOM definition of racial-ethnic health care disparities by classifying independent variables into two categories—those to be adjusted for (need) and those allowed to enter into the disparity calculation (system-level variables). Need variables included mental health status variables (psychological impairment and parent-reported mental health) and, given large differences across these categories in prevalence of mental illness, age and gender (39,40). System-level variables not related to need were income, region, urbanicity, insurance coverage status, and parents' insurance and education (as described above).

After logit model estimation, we adjusted for need-related variables using a rank-and-replace method (35,38) that created a counterfactual population of black or Latino individuals with the white distribution of need but the racial-ethnic group's own distribution of system-level covariates.

First, multivariate indicators of need were summarized with a uni-variate need-based linear predictor defined as the sum of the terms (coefficient times covariate) of the fitted model corresponding to need variables. Individuals were then assigned survey-weighted ranks within their racial-ethnic group on the basis of this need predictor. The need variable values of each minority individual were then replaced by those of the equivalently ranked white individual. Thus a black individual with a need-based predictor at a specific percentile for blacks would be reassigned the need variable values of the white individual at the same specific percentile for whites. Finally, we generated predicted anti-depressant use for each counterfactual racial-ethnic minority group using the original model coefficients and adjusted need variables, and we compared these rates with the actual rates of antidepressant use among whites. Model estimates and predictions that were concordant with the IOM definition of disparity were weighted to account for an oversampling of both blacks and Latinos in the MEPS sample and to make the sample generalizable to the U.S. population.

As a sensitivity analysis, we reestimated disparities with a subpopulation of MEPS respondents with any outpatient visit or prescription fill linked to a diagnosis of episodic mood disorders (*ICD-9* code 296). Unlike our main analysis, in this analysis the subpopulation included only individuals who received mental health treatment. Antidepressants are indicated for most but not all disorders in this *ICD-9* classification. This sensitivity analysis complemented our main analysis by providing information suggestive of decisions made by patients and providers for youths with needs once they had accessed care.

Variance estimation

Variance estimates for analyses were estimated for each of the subgroup predictions and black-white and Latino-white differences with a balanced repeated-replication procedure (41). This technique of calculating the standard errors of our probability estimates repeats the estimation process used on our entire sample on a set of population subsamples which are each half the size of our full sample. All analyses were performed with Stata version 10.

Results

Significant unadjusted differences by racial-ethnic group existed for all dependent and independent variables used in this analysis (Table 1). Overall, white children were more likely than both black and Latino children to have any antidepressant use in the past year. In unadjusted comparisons, antidepressant medication use among white children began higher in 2002–2003 compared with other youths and then declined compared with the other youths in 2004–2005.

Variables significantly associated with antidepressant prescription for children included black race, Latino ethnicity, and indicators for time periods 2004–2005 and 2006–2008. Also significant were the interaction between the 2006–2008 period and black race; having a psychological impairment; having parent-reported mental health that was good, fair, or poor; being between the ages of 12 and 17 years; being in a middle- or high-income bracket; being uninsured or receiving Medicaid; and having a parent with at least a high school education (Table 2).

Table 3 shows predicted probabilities of IOM-concordant disparities in antidepressant use for each racial-ethnic group by period, as well as changes in diffusion rates and predicted differences. Although whites were consistently more likely to obtain antidepressants, their rates of antidepressant use significantly dropped over the post-black-box warning periods (2004–2005 and 2006–2008), whereas both blacks and Latinos had steady rates or increases in rates of antidepressant use. Between 2002–2003 and 2006–2008, whites decreased use from 3.3 percentage points to 2.1 percentage points. During the same period, blacks doubled their use of antidepressants, from .5 to 1.0 percentage point, while Latinos' use remained steady at 1.2 percentage points. Trends across the three periods were significantly different across the racial-ethnic groups. Results were similar in direction and significance when limited to just the sample that had a mental health care visit or prescription fill linked to a diagnosis of an episodic mood disorder. [An appendix available online as a data supplement to this article provides further details.]

Discussion

We identified a precipitous drop in antidepressant use among white youths and a relatively steady rate of use among both black and Latino youth populations in the four-year period after the FDA black-box warning. These findings remained after analyses controlled for variables related to need in accordance with the IOM definition of racial-ethnic health disparities and when reconducted with a subpopulation of youths receiving care for episodic mood disorders.

