Research suggests off-label prescribing of medications is common

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A study evaluating off-label prescribing of medications in a primary care network in Canada suggests the practice is common, although it varies by medication, patient and physician characteristics, according to a report published Online First by *Archives of Internal Medicine*. The report is part of the journal's Health Care Reform series.

Off-label prescribing is the practice of using prescription medications for indications that have not received regulatory approval. The practice is suspected to be a factor of preventable adverse medication events, the authors write in their study background.

Tewodros Eguale, M.D., M.Sc., of McGill University, Montreal, Canada, and colleagues used the Medical Office of the XXI Century primary care electronic health record network research program in Quebec to examine off-label use. A total of 113 primary care physicians wrote 253,347 electronic prescriptions for 50,823 patients from January 2005 through December 2009.

Overall, 11 percent of medications were prescribed for an off-label indication and 79 percent of off-label use lacked strong scientific evidence, the results indicate. The authors note the magnitude of off-label use was less than in a U.S. study.

In the present study, the highest proportion of off-label prescribing involved central nervous system medications (26.3 percent), anti-infective agents (17.1 percent) and ear-nose-throat medications (15.2

percent), according to the study results.

The results indicate that medications with three or four approved indications were associated with lower off-label use compared to those with one or two approved indications. Medications approved after 1995 also were associated with lower off-label use than those approved before 1981. Physicians with high scores on evidence-based practice were less likely to prescribe off-label.

"In conclusion, our findings indicate that off-label prescribing is common in primary care and varies by drug class, the number of approved indications for the drug, the age of the drug, patients' sex and physicians' attitude toward evidence-based medicine," the authors conclude. "Electronic health records can be used to document treatment indication at the time of prescribing and may pave the way for enhanced postmarketing evaluation of drugs if linked to treatment outcomes."

In an editorial, Patrick G. O'Malley, M.D., M.P.H., of the Uniformed Services University of the Health Sciences, Bethesda, Md., writes: "The principles and goals of labeling are worthy in that they seek to systematically identify the benefits and harms associated with drugs in order to allow the public to optimize the trade-off between drug risk and harm. However, there is substantial room to grow in realizing these ideals in practice."

"The reality is that when faced with difficult symptom syndromes that are unresponsive to available treatments, clinicians resort to trying what seems reasonable in order to alleviate suffering," O'Malley continues.

"Here is my view about a way forward on this topic. First, the discourse needs to focus less on overuse or underuse or off-label use and more on evolving toward better measurement of use, better assessment of appropriate use based on linkage to clinical outcomes and better

processes to optimize use," he concludes.

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