Cardiovascular Drugs for Blacks: How Race and Ethnicity is used for Clinical Trials, Marketing, and Dosage Recommendations

The purpose of this study was to examine how race and ethnicity is used in clinical trials, marketing and dosage recommendations of cardiovascular agents for Blacks. Cardiovascular agents in the Physician's Desk Reference (PDR) were reviewed to assess differences in dosage recommendations and/or reporting of adverse events for African Americans. Of 135 cardiovascular agents, only the ACE inhibitor trandolapril (Mavik®) had different dosage recommendations for Blacks. ACE inhibitors contained a warning message regarding higher angioedema incidence among Blacks compared to non-blacks. Key informant interviews (n=11) were conducted to obtain information on the definition and use of race/ethnicity by the FDA, pharmaceutical companies, National Pharmaceutical Council, Association of Black Cardiologists, and renowned researchers in related fields. Key informants were consistent in their definition of race/ethnicity as a social construct, but were inconsistent regarding whether findings from the Human Genome Project will change the way pharmaceutical companies use race/ethnicity. Pharmaceutical companies use race/ethnicity for a wide range of purposes including the identification of populations with unknown medical needs and those at high risk for adverse events. Informants recognized that a clinical trial that includes only one racial group (e.g., African American Heart Failure Trial) should be the exception rather than the rule. Leading experts saw a role for the pharmaceutical industry in the elimination of health disparities, but varied in what the role is. Although race and ethnicity are crude markers for genetic variation, there is still a need to continue FDA's mandate for the collection of racial/ethnic data for clinical trial recruitment and adverse events reporting. (Supported by National Center on Minority Health and Health Disparities)

Key informant Questions

1. How do you define race and/or ethnicity?
2. How is race and ethnicity used by pharmaceutical companies? What are the reasons for these uses?
3. Do you think that the knowledge from the Human Genome Project will change how pharmaceutical companies use race and ethnicity?
4. How should race and ethnicity be used in recruitment for pharmaceutical clinical trials?
5. What are your views regarding clinical trials that include only one racial group?
6. What are your views regarding marketing specific drugs to African-Americans?
7. What do you think the role of the pharmaceutical industry is, if any, in eliminating health disparities?