

Periodic Survey #62 – Issues Surrounding Pediatric Drug Labeling

This survey was initiated by the Committee on Drugs (COD) as part of a contract awarded to the AAP by the U.S. Food and Drug Administration (FDA), to provide a list of drugs in need of additional study for use in the pediatric population. The survey addressed pediatricians' practices regarding drug utilization and opinions on the need for additional drug labeling. Pediatricians' needs for education and technical assistance, and preferred sources of information about pediatric dosing and labeling were also explored. Partial funding for this survey was provided by the FDA grant, "The Priority Drugs and Pediatric Labeling Education Project" (AAP/FDA contract solicitation number 223-02-3007/Requisition/Purchase No. D17612).

Findings from this survey will be used (in combination with a Delphi study of pediatric subspecialists and Academy leadership) to assist the FDA in identifying and prioritizing drugs requiring additional pediatric study, as well as to develop educational programs and resources to provide new or enhanced information on pediatric labeling.

Periodic Survey #62 was an eight-page self-administered questionnaire sent to 2,067 non-retired United States members of the AAP. An original mailing and six follow-up mailings to recontact nonrespondents were conducted from April through September 2005; 991 questionnaires were received for a response rate of 48%. Analysis was limited to respondents who provide direct patient care (n=925, or 93% of all respondents).

Drug Utilization and Information Needs

- Nearly all pediatricians (>90%) report prescribing analgesics, antibacterials, dermatologic agents, gastrointestinal and respiratory tract medications. Most pediatricians prescribe antiviral (85%) and mental health (66%) medications, while 47% say they prescribe sedatives/hypnotics and only 34% prescribe cardiovascular medications.
- Pediatricians say they have about the right amount of information for most classes of drugs. However, 67% of pediatricians say they do not have enough information on cardiovascular medications, 56% lack information on mental health medications and 46% say they have too little information on sedatives/hypnotics.
 - One-half of pediatricians (50%) think it is most important to have additional information on mental health medications, while 20% say information on cardiovascular medications is most important. Less than 10% named another class of drugs as most important to have additional information.
- Nearly all pediatricians (>90%) say they currently prescribe ibuprofen and inhaled steroids, 83% prescribe polyethylene glycol and 63% prescribe quinolones. About one-half prescribe atomoxetine (54%) and sumatriptans (50%), 43% prescribe SSRIs, and 19% prescribe atypical antipsychotics. Less than 10% each prescribe buspirone, isotretinoin or propofol.
- Most pediatricians think they have sufficient information on ibuprofen (92%), inhaled steroids (87%), polyethylene glycol (72%), quinolones (61%), isotretinoin (57%), and atomoxetine (53%). However, most pediatricians say they have do not have enough information regarding dosing, efficacy or safety on atypical antipsychotics (80%), buspirone (75%), propofol (70%), sumatriptans (64%) and SSRIs (60%).
 - There was no consensus on which drug was most important to have additional information: 35% named SSRIs, 20% named atypical antipsychotics, and 10% said sumatriptans. Less than 10% each named any other drug.

Availability of Drug Therapies

- A large majority of pediatricians think there are enough effective therapeutic choices currently available for otitis media (90%) and asthma (80%); about two-thirds think there are enough therapeutic choices for GERD (67%) and ADHD (61%). Opinion on therapies for headaches and depression is divided: regarding headaches, 48% say there are enough therapies and 40% say not enough; similarly, for depression, 37% of pediatricians say there are sufficient choices while 34% say there are not. However, more than half of pediatricians (57%) think there are not enough effective therapeutic choices for bronchiolitis.
 - About one-fourth of pediatricians each think it is most important to have more effective therapeutic choices available for bronchiolitis and depression (27%, 24%), and 16% named headaches as the priority condition in need of more effective therapies.

Methods of Receiving Drug Labeling Information

- Eight out of ten pediatricians currently receive new information about clinically important pediatric drug labeling from a pediatric dosage book (85%) and from *Pediatrics* (78%); 74% named *AAP News* as a source, 64% named other journals and 61% say they get their information from drug representatives. Other sources are less frequently used: PDA-based databases (39%), news media (29%), nonFDA Web sites (27%), PediaLink (16%), and FDA Web sites (15%).
- About 30% of pediatricians say receiving drug labeling information via a pediatric dosage book is most likely to influence a change in their prescribing behavior; 17% say information in *Pediatrics* and 16% say *AAP News* is most likely to influence them to change prescribing behavior.
- A majority of pediatricians say they often or sometimes use general search engines (29% often, 38% sometimes), online drug databases (26%, 34%) and disease-specific Web sites (7%, 44%) to search for information on new pediatric drug labeling. Most pediatricians never use the Web sites of patient or advocacy organizations (77%, 72%, respectively) or FDA Web sites (55%) to search for drug labeling information.

AAP Pediatric Drug Labeling Resources

- Forty-five percent of those who read the Pediatric Drug Labeling Update say its information has influenced them to change their prescribing practice for a specific drug, while 38% say they can't recall this ever happening.
- About one-third of pediatricians (32%) say they would be very likely to participate in an AAP-sponsored program on new pediatric drug labeling; 47% say they would be somewhat likely.
 - The preferred formats for such a program are: computerized course (38%), written self-instructional material such as PREP or PIR (34%), in-person CME course with a lecture and question/answer session (11%), and CME with a straight lecture/presentation (7%).