Our analyses showed variation in the utilization trends for antidepressant medication among adolescents from racial-ethnic minority groups, which may reflect a differential pattern of diffusion of medication health warnings among racial-ethnic minority communities and the physicians that serve them. This interpretation is consistent with other studies identifying slower diffusion of medical technologies (such as asthma medications [11]) among racial-ethnic minority communities. These findings build on previous literature identifying disparities in psychotropic drug and antidepressant use (10–15) and add to the broader body of research showing unequal access to mental health care between white and minority populations (1–9).

One explanation for these empirical results is that critical health information is incorporated into treatment differently by physician networks treating minority populations compared with whites. The general physicians who constitute the majority of these networks may be less likely to receive up-to-date risk information, may have fewer treatment alternatives to antidepressant medication (that is, no available specialty services to refer patients to), or may face differential demand from youths and their families. Partnerships connecting highly resourced health care organizations with community organizations that serve a large proportion of patients from racial-ethnic minority groups and uninsured patients ought to be strengthened, with clinicians in resource-poor settings given more opportunities to discuss up-to-date health information among their peers. Policy makers should ensure that health-related risk content reaches both providers and patients of all races and ethnicities by utilizing culturally appropriate strategies and channels of communication.

Our findings should be interpreted in the context of limitations of the study. Race-ethnicity indicator variables were only reductionist indicators of many complex, interrelated factors that have historically been barriers to equitable health care. By implementing the IOM definition of health care disparities, we incorporated systematic variables into the disparity calculation to the extent that they are available in the MEPS data set. However, numerous unobserved variables important to understanding racial-ethnic disparity trends remain unexplored. Examples of such factors include language barriers; lack of cultural familiarity or adherence to Western medicinal practices; geographic segregation; lack of a primary care physician, access to board-certified physicians, and health care specialists; and racial and ethnic prejudices that result in a physician's uncertainty about clinical decision making.

In addition, steady rates of antidepressant usage among nonwhite youths may reflect clinicians' appropriate weighting of the benefits and risks of antidepressant use rather than a lack of awareness about the black-box warnings. Replication of this study is needed with the addition of structured diagnostic and severity instruments that can distinguish more clearly the context of treatment.

Future research ought to continue exploring the reasons underlying the differential diffusion of medical technology and pharmaceutical drug safety information. One possible explanation is that the characteristics of providers treating youths from racial-ethnic minority groups may be different from those of providers treating white youths. Nonwhite patients living in segregated areas have limited choice and access to specialty providers (18,42), and black patients are more likely to receive care from providers with less clinical training and less access to resources than providers who treat white patients (22). These facts may help to explain why families from racial-ethnic minority groups are less likely to receive information about government risk warnings and choose a course of action, and further investigation is needed.

Conclusions

Although this study showed that black-white and Latino-white disparities in antidepressant use among youths have declined since the FDA black-box warnings, the changes are largely a result of declines in antidepressant use among white youths. These results provide evidence that government risk warnings diffuse differentially across racial-ethnic groups.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Table 1

Medical Expenditure Panel Survey data on antidepressant usage among youths, 2002–2008, in mean percentages^a

Characteristic	Whites (N = 18,932)	Blacks (N = 8,887)	Latinos (N = 16,603)
Antidepressant use in past year	2.6	.8	1.0
Period			
2002–2003	29.4	28.7	26.3
2004–2005	28.8	29.5	28.4
2006–2008	41.9	41.8	45.3
Psychological impairment score 16 ^b	10.7	10.5	6.1
Parent-reported mental health of child			
Excellent or very good	83.8	78.3	77.6
Good, fair, or poor	16.3	21.8	22.5
Gender			
Female	48.8	50.1	48.7
Male	51.2	49.9	51.3
Age			
5–11	52.0	51.3	56.6
12–17	48.0	48.7	43.4
Household income			
Under federal poverty level (FPL)	8.9	30.7	27.0
Near poverty (100%–199% FPL)	15.9	26.3	33.4
Middle income (200%–399% FPL)	37.6	28.5	27.5
High income (≥ 400% FPL)	37.7	14.6	12.1
Parent education high school or more	94.4	85.2	62.2
Parent offered health insurance via employer	66.7	54.3	45.6
Region			
Northeast	19.5	16.7	12.6
Midwest	27.6	19.5	8.7
South	33.5	54.9	33.6
West	19.4	8.9	45.1
Urbanicity			
Population > 250,000	21.4	11.8	7.5
Population ≤ 250,000 or nonmetropolitan	78.6	88.2	92.5
Insurance			
Private	74.5	42.6	35.2
Medicaid	19.5	51.8	49.9
Other public	.4	.6	.6
Uninsured	5.7	5.0	14.5
Health maintenance organization participation	36.4	52.6	45.7

