

POSTER ABSTRACTS

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Off-Label Prescription Drug Use in Children

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Background: Up to 75% of prescription medications are labeled by the manufacturer as having insufficient information on pediatric use. In some drug classes, there are no medications labeled for use in children, leaving providers little choice whether or not to prescribe a medication off-label. Safety concerns have been raised about medications used in children without adequate testing. For example, the selective serotonin reuptake inhibitors (SSRIs) have been associated with growth attenuation, an adverse effect not found in prelicensure studies in adults.

Objective: To determine the frequency of off-label drug dispensings for specific classes of newer medications prescribed to children.

Design/Methods: We conducted a study of 498,906 children, ages 0 to 16 years, enrolled in 9 geographically dispersed HMOs from January 1, 1999 through June 30, 2001. We assessed pharmacy records for 61 different medications for pharmacy dispensings below the lowest FDA-approved age for use (off-label dispensings). We limited our study to newer classes of medications commonly used in adults including anti-depressants and other psychotropic medications, proton-pump inhibitors, prescription nonsteroidal anti-inflammatory agents, allergy medications, quinolone antibiotics, and oral diabetes medications.

Results: A total of 327,210 children received 2,483,354 prescription medication dispensings from network pharmacies during the study period. Of all medications dispensed, 65,583 (2.6%) were off-label dispensings in one of the drug classes studied (individual HMO ranges 1.9%-3.5%). Of children dispensed any medication, 3.3% received at least one off-label medication in the drug classes we studied (10,858 children or 2.2% of all children). Among medications included in this study, 43.7% of off-label dispensings were SSRIs (28,674 dispensings). Other antidepressants accounted for an additional 36% of off-label dispensings.

Conclusions: Medications were frequently dispensed to children despite lack of safety, efficacy or appropriate dosing information. Newer anti-depressant medications accounted for the majority of off-label prescribing. Studies to determine dosing, efficacy and unique adverse effects of medications in the pediatric population need to be conducted and should focus especially on these commonly used drugs.