Only 40% of Parents Intend to Vaccinate Kids

BY MICHELE G. SULLIVAN

Despite clinical evidence suggesting that children are at higher risk for pandemic influenza A(H1N1) complications, only 40% of parents surveyed said they plan to have their children vaccinated against that strain of the flu.

The survey, conducted in August by the C.S. Mott Children's Hospital National Poll on Children's Health, also found that 54% of parents intended to have their children vaccinated against the regular seasonal flu.

The survey shows that many parents don't grasp the full implications of pandemic flu's possible effect on children, wrote Dr. Matthew M. Davis of the University of Michigan, Ann Arbor.

The survey cohort comprised 1,678 adult parents; the sample was then weighted to reflect population figures from the U.S. Census Bureau. Although 40% of parents said they were definitely or probably going to have their children vaccinated against pandemic flu, 29% said that they definitely or probably would not have their children vaccinated.

Most of these (56%) said they were worried about side effects of the vaccine. Other reasons for declining included not being concerned that their children would get H1N1 flu (46%); that medication can treat the flu, rendering vaccination unnecessary (42%); too much hassle to get two vaccine doses (30%); their school or day care provider doesn't require the vaccination (25%); worry about the vaccine's cost (23%); and the belief that H1N1 is not a serious disease (20%).

Parents who planned to have their children vaccinated held the converse views, with most believing that H1N1 is a serious disease (83%) and 80% being worried that their children with contract it.

A racial/ethnic breakdown of the results showed that Hispanic parents were far more likely than white or black parents to plan on having their children vaccinated against pandemic flu (52% vs. 38% and 30%, respectively). This was a "notable finding," Dr. Davis said. "It may reflect a higher perceived risk among Hispanics, given the well-publicized outbreak of H1N1 flu in Mexico in early 2009."

Dr. Davis suggested that health care providers can help parents understand the risk that H1N1 flu may present to their children.

"Public health officials and health care providers must play a critical role in ensuring that parents understand the risks of H1N1 flu illness and H1N1 flu vaccination, and that children have adequate and timely access to the vaccine," he wrote. ■

Table 1 (contd)

	Titration	Maintenance	
System Organ Class Preferred Term	**EMBEDA (N=547) n (%)[1]**	**EMBEDA (N=171) n (%)**	**Placebo (N=173) n (%)**
Vomiting	46 (8.4%)	7 (4.1%)	2 (1.2%)
General disorders and administration site conditions	39 (7.1%)	9 (5.3%)	10 (5.8%)
Fatigue	16 (2.9%)	1 (0.6%)	2 (1.2%)
Nervous system disorders	135 (24.7%)	12 (7.0%)	11 (6.4%)
Dizziness	42 (7.7%)	2 (1.2%)	2 (1.2%)
Headache	22 (4.0%)	4 (2.3%)	2 (1.2%)
Somnolence	76 (13.9%)	2 (1.2%)	5 (2.9%)
Psychiatric disorders	34 (6.2%)	10 (5.8%)	9 (5.2%)
Insomnia	7 (1.3%)	5 (2.9%)	4 (2.3%)
Skin and subcutaneous tissue disorders	46 (8.4%)	7 (4.1%)	7 (4.0%)
Pruritus	34 (6.2%)	0	1 (0.6%)
Vascular disorders	4 (0.7%)	5 (2.9%)	2 (1.2%)
Flushing	0	4 (2.3%)	1 (0.6%)