^aSource: Combined yearly cross-sectional data from the 2002–2008 Medical Expenditure Panel Survey. Calculations for blacks, Latinos, and non-Latino white children ages 5–17 were weighted to be representative of the U.S. population. The test of overall differences between groups was significant at $p < .001$ for all comparisons except gender and time period.

^bAs measured with the Columbia Impairment Scale. A score ≥ 16 indicates psychological impairment.

Table 2

Regression analyses of predictors of antidepressant prescription use among white, black, and Latino youths, by race and time^a

Characteristic	Coefficient	SE	p
Race (reference: white)			
Black	−1.76	.27	< .001
Latino	−1.18	.23	< .001
Period (reference: 2002–2003)			
2004–2005	−.30	.13	.02
2006–2008	−.60	.14	< .001
Race × time interaction			
Black × 2004–2005	.10	.43	
Black × 2006–2008	.89	.37	.02
Latino × 2004–2005	.50	.32	
Latino × 2006–2008	.58	.32	
Need-related variables			
Psychological impairment score 16 (reference: CIS score < 16) ^b	1.48	.11	< .001
Parent reported mental health of child as good, fair, or poor (reference: excellent or very good)	1.83	.11	< .001
Female (reference: male)	< .01	.11	
Age 12–17 (reference: age 5–11)	1.08	.11	< .001
Other variables			
Income (reference: below poverty line)			
Near poverty	−.09	.12	
Middle income	.47	.15	.002
High income	.50	.19	.01
Region (reference: Northeast)			
Midwest	−.16	.19	
South	.03	.15	
West	−.24	.18	
Population > 250,000 (reference: 250,000)	.23	.14	
Insurance (reference: private)			
Public	−.24	.20	
Medicaid	.66	.20	.001
Uninsured	−1.07	.27	< .001
Health maintenance organization participation (reference: none)	−.07	.11	
Parent with at least high school education (reference: high school not completed)	−.04	.14	< .001
Parent offered health insurance via employer	−.09	.14	
Constant	−5.43	.34	< .001

^aSource: 2002–2008 Medical Expenditure Panel Survey (MEPS). Logit coefficients and standard errors take into account sampling weights and stratification used to make the MEPS sample representative of the U.S. population.

^bCIS, Columbia Impairment Scale. A score 16 indicates psychological impairment.

Table 3

Trends in disparities in antidepressant use before and after the FDA black-box warning on antidepressant use by youths^a

Group and period	Predicted probability (%)	SE (%)	Disparity (%)	SE (%)	p	Change since previous period (%)	SE (%)	p
Whites								
2002–2003	3.3	.2						
2004–2005	2.7	.2						
2006–2008	2.1	.2						
Blacks								
2002–2003	.5	< .1	2.8	.2	< .001			
2004–2005	.6	.1	2.1	.2	< .001	–.7	.3	< .001
2006–2008	1.0	.1	1.1	.2	< .001	–1.0	.3	< .001
Latinos								
2002–2003	1.2	.1	2.1	.2	< .001			
2004–2005	1.5	.1	1.2	.2	< .001	–.9	.2	< .001
2006–2008	1.2	.1	.9	.2	< .001	–.3	.2	

^aSource: 2002–2008 Medical Expenditure Panel Survey. FDA, U.S. Food and Drug Administration. Black-white and Latino-white disparities were calculated according to the Institute of Medicine definition of racial-ethnic disparities. Standard errors were calculated with the balanced repeated-replication methodology.