Unpacking the Black Box: Do Patient and Prescriber Characteristics Predict Variation in Post-boxed Warning Prescribing?

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Abstract
Boxed warnings (BWs) are the highest-level prescription drug warning issued by the U.S. Food and Drug Administration (FDA). These warnings are reserved for the most serious adverse drug reactions, such as those causing death, hospitalization, serious disability, or congenital anomaly. The FDA uses boxed warnings to communicate important drug safety information to healthcare professionals for consideration in their prescribing decisions.

The objective of this dissertation is to increase knowledge about whether boxed warnings work as intended, and why boxed warnings vary in their impact on prescribing. I study five boxed warnings spanning multiple drugs, classes, and treatment areas: 1) suicidality risks of antidepressants among children and adolescents, 2) mortality risks of atypical antipsychotics among elderly with dementia, 3) cardiovascular risks of COX-2 inhibitors among patients with cardiovascular disease or risk factors, 4) congestive heart failure risks of glitazones among patients with heart failure, 5) decreased efficacy of Plavix among poor CYP2C19 metabolizers.

In Study 1, I assess the relative impacts of boxed warnings versus low-level FDA warnings. I find that prescribers generally do not change prescribing after initial low-level FDA risk communications, but that boxed warnings have dampening effect on prescribing, although statistical significance is limited. This suggests prescribers comprehend that boxed warnings indicate more serious risks and higher evidence levels than low-level warnings, and are calibrating their prescribing changes accordingly.

In Studies 2 and 3, I assess prescriber and patient heterogeneity in post-boxed warning prescribing changes to evaluate potential sources of variation in boxed warning impact. On the prescriber side, I hypothesize that certain prescriber characteristics will be correlated with net costs of learning, and will thus predict variation in post-boxed warning prescribing changes. I find little evidence that prescriber characteristics are related to boxed warning response. On the patient side, I examine whether patients subgroups who are at risk of receiving lower quality care are less likely to have a decrease in prescribing following the boxed warning. I find little evidence that patient characteristics predict variation in post-boxed warning prescribing, suggesting that there are not patient disparities in the rates at which patients receive boxed warning drug prescriptions.

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