Effect of US Food and Drug Administration–Approved Pediatric Labeling on Dispensing of Extended-Release Oxycodone in the Outpatient Retail Setting

For years, extended-release (ER) oxycodone has been prescribed to children for management of pain. In August 2015, based on studies conducted under the Best Pharmaceuticals for Children Act that are designed to better inform pediatric prescribing, the US Food and Drug Administration approved the use of OxyContin (Purdue Pharma) for management of pain requiring treatment with an ER/long-acting opioid in children 11 years and older who are already tolerating a daily opioid dose equivalent to at least 20 mg of oxycodone, as described in the labeling. The new labeling was not intended to expand pediatric use of ER opioids, but rather to help clinicians use OxyContin safely in pediatric patients.

Following the label change, some voiced concerns regarding the potential for increased prescribing and misuse of OxyContin in children. To understand the effect of the pediatric labeling for OxyContin on dispensing of all oxycodone ER products (OxyContin and authorized generics) in the pediatric population, we examined national data on dispensed prescriptions for oxycodone ER in outpatient retail pharmacies before and after the label change.

Methods | Prescription data were obtained from IMS Health Vector One: Total Patient Tracker, which collects deidentified data representing nearly 56% of all prescriptions dispensed in the United States. IMS Health uses this information to derive nationally projected estimates of the number of unique patients dispensed particular drug products. Unique patients were counted on a monthly basis (ie, patients receiving multiple prescriptions in that month were counted only once). We compared the mean monthly number of unique pediatric patients (age groups: 0-10 and 11-17 years) dispensed 1 or more oxycodone ER prescriptions for the 12 months before (August 2014-July 2015) and the 9 months after (August 2015-April 2016) the approval of pediatric labeling, using the Wilcoxon-Mann-Whitney test. This study was exempted from review by the US Food and Drug Administration’s Research Involving Human Subjects Committee.

Results | The monthly number of children dispensed prescriptions for oxycodone ER increased from 493 at the beginning of the study period to a peak of 586 in December 2014, followed by a decline to 323 at the end of the study period (Figure 1). The mean monthly number of children dispensed oxycodone ER declined from 470 in the 12 months prior to the new labeling to 389 in the 9 months after the new labeling, a statistically significant reduction of 17% (Wilcoxon-Mann-Whitney test; \( P = .01 \)).

Children accounted for 0.17% or less of all patients dispensed oxycodone ER in each month of the study (Figure 2). The proportion of all patients dispensed oxycodone ER who were 11 to 17 years old declined from an average of 0.13% prior to the relabeling to 0.11% after the relabeling, a reduction of 15% (Wilcoxon-Mann-Whitney test; \( P = .01 \)). In contrast, patients aged 0 to 10 years accounted for 0.01% or less of all
patients dispensed prescriptions for oxycodone ER during the study, with no significant change after the labeling change (Wilcoxon-Mann-Whitney test; P = .48).

Discussion | Our analysis demonstrates that the approval of pediatric labeling for OxyContin in children 11 years of age and older was not associated with an increase in the number of children dispensed oxycodone ER in the outpatient setting, and that such dispensing occurs at extremely low levels, particularly when viewed in the context of overall oxycodone ER dispensing. However, clinicians for this limited population of pediatric patients can now rely on age-appropriate prescribing information derived from clinical studies, and they need not base patient selection and dosing on clinical judgment alone. More research is needed to examine the long-term effect of pediatric labeling of opioids, including changes in prescription dosages, changes in prescribing of opioids that lack pediatric labeling, and the risks for subsequent misuse of prescription opioids.

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Vaccination Coverage Rates and Factors Associated With Incomplete Vaccination or Exemption Among School-age Children Based in Public Schools in New York State

Gaps in intentional and unintentional vaccination coverage persist and appear to be associated with socioeconomic factors that often drive social and geographic clustering. Nonmedical exemptions to school vaccination requirements are rising nationally and in New York State (NYS). In states, including NYS, that only allow religious and medical exemptions, the association between socioeconomic characteristics and vaccination coverage and exemptions is unknown. The objective of this study was to assess vaccination coverage rates and