[1]Adverse reactions are classified by System Organ Class and Preferred Term as defined by the Medical Dictionary of Regulatory Affairs (MedDRA) v9.1. If a subject had more than one AE that codes to the same Preferred Term, the subject was counted only once for that Preferred Term. *Long-Term Open-Label Safety Study:* In the long-term open-label safety study, 465 patients with chronic non-malignant pain were enrolled and 124 patients were treated for up to 1 year. The distributions of adverse events were similar to that of the randomized, controlled studies, and were consistent with the most common opioid related adverse events. Adverse reactions, defined as treatment-related adverse events assessed by the investigators, reported by ≥ 2.0% of subjects are presented immediately below. **Adverse Reactions Reported by ≥2.0% of Subjects in Long-Term Safety Study – Safety Population (N=465):** Any Related AE 288 (61.9%); Gastrointestinal disorders 219 (47.1%); Constipation 145 (31.2%); Diarrhoea 10 (2.2%); Dry mouth 17 (3.7%); Nausea 103 (22.2%); Vomiting 37 (8.0%); General disorders and administration site conditions 51 (11.0%); Fatigue 19 (4.1%); Nervous system disorders 99 (21.3%); Dizziness 19 (4.1%); Headache 32 (6.9%); Somnolence 34 (7.3%); Psychiatric disorders 42 (9.0%); Anxiety 10 (2.2%); Insomnia 13 (2.8%); Skin and subcutaneous tissue disorders 52 (11.2%); Hyperhidrosis 16 (3.4%); Pruritus 26 (5.6%). Adverse reactions are classified by System Organ Class and Preferred Term as defined by the Medical Dictionary of Regulatory Affairs (MedDRA) v9.1. If a subject had more than one AE that codes to the same Preferred Term, the subject was counted only once for that Preferred Term. *Adverse Reactions Observed in the Phase 2/3 Studies:* **Most common (≥10%):** constipation, nausea, somnolence **Common (≥1% to <10%):** vomiting, headache, dizziness, pruritus, dry mouth, diarrhea, fatigue, insomnia, hyperhidrosis, anxiety, chills, abdominal pain, lethargy, edema peripheral, dyspepsia, anorexia, muscle spasms, depression, flatulence, restlessness, decreased appetite, irritability, stomach discomfort, tremor, arthralgia, hot flush, sedation. *Adverse Reactions Observed in the Phase 2/3 Studies:* **Most common (≥10%):** *Gastrointestinal disorders:* constipation, nausea; *Nervous system disorders:* somnolence. **Common (≥1% to <10%):** *Gastrointestinal disorders:* abdominal pain, diarrhea, dry mouth, dyspepsia, flatulence, stomach discomfort, vomiting; *General disorders and administration site conditions:* chills, edema peripheral, fatigue, irritability; *Metabolism and nutrition disorders:* anorexia, decreased appetite; *Musculoskeletal and connective tissue disorders:* arthralgia, muscle spasms; *Nervous system disorders:* dizziness, headache, lethargy, sedation, tremor; *Psychiatric disorders:* anxiety, depression, insomnia, restlessness; *Skin and subcutaneous tissue disorders:* hyperhidrosis, pruritus; *Vascular disorders:* hot flush. **Less Common (<1%):** *Eye disorders:* vision blurred, orthostatic hypotension; *Gastrointestinal disorders:* abdominal distension, pancreatitis, abdominal discomfort, fecaloma, abdominal pain lower, abdominal tenderness; *General disorders and administration site conditions:* malaise, asthenia, feeling jittery, drug withdrawal syndrome; *Hepatobiliary disorders:* cholecystitis; *Investigations:* alanine aminotransferase increased, aspartate aminotransferase increased; *Musculoskeletal and connective tissue disorders:* myalgia, muscular weakness; *Nervous system disorders:* depressed level of consciousness, mental impairment, memory impairment, disturbance in attention, stupor, paraesthesia, coordination abnormal; *Psychiatric disorders:* disorientation, thinking abnormal, mental status changes, confusional state, euphoric mood, hallucination, abnormal dreams, mood swings, nervousness; *Renal and urinary disorders:* urinary retention, dysuria; *Reproductive system and breast disorders:* erectile dysfunction; *Respiratory, thoracic and mediastinal disorders:* dyspnea, rhinorrhoea; *Skin and subcutaneous tissue disorders:* rash, piloerection, cold sweat, night sweats; *Vascular disorders:* hypotension, flushing. **USE IN SPECIFIC POPULATIONS: Pregnancy:** *Teratogenic Effects*: Pregnancy Category C: Teratogenic effects of morphine have been reported in the animal literature. High parental doses during the second trimester were teratogenic in neurological, soft and skeletal tissue. The abnormalities included encephalopathy and axial skeletal fusions. These doses were often maternally toxic and were 0.3 to 3-fold the maximum recommended human dose (MRHD) on a mg/m^2 basis. The relative contribution of morphine-induced maternal hypoxia and malnutrition, each of which can be teratogenic, has not been clearly defined. Treatment of male rats with approximately 3-fold the MRHD for 10 days prior to mating decreased litter size and viability. *Nonteratogenic Effects:* Morphine given subcutaneously, at non-maternally toxic doses, to rats during the third trimester with approximately 0.15-fold the MRHD caused reversible reductions in brain and spinal cord volume, and testes size and body weight in the offspring, and decreased fertility in female offspring. The offspring of rats and hamsters treated orally or intraperitoneally throughout pregnancy with 0.04- to 0.3-fold the MRHD of morphine have demonstrated delayed growth, motor and sexual maturation, and decreased male fertility. Chronic morphine exposure of fetal animals resulted in mild withdrawal, altered reflex and motor skill development, and altered responsiveness to morphine that persisted into adulthood. There are no well-controlled studies of chronic *in utero* exposure to morphine sulfate in human subjects. However, uncontrolled retrospective studies of human neonates chronically exposed to other opioids *in utero*, demonstrated reduced brain volume which normalized over the first month of life. Infants born to opioid-abusing mothers are more often small for gestational age, have a decreased ventilatory response to CO_2, and increased risk of sudden infant death syndrome. There are no adequate and well-controlled