

Race and income affect responses to FDA drug safety warnings

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Among older adults with diabetes, certain subgroups—including white patients and those with lower incomes—were slower to discontinue the diabetes drug rosiglitazone after a US Food and Drug Administration (FDA) safety alert, reports a study in the April issue of *Medical Care*.

"This work speaks to the efficacy and equity of FDA safety advisories across important subgroups of the vulnerable elderly population," comments lead author Danya Qato, PharmD, MPH, PhD, who performed the research as a postdoctoral fellow at the Brown University School of Public Health. "Although the differences are modest, we believe they could have a significant impact as the FDA crafts programs and policies to improve the public's response to [drug safety](#) warnings."

What Factors Affected Response to FDA Warning on Avandia?

Rosiglitazone, marketed under the brand name Avandia, was developed as an insulin-sensitizer for the treatment of diabetes. In May 2007, the FDA issued a safety alert warning of an increased risk of heart attacks in [patients](#) taking rosiglitazone.

As expected—especially since other treatment options were available—use of rosiglitazone decreased sharply in response to the safety warning. However, Dr. Qato and colleagues write, "Little research has evaluated whether the effectiveness of FDA safety communications

varies as a function of racial and sociodemographic characteristics, especially among the most vulnerable elderly."

To address this issue, they analyzed data from about 45,000 Medicare Part D (prescription drug) beneficiaries who were taking rosiglitazone at the time of the safety warning. About 37,000 patients were white and 8,000 were black; 23 percent of the [white patients](#) and 19 percent of the black patients had evidence of a history of cardiovascular disease.

Promisingly, about two-thirds of patients stopped taking rosiglitazone within six months after the safety advisory. After adjustment for other factors, white patients and those with low personal income discontinued rosiglitazone significantly later, compared to their black or higher-income counterparts. Patients living in the highest- versus lowest-socioeconomic status community discontinued rosiglitazone significantly earlier. White race, low personal income, and area-level socioeconomic status were also significant factors on analysis of patients with a history of cardiovascular disease.

Other groups that were slower to stop taking rosiglitazone were men, older patients, those without previous cardiovascular disease, and those not previously taking other diabetes drugs.

The researchers note that the magnitude of the associations was small—for example, the median time to discontinuation of rosiglitazone among white patients was only twelve days later than black patients. "That difference may seem negligible, but when you consider that some drugs may have more acute side effects that are of greater health risk, those twelve days could be meaningful," Dr. Qato adds. "One of the challenges in measuring and interpreting the effectiveness of FDA risk management tools is that we don't have established benchmarks for successful responsiveness."

The reasons for the racial differences in drug discontinuation are unclear, but cost issues seemed to explain the later discontinuation of rosiglitazone by lower-income patients. The researchers note some important limitations of their study, including a lack of analysis on the potential shift from rosiglitazone to an alternative medication in the same drug class (pioglitazone).

"Although the FDA recommended lifting restrictions on rosiglitazone in November of 2013, the agency continues to utilize alerts as a tool to communicate serious concerns about drug safety," the researchers write. The results suggest that even when FDA safety warnings are effective in encouraging patients to stop using potentially dangerous medications, some population groups may be more or less responsive.

"The impact of FDA advisories can vary among sociodemographic groups," Dr. Qato and colleagues conclude. "Policymakers should continue to monitor whether risk management policies reach their intended populations." The researchers emphasize the need for further studies to understand the "causal mechanisms and clinical implications" of differing responses to FDA drug [safety](#) warnings.

More information: "Disparities in Discontinuing Rosiglitazone Following the 2007 FDA Safety Alert" [DOI: 10.1097/MLR.0000000000000502](#)

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