Race and ethnicity: bidil at the intersection of health disparities, pharmacother...

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Legal and Ethical Implications of BiDil Pharmacotherapy of the According to Stearsman, the definitions of race are still a thorn in the flesh due to different schools of thoughts which have diverse ways of explaining it (2009). Proponents have various ways to define race on the basis of social, physical or biological parameters. The concept of race either as a genetic entity or a subject of geographical inference has led to confusion within the medical field. This has led to various discrepancies in health service delivery to people considered of different racial backgrounds.

A case example is observed in the consideration of the development of the drug BiDil for management of hypertension in African Americans. BiDil is the common name that is used to refer to a combination of two drugs namely Isosorbide Dinitrate and Hydralazine that were believed to be effective in management of heart failure solely in African Americans (Khan, 2006). Although, the field of pharmacogenomics presents a new and more effective approach to management, the methodology employed in the approval of BiDil as a cardiac failure drug for drugs raises some legal and ethical concerns.

To begin with, the impetus that triggered the research that led to development of this drug was not entirely accurate and hence the foundation of the research was faulty from the start. According to Khan, the statistics used to base the argument for the development of the drug in 1981 suggested that the ratio of heart failure mortality and fatality of African Americans relative to White Americans stood at 2. 5 (2006). However, based on current data from 1999, this was disputed and it emerged that the ratio stood at 1. 1. The difference between the two values was explained by the

fact that African Americans present with symptoms of heart failure early in life (Stearsman, 2009). The assumption that African Americans were susceptible to this disease leading to mortality was false.

The observation of the age group that was used to obtain the statistics in the 1981 research also raises eyebrows. According to Khan, the prevalence of life threatening associated heart failure conditions increases with age with 93% of these factors arising in patients above 65 years of age (2006). The prevalence of these severe consequences is relatively minimal in patients who are less than 64 years of age (6%). However, statistics show that the 1981 research made use of subjects less than 64 years and hence this played a pivotal role in coming up with biased results. According to Silverstone, this selection bias could have been tailored to ensure consequent FDA approval of the drug (2009).

Moreover, the actual methodology that led to FDA approval of BiDil also raises concerns. According to Kahn, the research carried out to check the efficacy of the drug dubbed “ African American Heart Failure Trial” was carried out solely in African Americans (2006). Ideally, the results of this study should not have been considered as reflective of the efficacy of drugs in this race relative to other races. However, Khan states that even with this in consideration, publication went on that this drug was effective in management of heart failure in African Americans even though it was based on the study of African Americans only (2006).

The application information about racial discrepancies among people of different races proves to be a challenge for many healthcare providers. This stems from the fact that generalisation involved is not entirely true and from

the fact that physical diversity is not always representative of the degree of difference in terms of genetics. This leads to variation in the service acquired by different patients raising ethical and legal concerns (Silverstone, 2009). In the case example of the use of the drug BiDil for the management of heart failure in African Americans, various issues arise based on the rationale behind its approval. The age of the group used as subject for research in 1981 was biased and, the drug was approved without making interracial comparisons so as to outline the efficacy of the drug clearly (Khan, 2006).

References

Kahn, J. (2006). Race, Pharmacogenomics, and Marketing: Putting BiDil in Context. The
American Journal of Bioethics, 6 (5).

Stearsman, D. (2009). BiDal at the Intersection of Health Disparity, Pharmacotherapy &
Law. Race and Ethnicity, 22 (1).