studies of naltrexone in pregnant women. EMBEDA should only be used during pregnancy if the need for strong opioid analgesia justifies the potential risk to the fetus. **Labor and Delivery:** EMBEDA is not recommended for use in women during and immediately prior to labor, where shorter acting analgesics or other analgesic techniques are more appropriate. Occasionally, opioid analgesics may prolong labor through actions which temporarily reduce the strength, duration, and frequency of uterine contractions. However, this effect is not consistent and may be offset by an increased rate of cervical dilatation which tends to shorten labor. Neonates whose mothers received opioid analgesics during labor should be observed closely for signs of respiratory depression. A specific opioid antagonist, such as naloxone or nalmefene, should be available for reversal of opioid-induced respiratory depression in the neonate. **Nursing Mothers:** Morphine is excreted in the maternal milk, and the milk to plasma morphine AUC ratio is about 2.5:1. The amount of morphine received by the infant depends on the maternal plasma concentration, amount of milk ingested by the infant, and the extent of first pass metabolism. Withdrawal symptoms can occur in breast-feeding infants when maternal administration of morphine sulfate is stopped. Because of the potential for adverse reactions in nursing infants from EMBEDA, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** The safety and efficacy of EMBEDA in individuals less than 18 years of age have not been established. **Geriatric Use:** Clinical studies of EMBEDA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. The pharmacokinetics of EMBEDA have not been investigated in elderly patients (>65 years) although such patients were included in clinical studies. In a long-term open label safety study, the pre-dose plasma morphine concentrations after dose normalization were similar for subjects <65 years and those ≥65 years of age. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. **Neonatal Withdrawal Syndrome:** Chronic maternal use of opiates or opioids during pregnancy coexposes the fetus. The newborn may experience subsequent neonatal withdrawal syndrome (NWS). Manifestations of NWS include irritability, hyperactivity, abnormal sleep pattern, high-pitched cry, tremor, vomiting, diarrhea, weight loss, and failure to gain weight. The onset, duration, and severity of the disorder differ based on such factors as the addictive drug used, time and amount of mother's last dose, and rate of elimination of the drug from the newborn. Approaches to the treatment of this syndrome have included supportive care and, when indicated, drugs such as paregoric or phenobarbital. **Race:** Pharmacokinetic differences due to race may exist. Chinese subjects given intravenous morphine in one study had a higher clearance when compared to Caucasian subjects (1852 ± 116 mL/min versus 1495 ± 80 mL/min). **Hepatic Failure:** The pharmacokinetics of morphine was found to be significantly altered in individuals with alcoholic cirrhosis. The clearance was found to decrease with a corresponding increase in half-life. The morphine-3-glucuronide (M3G) and morphine-6-glucuronide (M6G) to morphine plasma AUC ratios also decreased in these patients indicating a decrease in metabolic activity. **Renal Insufficiency:** The pharmacokinetics of morphine is altered in renal failure patients. AUC is increased and clearance is decreased. The metabolites, M3G and M6G, accumulate several fold in renal failure patients compared with healthy subjects. Adequate studies of naltrexone in patients with severe hepatic or renal impairment have not been conducted. **Breakthrough Pain/ Adverse Experiences:** Patients should be advised to report episodes of breakthrough pain and adverse experiences occurring during therapy. Individualization of dosage is essential to make optimal use of this medication. **Mental and/or Physical Ability:** Patients should be advised that EMBEDA may impair mental and/or physical ability required for the performance of potentially hazardous tasks (e.g., driving, operating machinery). Patients started on EMBEDA or whose dose has been changed should refrain from dangerous activity until it is established that they are not adversely affected *[see Warnings and Precautions]*. **Avoidance of Alcohol or Other CNS Depressants:** Patients should be advised that EMBEDA should not be taken with alcohol, prescription or non-prescription medications containing alcohol, or other CNS depressants (sleeping medication, tranquilizers) except by the orders of the prescribing healthcare provider because dangerous additive effects may occur resulting in serious injury or death *[see Warnings and Precautions]*. **Pregnancy:** Women of childbearing potential who become or are planning to become pregnant, should consult their prescribing healthcare provider prior to initiating or continuing therapy with EMBEDA *[see Use in Specific Populations]*. **Cessation of Therapy:** Patients should be advised that if they have been receiving treatment with EMBEDA for more than a few weeks and cessation of therapy is indicated, it may be appropriate to taper the EMBEDA dose, rather than abruptly discontinue it, due to the risk of precipitating withdrawal symptoms. Their prescribing healthcare provider should provide a dose schedule to accomplish a gradual discontinuation of the medication. **Drug of Abuse:** Patients should be advised that EMBEDA is a potential drug of abuse. They should protect it from theft, and it should never be given to anyone other than the individual for whom it was prescribed *[see Warnings and Precautions]*. **Constipation:** Patients should be advised that severe constipation could occur as a result of taking EMBEDA and appropriate laxatives, stool softeners and other appropriate treatments should be initiated from the beginning of opioid therapy. **Storage/Destruction of Unused EMBEDA:** Patients should be instructed to keep EMBEDA in a secure place out of the reach of children. When EMBEDA is no longer needed, the unused capsules should be destroyed by flushing down the toilet.

FDA-Approved Patient Labeling

[See separate leaflet.]

Manufactured for: **King Pharmaceuticals, Inc., 501 Fifth Street, Bristol, TN 37620**

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EMBEDA is a trademark of Alpharma Pharmaceuticals LLC, a wholly owned subsidiary of King Pharmaceuticals, Inc.

To report SUSPECTED ADVERSE REACTIONS, contact King Pharmaceuticals, Inc. at 1-800-546-4905 or DSP@Kingpharm.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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CPT Codes for Giving H1N1 Vaccine Readied

The American Medical Association has created a new Current Procedural Terminology code (90470) and revised an existing code (90663) for use with H1N1 vaccinations, according to a statement.

The new and revised CPT codes are expected to help streamline vaccination reporting and reimbursement as physicians across the United States administer nearly 200 million doses of the new H1N1 vaccine this fall.

The details of the codes are as follows:

► 90470: H1N1 immunization, both intramuscular and intranasal, including counseling

► 90663: Influenza virus vaccine (pandemic H1N1 formulation)

Both the new Category I CPT Code 90470 and the revised code 90663 are effective immediately. Code 90470 was created for use when reporting H1N1 vaccination and counseling, while code 90663 was revised to include the specific H1N1 vaccine product.

To be paid for H1N1 vaccine administration, providers should bill 90663 in conjunction with 90470, the AMA said.

The 90663 code should be billed at zero dollars, because the vaccine itself is being provided by the federal government at no charge.

—Heidi Splete